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Introduction: chiropractic Philosophy & Science

Role of chiropractic Philosophy – A Doctrine of Strongly Held Beliefs: Provides chiropractors with a sense of Purpose, Vision, an Overview: timeless Wisdom.

1. Health comes from within
2. Health is a natural condition of the body
3. Chiropractic cares for people not treat diseases.
4. It helps improve health & restore internal resistance to disease not treat external causes of disease.
5. The patient is the center of care not a disease or symptoms
6. Health is multidimensional not just physical
7. Some things are not measurable
8. Science only acknowledges what it can quantify. It is materialistic.
9. The wisdom inherent in the body is capable of maintaining the body in health if there is no interference in its functioning
10. Ultimate responsibility for health is the patient's
11. The doctor's role is to unleash the natural healing power within
12. A shift away from disease to wellness care

Passive Care: Interventions that a patient passively receives (massage, physical therapy modalities, heat, cold, etc., mobilization, adjustments, pain meds, surgery, etc)

Active Care: care in which the patient actively participates: stretching strengthening, endurance exercises, cardiovascular fitness, stress reduction, weight loss, etc. Active care becomes essential in patient tending toward chronicity (>3 months). Helps reduce complications of prolonged passive care: 1) patient dependency & 2) passive coping, 3) overutilization, 4) chronicity.

Restoring Function

Teasell, MD & Harth, MD. Spine 1996; 21(7): 844-847. The failure of the medical model in relieving the pain suffering & disability of chronic low back pain has led to a gradual switch in management strategy characterized by the functional restoration approach. **The focus is no longer on diagnosis or treatment but on maximizing functional abilities.**

Waddell G, MD. The Back Pain Revolution. Churchill & Livingstone 1998. Figure 5-9: Back disability is increasing at the rate of 14 times the rate of population growth.

Saal, MD. Spine 1997; 22(14):1545-1552. Presidential Address to the North American Spine Society. We must remind ourselves that our care must be centered around patients' needs & desires. We must listen to our patients and understand their motivations for obtaining care. . . We must adopt the principle of improving patient function as our new paradigm. Improving patient function must be the credo of care.

Fordyce, PhD. Clin Orthop & Related Research 1997; 336:47-51. Changing Models of Care. The physician's mission is not as a repair mechanic but as a performance promoter.

Chapman-Smith, D. LLB. The Paris **Paradigm of chiropractic.** chiropractic Report 2001; 15(4): 1-3, 6-8. At the 6th biennial Congress of the World Federation of chiropractic (WFC) (May 22-28, 2001, attended by more than 750 DCs from 42 countries), **Gordon Waddell, MD** given a special award for outstanding lifetime contribution to the international growth and acceptance of the chiropractic profession. Dr. Waddell pioneered the biopsychosocial model of spinal pain and was a chief architect of the US and UK back pain guidelines. He has spoken at 3 WFC Congresses & has defended unfair criticism of the chiropractic profession in many

interprofessional settings including the pages of the British Medical Journal. WFC Congress adopted the Association of chiropractic College's (ACC) 1996 **Paradigm of chiropractic** on May 23, 2001 by the Assembly (with delegates representing 48 countries including every national chiropractic association in the world with over 20 members) based on a motion jointly proposed by ACA & ICA, establishing an international consensus on fundamental principles of education & practice, creating a common ground for all DCs, their associations & colleges. ACC represents all 17 accredited colleges in Canada & US. It developed a foundation for a **profession-wide shared vision**. ACC Board of Directors is comprised of the presidents of all colleges representing all perspectives. In July 1996 the ACC's Paradigm of chiropractic was unanimously agreed upon by all presidents. In 1999 the Congress of chiropractic State Assoc (COCSA) called a US Leadership Conference including reps from ACA, ICA, CCE, Federation of Chiropractic Licensing Boards, FCER, NBCE. The ACC Paradigm was unanimously accepted as a unifying vision of chiropractic in the US. This position was ratified by the ACA & ICA Boards which both submitted the ACC Paradigm to the WFC. The ACC Paradigm now assumes major significance because it has been adopted internationally as an appropriate guide to the development of chiropractic education & practice & the role of the DC w/I health care.

ACC Paradigm of chiropractic: chiropractic is a health care discipline which emphasizes the inherent recuperative power of the body to heal itself without the use of drugs or surgery. The practice of chiropractic focuses on the relationship between structure (primarily the spine) & function (as coordinated by the nervous system) & how that relationship affects the preservation & restoration of health. In addition, doctors of chiropractic recognize the value & responsibility of working in cooperation with other health care practitioners when in the best interest of the patient. The ACC continues to foster a unique, distinct chiropractic profession that serves as a health care discipline for all. The ACC advocates a profession that generates, develops, & utilizes the highest level of evidence possible in the provision of effective, prudent, & cost conscious patient evaluation & care. **Purpose:** The purpose of chiropractic is to optimize health. **Principle:** The body's innate recuperative power is affected by & integrated through the nervous system. **Practice:** The practice of chiropractic includes establishing a diagnosis, facilitating neurological & biomechanical integrity through appropriate chiropractic case management, & promoting health. **Foundation:** The foundation of chiropractic includes philosophy, science, art, knowledge, and clinical experience. **Impacts:** The chiropractic paradigm directly influences the following: education; research; health care policy and leadership; relationships with other health care providers; professional stature; public awareness and perceptions; & patient health through quality care. **The Subluxation:** chiropractic is concerned with the preservation & restoration of health, & focuses particular attention on the subluxation. A subluxation is a complex of functional &/or structural &/or pathological articular changes that compromise neural integrity & may influence organ system function & general health. A subluxation is evaluated, diagnosed, & managed through the use of chiropractic procedures based on the best available rational & empirical evidence.

Difficulty Diagnosing the Cause of Back Pain – Nonspecific & Mechanical Back Pain

Bigos, MD. Acute low back pain in Adults. Agency for Health Care Policy & Research, Dec 1994: 8. Different disciplines use a variety of diagnosis that suggest a cause for low back pain. However, these labels are often unreliable. **Even after an extensive work-up, only about 15% of patients can be given a definitive diagnosis.**

Lawrence RC, MPH et al. Arthritis & Rheumatism 1998; 41(5): 778-799. Low back pain is extremely common & will affect most adults at some time. About half of adults have low back pain in any given year. The precise etiology is unclear, but we presume that **most episodes are related to muscle & ligament injuries & bony or disc degenerative changes but definitive**

diagnosis is usually impossible. Up to 85% of patients cannot be given a definitive diagnosis because of the weak association among back symptoms, pathologic changes, & imaging results.

Devo RA, MD, MPH. Scientific American 1998; August: 48-53. BP may be a symptoms of serious underlying diseases such as cancer, bone infection, or rare forms of arthritis. Fortunately, such critical causes are extremely rare. **About 98% of BP patients suffer from injury, usually temporary, to the muscles, ligamentaments, bones or discs. Up to 85% of patients with low back pain are left w/o a definite diagnosis.** Most patients can't recall a specific incident that brought on their suffering, & heavy lifting or injuries, though risk factors, do not account for most episodes. BP often seems just to happen & the medical community has, by no means, reached a consensus as to the causes of garden-variety cases. If patients are confused, they are not alone.

Hadler MD, Carey MD. JAMA 2000; 248(21): 2780-1. The findings of Wassell et al. (JAMA, 200; 284: 2727-2732) suggest that back belts should be viewed as no more than an option in apparel. There is little direct evidence that most back pain stems from a discrete injury or repetitive trauma. There is little direct evidence that most back pain stems from a discrete injury or repetitive trauma. Regional musculoskeletal disorders afflict otherwise well, working-age adults who have had no physical exposure unusual for them. Back pain seldom results from a fall, direct impact or extraordinary physical demands.

Wiesel, S, MD. Are individuals with back pain at heightened risk of permanent spinal injury? Backletter 2002; 17(1): 1, 8-10. The injury model of low back pain – routine BP is attributable to a discrete injury. Many researchers believe that the injury model itself is flawed & outmoded. Most BP cannot be attributed to any specific injured structure. BP typically does not have any obvious traumatic precedent.

Devo, MD, MPH, Weinstein, osteopath. Low back pain. NEJM. 2001; 344(5): 363-369. 85% of patients with low back pain cannot be given a precise pathoanatomical diagnosis. The assoc between symptoms and imaging results is weak. Risk factors include heavy lifting, poor conditioning, although low back pain is common in subjects w/o these risk factors. Because a precise anatomical diagnosis is elusive, the diagnostic evaluation is often frustrating. For patients with nonspecific low back pain a precise pathoanatomical diagnosis is often impossible.

Bogduk, N. MD., PhD. What's in a name? The labeling of back pain. Med J of Australia. 2000; 173 (October 16): 400-401. In "The Taxonomy of Pain," the taxonomy subcommittee of the International Assoc for the Study of Pain (IASP) wrestled with the diagnosis of spinal pain. It recognized that many diagnosis labels were illegitimate, inappropriate, or fanciful & stipulated strict criteria to be satisfied if a particular diagnosis label was to be used to ensure consistent & accountable use of terms. However, often, the criteria could not be satisfied using history & exam alone, or even conventional investigations. In effect, the exercise established that it was essentially impossible to render any conventional or traditional diagnosis for low back pain. The means to do so were not available, reliable, nor valid. The subcommittee argued that the only intellectually & clinically honest diagnosis for most cases of low back pain was "**lumbar spinal pain of unknown or uncertain origin.**" This label is cumbersome. Despite its accuracy & honesty, the term conveys the sense that the doctor does not know what is going on. Facet joint pain & discogenic pain can not be diagnosis clinically. Some labels are simply wrong & can have deleterious effects. "Degenerative disc disease" conveys to patients that they are disintegrating, which they are not.

Devo, MD, MPH. Diagnosis of low back pain . Arch Intern Med 2002; 162 (July 8): 1444-1447. In most low back pain patients, the precise cause remains unclear. Anatomic abnormalities can be readily identified by imaging studies, but most of these are common in healthy subjects . This seems to be equally true for myelography, CT, mechanoreceptors. Often, these abnormalities result from age-related degenerative changes, which begin to appear even in early adulthood & are in some way analogous to gray hair & wrinkles. The high prevalence of anatomic abnormalities such as herniated discs, bulging discs, & annular tears among “normal” asymptomatic subjects in the absence of symptoms suggests that making causal inferences is often hazardous because many findings in symptomatic people may be coincidental. In the absence of corresponding clinical findings from history & PE, these anatomic derangements seem to be irrelevant & inconsequential. Thus, finding a cause for low back pain is often difficult or impossible.

Borenstein, MD et al. The value of mechanoreceptor I of the lumbar spine to predict low back pain in asymptomatic subjects: a 7 year follow-up study. J Bone Joint Surg Am 2001; 83-A (9): 1306-11. In 1989, 67 subjects (ave 35 years) w/o a history of BP had mechanoreceptor I of the lumbar spine. 31% of subjects had an abnormality of a disc or spinal canal (herniation, protrusion, extrusion, free fragment, stenosis, disc bulge, disc degeneration). Study investigates whether mechanoreceptor I findings predicted development of low back pain in asymptomatic subjects . The 1989 & a repeat mechanoreceptor, 7 years later of 31 subjects , were read by 2 neuroradiologists & an orthopedist spine surgeon. Results: Of 50 subjects (ave 43.6 years) followed 7 years later, 42% (21 subjects) developed low back pain < including 12 subjects with normal scans. Findings on mechanoreceptor I did not predict the development or duration of low back pain . Example: 5 of 6 subjects with herniation on mechanoreceptor in 1989 had repeat mechanoreceptor. Over 7 years, only 1 of the 5 had radiating pain longer than 2 wks. Findings discovered by mechanoreceptor can only confirm the clinical suspicions of the clinician. Treatment should not be based solely upon mechanoreceptor abnormalities in the absence of clinical indicators.

Wiesel S, MD. Biochemical diagnosis. Backletter 1998:13(8):85, 94. One of the greatest problems in contemporary spine care is diagnostic imprecision. Despite space age imaging capabilities, it is usually impossible to conclusively determine the tissue source of a patient’s pain.

Devo, MD, MPH, Weinstein, Osteopath. Low back pain. NEJM. 2001; 344(5): 363-369. Early or frequent use of imaging (plain films, mechanoreceptor I, CT) is discouraged because disc & other abnormalities are common among asymptomatic adults. Degenerated, bulging, & herniated discs are frequently accidental findings, even among patients with low back pain & may mislead to overdiagnosis, anxiety, dependence on medical care, conviction about the presence of disease & unnecessary test or treatments. Sequential mechanoreceptor studies reveal that the herniated portion of the disc tends to regress with time, with partial or complete resolution in 2/3 of cases after 6 months.

Ito T et al. Spine 2001; 26(6): 648-51 & Postacchini F. Lumbar disc herniation. Spine 2001; 26(6): 601. patients with uncontained lumbar disc herniation (UDH) – (one that has breached the annulus) can be treatment w/o surgery if they can tolerate their symptoms for the 1st 2 months. The body’s defense system attacks & absorbs uncontained disc herniations, leading to early radiographic & clinical resolution. Prospective study – all these orthopedic surgeons’ patients with symptoms disc herniations underwent conservative care for at least 8 wks – except with cauda equina syndrome, severe motor weakness. This protocol reduced disc surgery rate by almost 50%. None of the patients who waited at least 8 wks had an uncontained disc herniation

at surgery. Findings provide further evidence that uncontained disc herniations often resolve quickly. In most patients with an extruded & sequestered herniation, the symptoms & the herniation itself disappear in a few wks to a few months. Unable to accurately differentiate contained from uncontained on mechanoreceptor.

Waddell G, MD. The Back Pain Revolution. Churchill Livingstone 1998. We do not really understand the cause of most back pain & there is often very little relation between any physical pathology and the associated pain & disability. We often regard BP as an injury, but most episodes occur spontaneously with normal everyday activities. Our high tech investigations for spinal diseases tell us very little about simple backache. In BP we often cannot find the cause or even the exact source of pain. If BP becomes chronic, patients soon realize that we do not know what is wrong. Textbooks present diagnosis as a choice between a number of diseases. They give long lists of diseases which cause backache, but they are all rare. Simple backache is at the end of the list, almost an afterthought, & a diagnosis by exclusion (P. 137). BP is a problem to Drs & therapists because they cannot diagnose any definite disease or offer any real cure, so they are unsure & uncomfortable when dealing with BP. Finding a painful site does not diagnose the pathology. The various structures at one segmental level are closely linked, share common innervation & function together. So even when we localize pain to one level, that may not tell us which of the structures at that level is the cause of the problem.

Kuritzsky, MD. Physician & Sports Medicine 1997; 25(1): 56-64. Bend your index finger backward until it's intensely painful. A biopsy of the finger won't reveal a tumor, infection or any identifiable lesion, because there is none. But releasing the finger & letting it return to its "position of comfort" will allow the pain to subside. We need to reorient ourselves to think about low back pain in a similar way – **functionally instead of pathoanatomically**. Rather than focusing on discovering the pathoanatomic disturbance leading to dysfunction, clinicians should strive to restore correct posture & normal productivity. **97% of BP seen by primary care physicians is mechanical in origin** – there's something wrong with the muscles, ligaments, or connective tissues. Most patients with BP don't have ruptured discs, but it's notorious, partly because imaging studies dramatically overestimate the frequency. I want practitioners to understand that surgery is a last resort. If we prescribe mobilization & allow sufficient time, with rare exception, people will get better. I didn't know this when I experienced my own BP. I've addressed literally thousands of primary care physicians & they all tell me the same thing: They didn't know it either.

Devo, MD, MPH, Weinstein, osteopath. NEJM. 2001; 344(5): 363-369. Differential diagnosis of low back pain : Mechanical Back Pain: 97% (refers to anatomical or functional abnormality w/o ligament, neoplastic, or inflammatory disease.) **Mechanical low back pain or leg pain:** lumbar strain, sprain (70%); DJD of discs & facets (10%); Herniated disc (4%); Spinal Stenosis (3%); Osteoporotic compression Fx (4%); Spondylolisthesis (2%); Traumatic Fx (<1%); Congenital disease (<1%) [severe kyphosis, severe scoliosis, transitional vert]; Spondylolysis, Internal disc disruption or discogenic low back pain ; Presumed instability. **Nonmechanical Spinal Conditions:** (about 1%): Neoplasia (0.7%); Infections (0.01%); Inflammatory Arthritis (0.3%): ankylosing spondylitis, psoriatic spondylitis, Reiter's syndrome, inflammatory bowel disease, Scheuermann's, Pagets. **Visceral Disease** (2%): Disease of pelvic organs: prostatitis, endometriosis, Chronic PID; Renal disease; Aortic aneurysm; GI disease: pancreatitis, cholecystitis, penetrating ulcer.

Waddell, MD. The Back Pain Revolution. Churchill Livingstone 1998: 144. Abnormal muscle function, abnormal forces acting on musculoskeletal structures, abnormal posture or abnormal joint movement may all produce pain.

Waddell G. MD. The Back Pain Revolution. Churchill Livingstone 1998: 151-151. Dysfunction may become self-perpetuating. Pain may be due to disturbed function without any structural damage. You do not need structural damage to have pain from musculoskeletal dysfunction.

Role Manipulation in Mechanical Back Pain

Lauretti W, DC. J Am chiropractic Assoc 1998; 35(6):50-52. Spinal manipulation involves specialized examination techniques to evaluate the motion & a ligament of joints in the spine. We determine which joints are “locked up” – lacking the normal degree of movement. These joints are usually tender & are often accompanied by local muscle tightness. DCs use their hands to quickly apply a specific force that moves the joint beyond its limited range & through its complete, normal range of movement using the minimum force necessary. **DCs offer a mechanical solution to a mechanical problem.**

Redwood DC. What massage therapists should know about chiropractic. Massage Magazine 2000; 87:140-149. Evaluation of spinal joint mechanics is a key aspect of the DC’s initial exam. This portion of the spinal exam, which requires highly developed palpation skills, is wholly absent from the physical examination provided by most medical physicians. What chiropractors look for in this portion of the physical exam includes postural imbalances, muscular inequalities, and, most of all, abnormalities of joint movement.

Freedman, MD, musculoskeletal CE, Bernstein, MD, musculoskeletal . Educational deficiencies in musculoskeletal medicine. J Bone Joint Surg Am; 2002 84-A(4): 604-8. Authors previously reported the results of a study (J Bone Joint Surg 1998; 80:1421-7) in which a basic competency musculoskeletal medicine exam was given to a group of recent medical school graduates. The exam was validated by 124 orthopaedic program directors who established a passing grade of 73.1%. 82% of the examinees failed to demonstrate basic competency in musculoskeletal medicine. It was suggested that a different passing grade might be set by program directors of internal medicine departments. To test this, the validation process was repeated with program directors of internal medicine residency departments. 58% of the program directors of internal medicine residency departments in the US responded, suggesting a passing score of 70.0%. The mean test score of 85 examinees was 59.6%. 78% failed to demonstrate basic competency on the criterion set by the internal medicine program directors. Conclusions: A large majority of recent medical graduates failed to demonstrate basic competency in musculoskeletal medicine. Medical school preparation in musculoskeletal medicine is inadequate. The average amount of time spent in courses or rotations dedicated to orthopedics was only 2.1 weeks for all examinees, & 33% had graduated from medical school with no such exposure. One or two wks, representing <2% of the entire typical curriculum, is probably insufficient. Medical schools must place a greater emphasis on musculoskeletal med. Because of the aging of the population, the prevalence of bone & joint diseases, already the primary reason that people seek medical care – is sure to rise. The demands will soon be even greater. Students must master the topic of musculoskeletal medicine. The results of these studies suggest that they have not. A patient comes in complaining of low back pain that wakes him from sleep. What 2 Diagnoses are you concerned with? Tumor & infection: 33% correct. A patient has a disc herniation pressing on the 5th lumbar nerve root. How is motor function of the 5th lumbar nerve root tested? Dorsiflexion of the great toe or tow extensors. 20% correct. A patient presents with a new onset of low back pain . Under what conditions are plain radiographs indicated? Name 5 (full credit for 4 responses). Age >50, neuro deficit, bowel or bladder changes, history of cancer, pregnancy, drug use of steroid use; systemic symptoms (night pain, fever); pediatric population. 50% correct. What muscle(s) are involved in lateral epicondylitis? Wrist extensors (extensor carpi radialis brevis/longis, digitorum communis). 18% correct. What

muscle(s) control external rotation of the humerus? Infraspinatus or teres minor or rotator cuff.
28% correct.

Deconditioning Syndrome: 1. Decreased strength, 2. Decreased endurance, 3. Decreased flexibility, 4. Decreased cardiovascular fitness, 5. Decreased awareness of position sense & kinesthesia.

Carpenter, Nelson. Low back strengthening for the prevention and treatment of low back pain. *Med Sci Sports Exerc* 1999; 31(1): 18-24. Because of the association of physical activity with increased pain, chronic low back pain patients often avoid using their backs. Their decreased joint mobilization is assoc with wasting of trunk muscles, a decrease in muscular strength & endurance and cardiovascular fitness, as well as, stiffness of ligaments & joints, reduced metabolic activity, & an increased susceptibility to sprains, strains, & muscle spasms. These deleterious effects of muscle/joint disuse provoke symptoms, causing greater avoidance of activity. This cyclical pattern of pain/avoidance of activity/deconditioning/more pain, referred to as the “Deconditioning Syndrome” is a defining characteristic of the chronic low back pain patient. Studies show that chronic low back pain patients have significant lower trunk strength compared with controls . Also, weak trunk muscles are an important risk factor for LB problems.

Fear Avoidance Behavior leads to inactivity, immobilization & disuse. This may result in tissue impairment, reduced strength & ROM, stiffness & weakness. As a result there are reduced motor skills, proprioception, balance, stability, & increased risk of injury leading to more fear/avoidance.

Fritz, George, et al. The role of fear-avoidance beliefs in acute low back pain : relationships with current & future disability & work status. *Pain*; 2001 94(1): 7-15. Waddell et al (1993) developed the Fear-avoidance beliefs questionnaire & showed that fear-avoidance beliefs (FABs) are an important psychosocial variable in patients with chronic disability due to low back pain . The importance of FABs in acute low back pain patients has not been explored. In 78 subjects with work-related low back pain <3 wks, measures of pain intensity, physical impairment, disability, nonorganic signs & symptoms, & depression were initially evaluated, as were FABs. Disability & work status were reassessed after 4 wks of PT. FABs were significant predictors of 4-wk disability & work status after controlling for all other variables. FABs are present in acute low back pain patients & may be the most important factor in determining the transition from acute to chronic low back pain . Higher FABs are established early in the course of low back pain & are related to more persistent disability & difficulty returning to full work status. Screening for FABs may be useful for identifying patients at risk of prolonged disability and work absence.

Wiesel, MD. No evidence that backpacks cause childhood back pain. *Backletter*; 2002 17(9):98. Backpacks do not appear to be a significant cause of BP among schoolchildren. In a study of 900, 11 to 14 year old British school children free of BP at baseline, researchers took baseline measures & weighed their backpacks (ave 13 lbs.) at 1 year follow-up, 19% of the kids reported a new episode of low back pain. The strongest predictors of low back pain were behavioral & psychological problems. In addition, kids who reported somatic complaints such as abdominal pain at baseline had nearly twice the risk of developing low back pain 1 year later. Risk of developing low back pain was 2.5 times greater in kids reporting conduct problems at baseline. The weight of a kid’s backpack did not predict BP. “Onset of low back pain was assoc with neither daily mechanical load nor load relative to body weight.” Authors question the widely held view that backpacks are a significant cause of BP among children. A previous study of 1446

kids including those with & w/o low back pain found similar results. “No mechanical factor was assoc with reporting low back pain.” Children having low back pain were more likely to have emotional problems & other somatic complaints.

Negative Effects of Bedrest & Inactivity

Waddell, MD. Spine 1987;12(7):632-644. Protracted rest leads to a catabolic state with general malaise. There is demineralization of bone & **a 3% loss of muscle strength per day**. Rest, particularly prolonged bed rest may be the most harmful treatment ever devised & a potent cause of iatrogenic disability.

Waddell, MD. Annals of the Rheumatic Diseases 1993;52: 317-319. Prolonged bed rest is the most effective method known for producing a severe disuse syndrome.

Bigos, MD. Acute Low Back Problems in Adults. Clinical Practice Guidelines. December 1994. Potential Harms & Side Effects of Bed Rest (p. 53). **1. Muscle atrophy: 1.0 to 1.5% of muscle mass lost per day, 2. Cardiopulmonary deconditioning (15% loss of aerobic capacity in 10 days); 3. Bone mineral loss with hypercalcemia & hypercalcuria; Risk of thromboembolism, 5. Social side effects such as perception of severe illness; 6. Economic loss due to increased time lost from work.**

McGuire, MD, MHS et al. A 30-Year Follow-Up of the Dallas Bed Rest and Training Study. Circulation 2001; 104:1350-1357. In 1966, 5 healthy 20 year old men underwent 20 days of bed rest to see how quickly men lose aerobic capacity with bed rest. The men became seriously deconditioned after 20 days of complete inactivity. Their fitness was completely restored by a state-of-the-art exercise training program. Recently, the same 5 men were evaluated 30 years later to evaluate the effects of aging. They had become sedentary. Their body weight had increased 25 percent of body fat had doubled. They had a 6% decrease in maximum heart rate & an impaired efficiency of maximal peripheral oxygen extraction. Though these men had gone downhill – the most remarkable finding of the study is the observation that 3 wks of bedrest in 1966 caused a more profound deterioration in cardiovascular & physical work capacity than did 30 years of aging!

D’Espiro, N. (contrib editor). Patient Care 1998; April 30:85-103. Most back pain is mechanical, self-limited, & probably assoc with overuse of back muscles &/or degen of bony structures. For uncomplicated mechanical BP< imaging studies are more likely to confound than aid the diagnostic process. Up to 90% of all spinal mechanoreceptor Is can be read as abnormal say experts even in the complete absence of symptoms . Similarly, many abnormalities seen on CT & X-ray films have no clinical manifestations.

Liebenson, DC. Rehabilitation of the Spine. Wms & Wilkins, Baltimore 1996: 13. Deconditioning affects not only peripheral anatomic structures, but also afferent systems, such as **proprioception** involved in **balance** as well as central **neuromotor control of movement & posture**.

Luoto, BM et al. Reaction time & Postural Control in chronic low back pain patients. Spine 1996;21(22):2621-2627. Reaction Time (RT) & postural control in 61 healthy controls & 99 chronic low back pain patients before & 6 months after an active, functional restoration back rehab. Methods: RTs for responses by hands and feet were tested separately in response to visual cues on a computer monitor. Postural stability was measured with a vertical force platform. Results: low back pain patients had slower reaction times than controls . Men with severe low back pain had significant longer hand reaction times than control men. Women with severe low

back pain also had poorer postural control. Functional restoration effected reaction times. Controls & patients who had a good response to rehab, had improved RTs but patients with a poor outcome, had slowed down RTs. Conclusion: chronic low back pain patients have slowed RTs &, in women, impaired postural control. RTs improved during an active, functional, restoration program. Suggests that low back pain syndromes cause not only peripheral problems but also impaired functioning of the CNS. This is interesting because RTs were not specifically trained during rehab. Reduced proprioceptor awareness may explain some spinal disorders characterized by deficits of motor skills & coordination. It may be that pain & other disturbing stimuli (abnormal proprioceptor) hamper RTs. Reduction of impairment & pain would result in faster Rts.

Leape, MD. JAMA 1994; Dec 21:1851-57. 20% of patients admitted to a university hospital medical service suffered iatrogenic injury & that 20% of those injuries were serious or fatal. Steel et al found that 36% of patients admitted to university medical service suffered an iatrogenic event, of which 25% were serious or life threatening. More than ½ of injuries were related to meds. 1991 Harvard Medical Practice Study reported that nearly 4% of patients hospitalized in NY state suffered an injury that prolonged their hospital stay or resulted in measurable disability. This equaled 98,609 patients in 1984. Nearly 14% of these injuries were fatal. If these rates are typical of the US then 180,000 people die a year partly as a result of iatrogenic injury, the equivalent of 3 jumbo jet crashes every 2 days. 35% to 40% of diagnoses of cause of death were incorrect when confirmation was attempted on autopsy.

The Biomedical Model of Disease is based on the premise that: **Diagnosis Dictates Treatment**. The doctor must identify the unique characteristics that distinguish one disease (distinct pathology) from another before treating the patient, because each disease has its own unique treatment plan.

Wilson, MD, MSc, **Cleary**, PhD. JAMA 1995; 273(1):59-65. Medicine is based on **The Biomedical Model** of disease which focuses on etiology, pathology & biologic, physiologic & clinical outcomes. (It does not focus on function). The goal is to understand causation in order to guide diagnosis & treatment . Research is directed at molecular, genetic, & cellular mechanisms of disease. The focus is on function of cells, organs & organ systems & includes diagnosis & physiological function (pulmonary function tests) & PE. Processes are mediated by changes in cells, organs & organ systems.

Korr, PhD. JAOA 1991;91(2): 156,161-8, 170. By reducing an organism to its component parts, we conceptually demolish the very entity we seek to understand. What is lost is the organizational complexity, the interaction & interplay of the parts which can't be understood nor predicted from properties of the individual components.

Mootz, DC, DABCO. J chiro Humanities 1995;5(1):28-40. In the process of analyzing complex systems by breaking them into components, we divide nature into pieces that are unnatural or meaningless – a process of fragmentation. Scientists assume they can generalize from simplified, reductionistic models to the real world, but this is exceedingly difficult.

Backman J, DC, MPH. JACA 1997; 34(1):8-17. It is difficult if not impossible, to generalize the results from the carefully defined & selected population of a randomized controlled trial to the heterogeneous population one finds in a clinic. After a randomized controlled trial is published, the question arises how useful is it, really, in the diversified setting of a real world clinical practice? The very conditions that make a formal study scientifically rigorous, like strict

inclusion/exclusion criteria for patient enrollment may make it a very tricky matter to extrapolate its conclusions to the mixed population of patients seen every day.

i) **How much can you generalize** from a clinical trial with strict inclusion criteria such as: Healthy young men; b) First episode of back pain; c) Acute injury at work; d) Less than 2 wks duration; e) No previous history of BP; f) No other health problems; g) How long until return to work? What does this tell us about the prognosis of 1) Women; 2) Older or younger patients; 3) patients with BP of >2 wks. 4) Pain of gradual onset; 5) patients with a history of BP; 6) patients with other health problems?

Errors in Medicine

CNN 1999. National Academy of Sciences' Institute of Medicine. Medical errors kill tens of thousands annually, panel says. A report released November 29, 1999 from the **National Academy of Sciences' Institute of Medicine** (a federal advisory panel) **reports that more people die each year in the US from medical errors than from highway accidents, breast cancer or AIDS. The report cited studies showing between 44,000 & 98,000 people die each year because of mistakes by medical professionals. That's probably an underestimate** because there are different kinds of errors we never learn about because they are never written down & because studies did not cover areas of care like home care, nursing homes, & ambulatory care centers, says Dr. Berwick of The Institute of Medicine. The report urges Congress to create a **National Center for Patient Safety** within The Department of Health and Human Services to set goals for avoiding medical mistakes, track progress & fund research on better ways to prevent such errors. It suggested as **a minimum goal a 50% reduction in medical errors w/i 5 years.** Most errors involve meds – including the improper administering of meds due to illegible writing in a patient's medical record. The Institute said tens of thousands die in hospitals alone each year as a result of medical errors. One study put the number of such deaths at 44,000 & another more than doubled that figure. **Med errors that take place in & out of hospitals total >7,000,000**, exceeding those from workplace injuries. These stunningly high rates of medical errors – resulting in death, permanent disability & unnecessary suffering are simply unacceptable in a medical system that promises first to do no harm, said WM Richardson, chairman of the committee that wrote the report & CEO of the Kellogg Foundation. The report said the creation of federal agencies focusing on safety has dramatically reduced the number of deaths from airline accidents & in the workplace. Creating such an agency for the regulation of health care is at least a decade overdue.

Doctors' Deadly Mistakes. TIME 1999; Dec 13:74-76: Causes of death in thousands: Heart disease 727, Stroke 160, Cancer 158, Medical Errors 98, Pneumonia 86, Diabetes 63, motor vehicle accident 43, Breast cancer 42, Suicide 31, Homicide 20, AIDS 17.

CNN 1999. U.S. task force to find ways to reduce medical errors. Within 60 days a newly charged federal task force is to compile means of preventing medical errors & increasing safety of patients in American hospitals. In announcing the formation of the interagency task force, President Clinton cited what he called the “disturbing report” issued last week that as many as 98,000 Americans lose their lives each year due to medical mistakes. He added that American hospitals & other medical providers “**must first do no harm**” & enhance “a culture of safety. . .to improve health-care quality.” Clinton is directing federal agencies that administer health plans to find ways to identify and tighten parts of the medical system that leave room for error.

Berwick DM, Leape LL. Reducing errors in medicine. BMJ 1999;319:136-137. With the rising complexity of modern medical care have come startling levels of risk & harm to patients. A recent study in 2 highly regarded hospitals discovered serious or potentially serious medication errors in

the care of 6.7 out of every 100 patients & another study which reviewed over 30,000 hospital records found injuries from care itself to occur in **3.7%** of hospital admissions, over half of which were preventable & 13.6% of which lead to death. If these figures can be extrapolated to American health care in general, then over **20,000 Americans die each year as a result of preventable errors in their hospital care.**

Davis R, Appleby J. Report: Health system broken. USA Today; 2001:1A. The nation's health care system is not able to provide consistent, high quality medical care to all Americans & must be "reinvented" The Institute of Medicine (IOM) warned Thursday (3-1-01) in its 320 page report. . . patients, esp those with long-term illnesses, fall thru the gaps when medical professionals don't communicate or when records are lost, or not easily retrievable. IOM which warned in 1999 that up to 998,000 deaths from medical error occur each year – wants Congress to create a \$1 billion fund to spend on efforts to fix the system over 3 to 5 years. "Pt safety was the tip of the iceberg," says Wm Richardson, who chaired the IOM committee, "This is the rest of the iceberg." The report says the system needs to vastly improve the way Drs & other professionals communicate & train them to act as teams. It also says that patients should have more control of their treatment & medical records. They should be able to get data on how Drs & hospitals measure up. Financial incentives are needed to reward quality. But obstacles abound including Drs' & hospitals' reluctance to releasing data about their performance. There is an urgent need for change particularly as baby boomers age & develop more chronic conditions.

Astin, PhD. Stanford Univ Center for Research in Disease Prevention. Dyn chiro 1998;16(15):1, 46, 47. The proportion of conventional medicine that is evidence based depends on how you define evidence-based. If you consider randomized controlled trials, there is an enormous amount of medicine that cannot be ethically or practically tested by randomized controlled trials. (Ex: Can't ethically perform sham surgeries.) This is complicated because a lot of alternative medicine is being held to the randomized controlled trial gold standard, which doesn't hold for a lot of how medicine is actually practiced. Any good health care must be tailored to the individual pt. But randomized controlled trials are not, but rather attempt to test an intervention systemically applied in the same way across a group of individuals. The debate becomes what qualifies as good enough evidence? It's too limiting to say that the randomized controlled trial is the only irrefutable evidence. .Sometimes you have to look at outcome based research that is occurring in a natural setting rather than the more contrived or controlled setting of the randomized controlled trial. One of the problems with randomized controlled trials is that you attempt to control extraneous variables, but these are often the very same variables operating in the real lives of patients. Therefore, one can question how externally valid (how much can you generalize) the tightly controlled randomized controlled trial or experiment really is?

Tenover, Hughes. JAMA 1996;275(4)Jan 24-31:300-304. Resistance to antibiotics is an emerging problem in human medicine. Multiresistant organisms are diminishing our ability to control the spread of infectious diseases. The multiresistant organisms of the 1990s are a grim warning of the possibility of a postantibiotic era.

Manning Anita. 2 million are infected in hospitals each year. USA Today 1998; March 15. The rate of infections acquired by patients while in the hospital has increased 36% since last evaluated in a 1975-80 study. **About 2 million people a year acquire such infections, & nearly 90,000 die of them,** says Wm Jarvis for CDC reporting a survey of 265 hospitals nationwide. The increase is due in part because the proportion of severely ill patients has increased. Hospitals have become ICUs. These very sick patients are vulnerable to infections because they have depressed immune systems. Also of concern is the increasing rate of antibiotic resistant

organisms found in hospitals. Hospital acquired infections add about \$4.5 billion a year to health care costs.

Hart CH (Microbiologist). BMJ 1998; 316:1255-6. In recent years concern has increased that the antibiotic era might be coming to an end because viruses, bacteria, fungi, protozoa & parasites are showing great ingenuity in devising mechanisms for circumventing the killing power of antibiotics. Under optimal conditions bacteria double in number every 20 minutes. Bacteria thus have infinitely expandable and mutable populations to throw in waves at the barrier of antibiotics. Not only can resistance be passed vertically from generation to generation, methods of horizontal gene transfer have evolved & resistance can be passed to other species & genera.

Lazarou J, MS, Pomeranz BH, MD, PhD, Corey PN, MD. JAMA 1998; 279:1200-1205. Data extracted to obtain the overall incidence of adverse drug reactions (ADRs) in hospitalized patients. Combined incidence of ADRs occurring in the hospital plus incidence of ADRs causing admissions to hospital. Excluded errors in drug administration, noncompliance, overdose, drug abuse, therapeutic failures & possible ADRs. Serious ADRs defined as those that 1) required hospitalization, 2) were permanently disabling or 3) resulted in death. The overall incidence of serious ADRs was 6.7% & of fatal ADRs was 0.32% of hospitalized patients. We estimated that in 1994 overall 2,216,000 hospitalized patients had serious ADRs & **106,000 had fatal ADRs, making these reactions between the fourth & sixth leading cause of death.**

Relative Risk of NSAIDs & Cervical Spinal Adjustment

DEATH RATE/COMPLICATION RATIO OF OVER THE COUNTER NSAID'S IS 400 TIMES GREATER THAN CHIROPRACTIC CERVICAL ADJUSTMENTS... Journal of Manipulative and Physiological Therapeutics Oct. 1995; vol.18, no.8, pp.530-536. In a study published in Journal of Manipulative and Physiological Therapeutics (JMPT) it was reported recently that, use of over-the-counter non-steroidal anti-inflammatory drugs (NSAID'S) is 400 times more likely to result in death or other complications which could result in death than a Chiropractic Cervical Spine Adjustment! Dabbs V,Lauretti W. A risk assessment of cervical manipulation vs. NSAID'S for the treatment of neck pain.

USE OF NSAID'S CAUSES 16,500 PEOPLE TO DIE FROM BLEEDING STOMACH ULCERS...

On December 12, 1998 USA Today reported that the use of non-steroidal anti-inflammatory drugs (NSAID'S) caused the deaths of 16,500 people in the United States last year. About the same number of people died from AIDS. A disturbing fact, revealed in the article, is that 3 out of 4 people who take NSAID'S are unaware of the risks involved!

Dabbs V, Lauretti WJ. A risk assessment of cervical manipulation vs. NSAIDs for the treatment of neck pain. J Manipulative Physiol Ther. 1995 Oct;18(8):530-6. OBJECTIVE: We reviewed the literature to evaluate the risk of serious injury or death resulting from cervical manipulation and to assess the evidence that cervical manipulation is an effective treatment for mechanical neck pain. We also reviewed the literature to assess the risks and effectiveness of nonsteroidal anti-inflammatory drugs (NSAIDs), which are often used as the "conventional" first-line treatment for similar musculoskeletal conditions. DATA SOURCES: A series of Medicine literature searches were performed, and materials were reviewed from 1966-1994. Key words included: Chiropractic or Orthopedic Manipulation; Non-Steroidal Anti-Inflammatory Agents; Neck or Back Pain; Randomized Controlled Trials; Adverse Effects. STUDY SELECTION: Studies and literature reviews that provided a numerical estimate of the risk of

serious adverse effects or death from cervical manipulation or NSAID use were selected. Also, randomized, controlled studies that evaluated the effectiveness of manipulation or NSAID use for neck pain were included. DATA SYNTHESIS: Although there are a small number of well-performed trials of cervical manipulation for neck pain, we were unable to locate even a single randomized, controlled trial examining NSAID use specifically for neck pain. As for comparative safety, the best available evidence indicates that NSAID use poses a significantly greater risk of serious complications and death than the use of cervical manipulation for comparable conditions. CONCLUSION: The best evidence indicates that cervical manipulation for neck pain is much safer than the use of NSAIDs, by as much as a factor of several hundred times. There is no evidence that indicates NSAID use is any more effective than cervical manipulation for neck pain.

Wolfe MM, MD et al. Gastrointestinal Toxicity of Nonsteroidal Antiinflammatory drugs. *New Eng J Med* 1999; 340(24):1888-99. The annual number of hospitalizations for serious GI complications related to NSAIDs is estimated to be at least 103,000. Conservative estimates of NSAID-related deaths in the US is 16,500. If deaths from GI toxic effects of NSAIDs were tabulated separately, these effects would constitute the 15th most common cause of death in the US (similar to number of deaths related to AIDS & considerably greater than the number of deaths from multiple myeloma, asthma, cervical cancer & Hodgkin's disease).

Lauretti W, DC. What are the risks of chiropractic neck adjustments? *JACA* 1999;36(9):42-47. NSAIDs: one study found a 4/10,000 annual mortality rate for NSAID induced ulcers in patients treated for non-rheumatic conditions such as musculoskeletal pain & DJD, extrapolates to 3,200 deaths in US/ year . A conservative estimate of risk from death due to stroke caused by cervical spinal manipulation is @ one fatality per 4 million. **Summary:** ½ of 2 CVAs per million Cervical treatments. @ 1/3 of cases resolve with mild to no residuals. @ ¼ will prove fatal. Therefore, there are about 40 to 50 spinal manipulation caused strokes in the U.S. per year & perhaps a dozen deaths. There may be as much as 100 times greater risk of dying from an ulcer due to taking NSAIDs. If you drive @ 8 miles each way to get to your chiropractic visit, you have a statistically greater risk of being killed or seriously injured in a car accident while traveling to the office than of having a serious complication from a neck adjustment .

Tramer et al. Quantative estimate of rare adverse events which follow a biological progression: a new model applied to chronic NSAID use. *Pain* 2000; 85(1-2):169-82. Combined data from randomized controlled trials and observe national studies of chronic (>=2 months) use of NSAIDs which gave information on gastroduodenal ulcer, bleed or perforation, & death due to these complications. In a total of more than 250,000 patients included in the trials reviewed, the authors calculated the number of patients who die due to gastroduodenal complications with >=2 months NSAIDs: On average 1 in 1,200 patients taking NSAIDs for at least 2 months will die from gastroduodenal complications who would not have died had they not taken NSAIDs. That is 833 deaths per million patients who use NSAIDs for 2 months or more. This is 3332 times more deaths per million than from cervical spinal manipulation !

Beneliyahu DJ. Chiropractic management and manipulative therapy for MRI documented cervical disk herniation. *J Manipulative Physiol Ther.* 1994 Mar-Apr;17(3):177-85. OBJECTIVE: This case study reports on three cases of patients with documented cervical disk herniations, who responded to chiropractic management and manipulative therapy. CLINICAL FEATURES: Three patients complaining of neck pain with radiation of pain and tingling into the upper extremities had positive magnetic resonance imaging scans consistent with cervical disk herniations. They also had positive neurophysiologic testing with positive thermography scans and electrodiagnostic studies. INTERVENTION AND OUTCOME: The patients were

prescribed a treatment regimen consisting of chiropractic management including bracing, physiotherapy, cervical manipulative procedures, traction and exercises. The patients responded well to care as evidenced by posttreatment MRI, electrodiagnostic studies, clinical exam findings and thermography scan findings. **CONCLUSION:** Patients with and without nerve root compression secondary to cervical disk herniation can and do respond well to chiropractic care. Chiropractic management of this condition can and should be employed prior to more invasive treatment.

Van Tulder, PhD et al. NSAIDs for low back pain : A systematic review within the framework of the Cochrane collaboration back review group. Spine 2000; 25:2501-13. NSAIDs are the most frequently prescribed medications worldwide and are widely used for low back pain . This review of 51 trials (6057 patients) of NSAIDs in treatment of nonspecific low back pain (acute \leq 12 wks; chronic $>$ 12 wks) with or without radiation found global improvement after 1 week was 1.24 with NSAIDs indicating a small effect in favor of NSAIDs compared to a placebo. 4 studies reported on chronic low back pain . Evidence could not be provided on the effectiveness of NSAIDs in managing chronic low back pain . Sufficient evidence on chronic low back pain is still lacking. 2 studies found no differences between NSAIDs & PT or spinal manipulation to manage acute low back pain . Thus, there is moderate evidence that NSAIDs are not more effective than PT or spinal manipulation for acute low back pain. There's conflicting evidence that NSAIDs are more effective than bed rest for acute low back pain & conflicting evidence that NSAIDs are more effective than acetaminophen/paracetamol for acute low back pain . There's moderate evidence that NSAIDs are not more effective than other drugs for acute low back pain .

Plaugher, DC. Textbook of Clinical chiropractic. Williams & Wilkins 1993:309.

Haldeman S, MD, PhD et al. Risk factors and precipitating neck movements causing vertebrasilar artery dissection after cervical trauma and spinal manipulation. Spine 1999; 24(8):785-794. The potential risk of vertebrasilar artery dissection after spinal manipulation is reported to be somewhere between one in 400,000 to one in 1.3 million spinal manipulation sessions. In the absence of a definitive trial, the current understanding of the exact mechanism & risk factors for vertebrasilar artery dissection must be considered no more than speculation. Vertebrasilar artery dissection after neck movement, trauma, or manipulation should be considered a rare, random, unpredictable complication assoc with these activities.

Malpractice: Without conscientious care and record keeping, you could lose it all. JACA 1999;36(9):6-15. "We would have to study manipulation over generations before we had a large enough sample size of incidents to use scientifically. As a result, we have to use databases of preexisting cases where people claim they have been hurt. The results show patients with serious complications number between one in 500,000 to 1 in 4 million, depending on the research cited." John Triano, DC, PhD.

Terrett A, DC. Current Concepts in Vertebrasilar Complications following Spinal Manipulation. Nociceptor MIC 2001. Age distribution of 255 cases of post- spinal manipulation stroke. 1934-1999. Average age: Males 39.5; females 37.1. Often the words chiropractic &/or chiropractor have been used in publications to describe any practitioner of manual therapy regardless of the training of the practitioner. The 1999 J Neurology report on 10 cases in an article titled "Stroke following chiropractic manipulation of the cervical spine." These chiropractic maneuvers were performed by 7 orthopedists, one PT & 2 health practitioners who cannot be accurately identified (no DCs). In the text of the article the words "chiropractic manipulation" were used 14 times, "chiropractic manipulations" eight times, "chiropractic

maneuver” twice, “chiropractic cervical spine manipulation” once, & “chiropractic cervical spine manipulations” once. Age & gender distribution indicates no greater risk in any age range. The increased number of accidents reported in the 30 to 45 year age group appears to reflect the age group most likely to seek spinal manipulation. Patients’ age & the presence or absence of degenerative or vascular changes don’t seem important in assessing a patient’s risk. Exact age & gender are known for 233 of 255 (91.4%) of patients. Males (n=101; 43.3%) age 7-87 with an average of 39.5. Females (n=132; 56.6%) ages 20-74 with an average 37.1. Reflects the greater number of female patients in chiropractic offices. Studies of chiropractic patients reveal male 40.7% to female 59.3% and 44.8% to 55.2%. Patients who suffer VBS (vertebrobasilar stroke) after neck spinal manipulation generally are young healthy adults, have an uneventful medical history, have none or only a few of the stroke risk factors, cannot be identified a priori by clinical or radiologic exam & women do not appear to be at greater risk.

Terrett A, DC. Current Concepts in Vertebrobasilar Complications following Spinal Manipulation. Nociceptor MIC 2001. In the 65 year period 1934-1999, there are only 37 cases of death known to have occurred in the world, from all different types of spinal manipulation practitioners, with only 19 being related to DCs or chiropractic manipulation. Some may already have a stroke in evolution, & therefore had an identical outcome even if they had not consulted a DC. Yet MDs often portray DCs as a serious risk to the public. While it may be argued that years ago there may have been an element of under-reporting, this is now less likely with increased awareness, & claims experience indicates that significant injury will nearly always lead to litigation.

Licht, P. MD, PhD. Vertebral artery blood flow during chiropractic treatment of the cervical column. PhD. Thesis. Odense University, Denmark 2000: 63. Cervical manipulation is used millions of times each year to treat neck pain & headache. Patient satisfaction is high compared to what General Practitioners achieve. Reports on serious complications following cervical manipulation are extremely rare. It is estimated that CVAs occur in one in 400,000 to one in 3 million cervical spinal manipulations. In comparison, the risk assoc with several generally accepted pain relieving procedures in hospitals is much higher (coronary artery bypass grafting: mortality 1.2%, & serious complications >7%, or hip arthroplasty: mortality 1-2%). Even cosmetic procedure like liposuction has a mortality rate of 1 in 13,000. Therefore, one can hardly accuse cervical spinal manipulation of being a risky procedure as long as there is a relevant indication for its use. It may even be tempting to speculate that the widespread fear of cervical manipulation among MDs could be a political issue rather than a clinical one.

Haldeman, DC, MD, PhD, Carey, DC. Arterial dissections following cervical manipulation: the chiropractic experience. Can Med Assoc J 2001; 165(7):95-6. Review of malpractice data from the Canadian Chiropractic Protective Assoc (CCPA) to evaluate all claims of stroke following chiropractic care for 10 years between 1988 & 1997. The diagnosis by the treating neurologist was obtained. Results suggested that @ 134.5 million cervical manipulations were performed by DCs covered by CCPA during this period. There were 43 cases of neurological symptoms following cervical manipulation over 10 years. Of these, 20 were minor & not diagnosis as a stroke. 23 cases of stroke or vertebral artery dissection following cervical manipulation were reported. There are over 4500 DCs in Canada. The likelihood that a DC will be made aware of an arterial dissection following cervical manipulation is approx 1:8.06 million office visits, 1:5.85 million cervical manipulations, 1:1430 chiropractic years & 1:48 chiropractic careers. This is significant less than estimates of 1:500,000 – 1 million cervical manipulations based on surveys of neurologists. It’s probable that the experience of DCs does not reflect all dissections that occur following cervical manipulation.

Haldeman, S., DC, MD, PhD, et al. Unpredictability of cerebrovascular ischemia associated with cervical spine manipulation therapy. *Spine* 2002; 27(1):49-55. A review of 64 unpublished medicolegal records with extensive documentation describing cerebrovascular ischemia (CVI) after cervical spinal manipulation. This is the largest case series of CVI associated with cervical spinal manipulation. The next largest was only 10 cases. These 64 cases were referred to Haldeman for review over 16 years from the United States & Canada. The study was unable to identify factors from the history & P.E. that would assist in isolating patients at risk of CVI after cervical spinal manipulation. CVI after spinal manipulation appears to be unpredictable & should be considered an inherent, idiosyncratic, rare complication of cervical spinal manipulation. It's assumed CVI may be avoided by screening patients thru history and head & neck positioning to evaluate patency of the vertebral arteries. In 27 cases, DC described screening before spinal manipulation with patient's neck in ext/rot. None of these patients showed adverse responses to this screening test. Current frequency estimates vary from 1 in 400,000-500,000 to 1 in 3.85 million. Most CVAs occur in patients 30-50 years. There is no evidence that older patients at risk for atherosclerotic vascular ischemia are more likely to incur complications from spinal manipulation. None of the arteriographs in 64 cases showed the presence of arteriosclerotic plaquing. Therefore, the widely accepted risk factors for arteriosclerotic & thrombotic strokes probably do not apply; screening for bruits, hypertension, DM, smoking, to identify patients at risk for arteriosclerotic strokes does not appear to be of any benefit in determining the likelihood that a patient may be at risk for a stroke after spinal manipulation. Of 64 cases, 2 resulted in death & neither showed a pathology in the vertebral arteries on autopsy. One patient had a hemangioma of the venous plexus in the pons which hemorrhaged and the other had a ruptured berry aneurysm. None of the dissections resulted in death. Only 2 cases resulted from dissection of the internal carotid artery. Only 5 cases of carotid artery dissection are found in English lit. The current data on screening before spinal manipulation by placing the head/neck in extension/rotation suggest that this test is not capable of screening out patients at risk, is consistent with recent studies showing that rot/ext of the neck in vivo may not significantly reduce vert artery flow. Most dissections occur in the absence of C-spinal manipulation, spontaneously or after trivial trauma or common daily mov'ts of the neck, such as backing out of a driveway, painting the ceiling, playing tennis, sneezing, or yoga. Suggestions that there may be an inherited arterial defect in the cerebral arteries that makes some people prone to cerebral artery dissection may hold the answer for these seemingly random CVAs after spinal manipulation.

Rosner, PhD. Response to PBS. *Advance (FCER)* 2002; 23(1):4, 30-32. Risk of deaths from the use of medicines such as NSAIDs or from surgery to treat many of the same conditions as those managed by chiropractors is 400 to 700 times greater; yet warnings about the use of these particular options were not mentioned by anyone in your program. Rates of spontaneous arterial dissections have been reported annually to be 1.5-3 per 100,000, substantially larger than most rates of severe strokes associated with [let alone caused by] cervical manipulation. Shievink WT, et al. Recurrent spontaneous cervical-artery dissection. *NEJM* 1994; 330: 393-397. Shievink WT, et al. Internal carotid artery dissection in a community: Rochester, Minnesota, 1987-1992. *Stroke* 1993; 24: 1678-1680. Giroud M, et al. Incidence of internal carotid artery dissection in the community of Dijon [Letter]. *J Neur Neurosurgical Psychiatry* 1994; 57:1443.

Symons, DC, Leonard, Herzog, PhD. Internal forces sustained by the vertebral artery during spinal manipulation T. *JMPT*; 2002 25(8): 504-10. Study quantifies strains & forces sustained by the vertebral artery (VA) during spinal manipulation in 6 VAs from unembalmed cadavers. The cephalad (C0-C1) loop VAs were exposed & instrumented with a pair of piezoelectric ultrasonographic crystals. Strains were recorded during ROM, vertebrobasilar functional maneuvers, & during several spinal manipulation s. VAs were then strained on a materials

testing machine until mechanical failure (first point at which the elongation of the VA produced a decrease in force). Results: spinal manipulation on contralateral side of cervical spine resulted in an average strain of 6.2% +/- 1.3% to the cephalad loop of the VA – similar to or lower than the strains recorded during vertebrobasilar functional maneuvers & ROM. Failure testing: VAs could be stretched to 139% to 162% of their resting length before mechanical failure occurred. Therefore the strains sustained by the VA during spinal manipulation represent about one ninth of the strain at mechanical failure. Conclusions: spinal manipulation resulted in strains to the VA almost an order of magnitude lower than the strains required to mechanically disrupt it. Under normal circumstances, a typical High velocity low amplitude spinal manipulation thrust is very unlikely to mechanically disrupt the VA.

Norris, MD et al. Sudden neck movement and cervical artery dissection. The Canadian Stroke Consortium. Canadian Med Assoc J 2000; 16(1): 38-40. Based on a survey of 38 Canadian neurologists: Stroke due to neck manipulation occurred in 28% (21/74) of our cases. . .there is little doubt that chiropractic neck manipulation can result in dissection of the carotid or vertebral arteries leading to stroke. DCs should inform all patients about possible serious complications. Information Bulletin from the Inquest on the death of Ms. Lewis 2002: Dr. Norris invited Dr. Murray Katz to speak on chiropractic stroke to a hospital medical staff. After the talk Dr. Norris agreed that Dr. Katz's presentation was "unfair, unprofessional & completely unscientific" but he did nothing to stop it. In January 2001 Dr. Norris prepared a medical/legal report for the inquest which connected Ms. Lewis' stroke to a chiropractic adjustment. He testified that he couldn't recall what information he used in reaching his opinion. Dr. Norris conceded that he had never reviewed Ms. Lewis' medical records & knew nothing of her medical history when he wrote his opinion. He agreed that seeing her medical records would be important to coming to a conclusion.

Licht, MD, Christensen DC, MD., Hoiland-Carlson MD, D musculoskeletal c, Is there a role for premanipulative testing before cervical manipulation? JMPT 2000; 23(3):175-179. Study at a university hospital vascular lab of vertebral artery blood flow in 20 patients with a positive premanipulative test for contraindication to spinal manipulation referred by DCs in Denmark. Flow velocities were measured in both vertebral arteries by color duplex sonography. 5 patients were excluded because symptoms were not reproduced in the vascular exam. In 15 patients with symptoms (vertigo, blurred or double vision, nausea, hemicranial paresthesia) no significant difference in peak flow velocity or time averaged mean flow velocity with different head positions was found. 19 of 21 DCs surveyed would treatment a patient with a positive premanipulative test if the vascular exam was normal. 8 of the patients with a positive premanipulative test were treated without complications. 7 are now symptom free & 2 have improved symptoms. The remaining 8 patients refused manip & continue to have the same symptoms. Conclusion: A positive premanipulative test is not an absolute contraindication to cervical spinal manipulation. If the test is positive & reproducible, patients should be referred for a duplex exam of the vertebral artery flow. If the duplex flow is normal, the patient should be eligible for cervical spinal manipulation despite the positive premanipulative test. Controversy exists about the sensitivity & specificity of premanipulative tests. Studies indicate a test may be negative, despite occlusion of the vert artery, & CVAs may occur despite a negative test. Functional tests of the vertebral arteries include: Barre-Leiou's sign test, Geroge's cerebrovascular craniocervical functional test, Maigne's test, Hautant's test, Underberg's test, Hallpike maneuver, & deKleyn's or Wallenberg's tests. All are variations of the same theme: extreme rotation & extension of the head to provoke cerebral ischemia during positional change of the cervical spine. A test is positive if it provokes S&S of vertebrobasilar insufficiency (nystagmus, vertigo, dizziness, tinnitus, visual blurring, nausea or faintness). In this study there was no significant difference in either peak flow or time-averaged mean flow velocity in the

various head positions. Results suggest that a positive test is seldom assoc with changes in vert artery blood flow & that a positive deKleyn's test should not be considered an absolute contraindication to cervical spinal manipulation .

Terrett A, DC. Current Concepts in Vertebrobasilar Complications following Spinal Manipulation. *nociceptorMIC* 2001. Functional vascular tests are not a reliable indicator or predictor of VBI (vertebrobasilar ischemia). The tests have problems with false positive results, & often following spinal manipulation to the neck &/or other spinal regions, the positive result cannot be reproduced. Functional vascular tests have problems with false negative results. The absence of a positive functional test cannot be absolutely interpreted to mean that there is no underlying arteriopathic process. In all but the most grossly pathological or highly susceptible cases, these tests will give a false negative result & a false sense of security to the practitioner. It makes no sense to subject patients to a screening test that is invalid & gives the practitioner a false sense of security regarding the degree of risk for spinal manipulation . This can only lead to the conclusion that the tests should be abandoned, for clinical & medicolegal purposes, & should not be used for non-clinical risk management reasons. There is no evidence that suggests positive results have any correlation with future VBS if spinal manipulation is used. Current testing procedures are not able to predict susceptibility to VBS.

Proprioception, Dizziness, the Cervical Spine and Spinal Adjustment

Licht, MD, Christensen DC, MD, Hoilund-Carlsen MD, D musculoskeletal c, Is there a role for premanipulative testing before cervical manipulation? *JMPT* 2000;23(3):175-179. Other conditions may be responsible for the symptoms evoked by a premanipulative test. Neck proprioceptors involved in postural adjustment, are closely related to vestibular function. The proprioceptors are the joint receptors of the first 3 upper cervical vert. A positive premanipulative test could be from proprioceptor dysfunction, resulting in "cervical vertigo" by way of their projections to the vestibular nucleus. This presents a dilemma – the very symptoms that contraindicate therapy may most likely be relieved by the treatment they exclude. Patients in this study who were treatment got relief which favors an explanation of this kind & suggests that a positive deKleyn's test should generally not be considered a contraindication to spinal manipulation .

Norre. Vertigo & the Cervical Spine. *Medica Physica* 1986; 9:183-194. Vertigo results from a disturbance in sensory input from vestibular apparatus, eyes, & proprioceptors (especially of the neck) which renders the pattern abnormal & dysharmonic. The dysfunction of one sensor makes its signal contradictory to that of the others resulting in a Sensory Mismatch. Neck proprioceptors have a sensory function equivalent to vestibular function. Stimulation of neck proprioceptors produce the same ocular reflexes as does the vestibular system: Cervico-ocular Reflex.

Hinoki, MD. Vertigo post-Whiplash due to over excitation of cervical proprioceptors. *Acta Otolaryng* 1988; Suppl 419:9-29. As a result of tissue injury & inflammation there is overexcitation of cervical & lumbar proprioceptors. Their abnormal input produces dysregulation of the CNS. This is a TRIGGER – TARGET effect. In 68.4% of patients there is increased disequilibrium due to pulsed stimulation or saline injections applied to injured neck muscles which was reduced by a cervical collar.

Nelson CF et al. The efficacy of spinal manipulation, amitriptyline and the combination of both therapies for the prophylaxis of migraine headache. *J Manipulative Physiol Ther.* 1998 Oct;21(8):511-9.

BACKGROUND: Migraine headache affects approximately 11 million adults in the United States. Spinal manipulation is a common alternative therapy for headaches, but its efficacy compared with standard medical therapies is unknown. **OBJECTIVE:** To measure the relative efficacy of amitriptyline, spinal manipulation and the combination of both therapies for the prophylaxis of migraine headache. **DESIGN:** A prospective, randomized, parallel-group comparison. After a 4-wk baseline period, patients were randomly assigned to 8 wk of treatment, after which there was a 4-wk follow-up period. **SETTING:** Chiropractic college outpatient clinic. **PARTICIPANTS:** A total of 218 patients with the diagnosis of migraine headache. **INTERVENTIONS:** An 8-wk course of therapy with spinal manipulation, amitriptyline or a combination of the two treatments. **MAIN OUTCOME MEASURES:** A headache index score derived from a daily headache pain diary during the last 4 wk of treatment and during the 4-wk follow-up period. **RESULTS:** Clinically important improvement was observed in both primary and secondary outcomes in all three study groups over time. The reduction in headache index scores during treatment compared with baseline was 49% for amitriptyline, 40% for spinal manipulation and 41% for the combined group; $p = .66$. During the posttreatment follow-up period the reduction from baseline was 24% for amitriptyline, 42% for spinal manipulation and 25% for the combined group; $p = .05$. **CONCLUSION:** There was no advantage to combining amitriptyline and spinal manipulation for the treatment of migraine headache. Spinal manipulation seemed to be as effective as a well-established and efficacious treatment (amitriptyline), and on the basis of a benign side effects profile, it should be considered a treatment option for patients with frequent migraine headaches.

Heikkila. Scand J Rehab 1996; 28:133-138. Study of kinesthetic sensibility in 14 whiplash patients (motor vehicle accident 2-3 years before) vs 34 healthy subjects & the effects of a rehab program. subjects were tested in terms of head repositioning accuracy. All patients had pain & decreased ROM immediately after injury & persistent neck symptoms . Whiplash patients were significant less precise in repositioning their heads but this improved after 5 wks of rehab. Cervicocephalic kinesthesia is probably linked to sensory info from muscular & articular proprioceptor. A flexion-extension injury results in proprioceptor dysfunction either by lesioning or functional impairment of muscular & articular receptors, or by alteration in afferent integration & tuning.

Heikkila, MD, Wengren, MD, PhD. Arch Phys Med Rehabil 1998;79:1089-1094. The nociceptor-interneuron-motor neuron connection in the spinal cord may contribute to increased muscle tension. With increased muscle tension & sensitized muscle spindles, the increased sensitivity may give rise to erroneous proprioceptor signaling, esp if spindles in different neck muscles or on different sides of the neck are unequally sensitized. Erroneous cervical proprioceptor info converges in the CNS with vestibular & visual signals, with a consequent feeling of dizziness or unsteadiness caused by distorted mental representation of body orientation & by a misinterpreted relation to surroundings.

Rogers, DC. MPHT 1997;20(2):80-85. Effects of spinal manipulation on cervical kinesthesia in patients with chronic neck pain. Study of spinal manipulation vs stretching exercise's effect on pain & head repositioning in 20 patients with chronic neck pain in a randomized controlled trial. ½ of patients received 6 treatments of high-velocity, low amplitude cervical spinal manipulation & ½ got stretching of upper thoracic muscles 2 sessions daily. **Results:** spinal manipulation patients had a mean reduction in VAS scores of 44% & a 41% improvement in head repositioning skill. Stretching patients had a 9% reduction in VAS & a 12% improvement in head repositioning scores. **Conclusion:** Results suggest a possible effect of spinal manipulation on proprioceptor in patients with chronic neck pain. **Limits:** Small sample size, lack of blinding of examiner.

Heikkila, MD, PhD et al. Effects of Acupuncture, Cervical Manipulation and NSAID Therapy on Dizziness and Impaired Head Repositioning of Suspected Cervical Origin, *Man Ther* 2000;5:151-157. 14 patients with chronic (>3 mo) dizziness/vertigo of suspected cervical origin were given in random order: 1) acupuncture – 3 treatment within 2 weeks, 2) cervical spinal manipulation – 3 treatment within 2 weeks, 3) no therapy, and 4) NSAID-percutan applied 2-3X/day over sore muscles in neck/shoulders for 1 week to evaluate their effect on kinesthetic sensibility, dizziness/vertigo and pain. Outcomes were based on effects of each treatment on 1) cervical kinesthetic performance, 2) vertigo, 3) pain & 4) active cervical ROM. Results were compared with 39 controls. Spinal manipulation was the only treatment to diminish the duration of dizziness/vertigo complaints in the past 7 days (before 4.5 & after treatment 2.2) & increase cervical ROM. Both acupuncture & spinal manipulation reduce dizziness/vertigo & positively effect head repositioning. NSAID-percutan application & acupuncture alleviated pain. Results suggest spinal manipulation may impact most efficiently on the complex process of proprioceptor & dizziness of cervical origin. Symptoms of cervical vertigo are caused disturbed proprioceptor input from the neck. Erroneous cervical proprioceptor info converges in the CNS with vestibular & visual signals, affecting perception of body, orientation & the relation to the surroundings, which may be misinterpreted, resulting in a feeling of dizziness of unsteadiness. Disturbed kinesthetic sensitivity may contribute to functional instability of joints & susceptibility to reinjury, chronic pain & DJD. Removal of abnl afferent input from joints may improve proprioceptor & motor response. Conclusion: Results suggest that spinal manipulation may be most effective in influencing the complex process of proprioceptor sensibility & dizziness of cervical origin.

Medical Management, Prescription Drugs, Surgery – Risks, Marketing, Manipulation

Classen DC, Pestonik SL, Evans RS, et al: Adverse drug events in hospitalized patients. Excess length of stay, extra costs, and attributable mortality. *JAMA* 1997;277(4):301
ADVERSE DRUG REACTIONS FOUND TO BE RESPONSIBLE FOR LOSS OF LIVES
AND BILLIONS OF DOLLARS IN ADDED HEALTH CARE COSTS...

Chiropractic has always advocated drug free health care and it seems, with good reason! In the past few years a number of studies, concerning the effects that adverse prescription drug reactions have on patients and on the health care industry, have been published. These studies reveal some disturbing facts about health care in The United States. For example, it is estimated that adverse prescription drug reactions increase the risk of death to a patient approximately 2 times. In fact, it is estimated that as many as 140,000 people die every year from adverse prescription drug reactions! In addition, in The United States alone, the ill effects of adverse prescription drug reactions and the deaths that they cause cost an estimated \$136 billion dollars per year in added health care costs. That figure is more than what it costs for all the cardiovascular care or diabetes care in The United States per year. If you suffer from an adverse prescription drug reaction you are likely to have to stay in the hospital for 2 to 5 more days at an added cost of \$3000 to \$5000 dollars! This knowledge, though shocking, is not new. As far back as 20 years ago, it was known that approximately 30% of hospitalized patients experience an adverse prescription drug reaction. In fact, it was estimated back then that 1 in every 300 hospital patients suffer a fatal reaction to prescribed medication.

Lasser, MD, MPH, et al. Timing of New Black Box Warnings and Withdrawals for Prescription Medications. *JAMA*; 2002; 287(17):2215-2220. Of 548 new chemical entities approved from 1975-1999, 56 (10.2%) acquired a new black box warning, (problems that may lead to death or serious injury, are required by FDA to be in a prominent box). 16 new drugs were withdrawn

from the market (a 4% probability of being withdrawn). Half of withdrawals occurred within 2 years of the drug's introduction. Many serious adverse drug reactions (ADRs) are discovered only after a drug has been on the market for years. Why? FDA drug trials are often underpowered to detect ADRs & have limited follow-up. Despite limited knowledge about the safety of new drugs, their market uptake & sales volume may be explosive. The pharmaceutical industry promotes the early use of new drugs & influences Drs' adoption of such drugs. Direct-to-consumer drug advertising generates a high volume of new drug prescriptions. Drug firms rush new drugs to market because of concerns about patent life, a desire to mold prescribing habits before the market entry of competitors, & hopes for brisk sales to encourage investors & increase stock prices. patient exposure to new drugs with unknown toxic effects may be extensive. Nearly 20 million patients in the U.S. took at least 1 of 5 drugs withdrawn from the market between September 1997 & 1998. 7 drugs approved since 1993 & later withdrawn are reported to contribute to 1002 deaths. Clinicians should avoid using new drugs when older, similarly efficacious agents are available. Patients who must use new drugs should be informed of the drug's limited experience and safety record, & be observed for toxicity. Conclusions: Serious ADRs commonly emerge after FDA approval. The safety of new agents cannot be known with certainty until a drug has been on the market for many years.

Moynihan, R. et al. Selling sickness: the pharmaceutical industry and disease mongering. *BMJ*; 2002 324 (April 13): 886-897. Moynihan, R. et al. Selling sickness: the pharmaceutical industry & disease mongering. *BMJ*; 2002; 324 (April 13): 886-91. Pharmaceutical companies are actively involved in sponsoring the definition of diseases & promoting them to prescribers & consumers. Ostensibly engaged in raising public awareness about undiagnosed & undertreated problems, these disease awareness campaigns are linked to companies' marketing strategies to expand markets for new pharmaceutical products. Drug companies are engaged in invisible, unregulated attempts to change public perceptions about health & illness in order to widen markets for new drugs. The social construction of illness is being replaced by the corporate construction of disease. A key strategy is to target the news media with stories designed to create fears about the condition or disease & draw attention to the latest treatment. Company sponsored advisory boards supply "independent experts" for these stories. Public relations companies provide media outlets with the positive spin about the latest "breakthrough" medications. Drug companies sponsor meetings where a disease is being defined, fund studies of therapies, & develop close financial ties with leading researchers. They fund patient support groups, disease foundations, & advertising campaigns on both drugs & disease targeted at MDs & sponsor media awards with lucrative prizes to journalists who write about the disease. The promotional focus on chemical solutions for complex problems takes attention away from a variety of modestly effective non-pharmacological strategies, such as dietary supplements, smoking cessation & exercise which are played down or ignored. Irritable Bowel Syndrome (IBS) – long considered a common functional disorder is currently experiencing a global makeover. With the arrival of new drugs, the manufacturers seek to change the way the world thinks about IBS. It is currently being reframed as a serious disease attracting a label & a drug. The authors acquired a confidential document which describes a 3 year "medical education program" to create a new perception of IBS as a "credible, common & concrete disease" & establish in the minds of Drs that it is a significant & discrete disease state. Patients also need to be convinced that "IBS is a common & recognized medical disorder." The educational program is part of the marketing strategy of GlaxoSmithKline's drug Lotronex. First they set up an "Advisory Board" comprised of a key opinion leaders from each state of Australia to provide advice on the "current opinion in gastroenterology & on opportunities for shaping it." The need is to establish a market & convince the "specialist market" that the condition is a "serious & credible disease." Advertorials in medical journals featuring interviews with members of the company's expert advisory board is invaluable in "reassuring General Practitioners that the material they receive is clinically valid."

Other groups to be targeted include pharmacists, nurses, patients. Although billed as a medical education plan, the document is clearly part of the Lotronex marketing strategy. Also noted is that “proprioceptor & media activities are crucial to a well rounded campaign particularly in the area of consumer awareness.” The conflict of interest is obvious. The drug company’s primary interest is shaping public opinion about IBS in a way that will maximize sales of its medication. In this case the campaign was stopped because of the withdrawal of Lotronex from the market after reports to the FDA of serious & sometimes fatal adverse reactions. Pharmaceutical Marketing: How to establish a need & create desire to prescribe. Risk factors being conceptualized as diseases: Osteoporosis (3.8 vs 2.1). High cholesterol: lowering top normal range: Lipitor, Zocor.

Nuovo, MD et al. Reporting number needed to treatment & absolute risk reduction in randomized controlled trials. JAMA, 2002; 287 (21):813-4. Wiesel, MD. Backletter; 2002 17(10): 109, 11822. Med journals permit authors to present new treatments in a misleading fashion. They allow statistics that paint findings in a maximally positive light to ensure maximal impact in the mass media. A review of studies had a 9% reduction in VAS & a 12% improvement in head repositioning scores. Conclusion: Results suggest a possible effect of spinal manipulation on proprioceptor in patients with chronic neck pain. Limits: Small sample size, lack of blinding of examiner.

Heikkila MD, PhD. Et al. Effects of Acupuncture, Cervical Manipulation and NSAID Therapy on Dizziness and Impaired Head Repositioning of Suspected Cervical Origin, Man Ther 2000;5:151-157. 14 patients with chronic (>3 mo) dizziness/vertigo of suspected cervical origin were given in random order: 1) acupuncture – 3 treated within 2 weeks, 2) cervical spinal manipulation – 3 treated within 2 weeks, 3) no therapy, and 4) NSAID-percutan applied 2-3X/day over sore muscles in neck/shoulders for 1 week to evaluate their effect on kinesthetic sensibility, dizziness/vertigo and pain. Outcomes were based on effects of each treatment on 1) cervical kinesthetic performance, 2) vertigo, 3) pain & 4) active cervical ROM. Results were compared with 39 controls. spinal manipulation was the only treatment to diminish the duration of dizziness/vertigo complaints in the past 7 days (before 4.5 & after treatment 2.2) & increase cervical ROM. Both acupuncture & spinal manipulation reduce dizziness/vertigo & positively effect head repositioning. NSAID-percutan applications & acupuncture alleviated pain. Results suggest spinal manipulation may impact most efficiently on the complex process of proprioceptor & dizziness of cervical origin. symptoms of cervical vertigo are caused disturbed proprioceptor input from the neck. Erroneous cervical proprioceptor info converges in the CNS with vestibular & visual signals, affecting perception of body, orientation & the relation to the surroundings, which may be misinterpreted, resulting in a feeling of dizziness of unsteadiness. Disturbed kinesthetic sensitivity may contribute to functional instability of joints & susceptibility to reinjury, chronic pain & DJD. Removal of abnl afferent input from joints may improve proprioceptor & motor response. Conclusion: Results suggest that spinal manipulation may be most effective in influencing the complex process of proprioceptor sensibility & dizziness of cervical origin.

Nuovo, MD et al. Reporting number needed to treatment & absolute risk reduction in randomized controlled trials. JAMA, 2002; 287(21):813-4. Wiesel, MD. Backletter; 2002 17(10): 109, 11822. Med journals permit authors to present new treatments in a misleading fashion. They allow statistics that paint findings in a maximally positive light to ensure maximal impact in the mass media. A review of studies published in NEJM, JAMA, BMJ, The Lancet, & Ann Intern Med found in the vast majority, only the most favorable statistic – relative risk reduction (proportion of baseline risk removed by treatment) was used when reporting

results. Of 359 articles only 5 reported on the “number needed to treat” (number of patients who must be treated to prevent one adverse event) & only 18 portrayed the results in terms of “absolute risk reduction” (proportion of patients who are spared an adverse outcome by the treatment). Journals need to improve reporting of randomized controlled trials & enable readers to better interpret results. There are allegations that drug companies have oversold the benefits of osteoporosis meds by overemphasizing measures of relative risk reduction – ignoring absolute risk reduction & number needed to treat. A 1998 study found 2.1% of women with low bone density treatment with alendronate (Fosamax) developed vert Fx vs 3.8% treatment with a placebo. This is a 44% reduction in relative risk. The authors stated: “Alendronate reduced risk of vert Fx by about half.” This got splashy media coverage. Results are much less impressive in terms of absolute risk reduction: only 1.7%. In terms of the number needed to treat: 60 women had to be treated with alendronate for 4 years to prevent a single vert Fx. In women with higher ranges of bone density, 363 would have taken alendronate for 4 years to prevent a single silent Fx. Among women in the osteoporotic range, 35 would have had to take alendronate for 4 years to prevent a single Fx. Ex: at 1 year follow-up, raloxifene (Evista) decreased the risk of new vertebral Fx by 68%. Sounds impressive, but, very few women in either group had vert Fx: 0.08% of subjects in placebo group & 0.03% in raloxifene group. The absolute risk reduction was 0.05%. An absolute risk reduction of one half of 1% sounds a lot less impressive than a relative risk reduction of 68%. The authors didn’t state the number needed to treat: 200 women would have had to take 60 mg/day of raloxifene for a year to prevent a single vertebral Fx.

Gorman C, Park A. The truth about hormones. Time 2002; July 22:32-39. Fletcher, MD, MSc, Colditz, MD, DrPH. Failure of Estrogen Plus Progestin Therapy for Prevention. JAMA; 2002 28(3), July 17. Hormone replacement therapy (HRT) for aging women began around 1966. More than 40% of all women in the US start some form of HRT in their menopause years & many continue well into their 70s & 80s. Treatment was based on observational studies which showed that women on HRT lived longer with fewer health problems (lower cholesterol, less heart attacks & strokes). However, when reviewing all the data for guidelines on HRT for the American College of Physicians, it was realized that the data wasn’t definitive and the Women’s Health Initiative (WHI) was initiated. This involved randomized controlled trials enrolling >160,000 women including >16,000 healthy 50-79 year olds to study estrogen & progestin: Prempro by Wyeth Pharmaceuticals. 8,506 taking HRT & 8,102 taking placebo. The 8 year study was stopped 3 year early because of dangers associated with HRT: increased risk of blood clots in the legs & lungs, heart attacks & breast cancer. HRT increase in breast cancer: 26%; increase in heart disease: 29%; increase in strokes: 41%; increase in pulmonary embolism; 113%; decreased hip Fx: 34%; decreased colon cancer: 37%.

Moseley, MD, et al. A Controlled Trial of Arthroscopic Surgery for Osteoarthritis of the Knee. NEJM 2002; 347: 81-88. Arthroscopy is the most commonly performed type of orthopedistopedic surgery & the knee is by far the most common joint on which it is performed. A randomized, placebo-controlled trial to evaluate the efficacy of arthroscopy for osteoarthritis (OA) of the knee. Patients with knee OA were randomly assigned to receive 1) arthroscopic debridement, 2) arthroscopic lavage, or 3) placebo surgery (skin incisions & simulated debridement w/o insertion of the arthroscope). patients & assessors were blinded to the treatment assignment. Outcomes assessed 2 & 6 weeks, 3, 6, 12, 18 & 24 months. 3 pain, 2 function scales & an objective test of walking & stair climbing. 165 patients completed the trial. Results: At no point did either of the intervention groups report less pain or better function than the placebo group. Knee-Specific Pain Scale were similar in placebo, lavage, & debridement groups at one & two years. Differences between placebo group & intervention groups exclude any clinically meaningful difference. Conclusion: outcomes after arthroscopic lavage or debridement were no better than those after a placebo procedure. At no point did either

arthroscopic intervention group have either greater pain relief greater improvement in function than the placebo group. Indeed, objectively measured walking & stair climbing were poorer in the debridement group than the placebo group at 2 weeks & at 1 year & showed a trend toward worse functioning at 2 years. More than 650,000 arthroscopic lavage or debridement procedures are performed each year at a cost of roughly \$5000 each. There is no evidence that arthroscopy cures or arrests OA. If the efficacy of arthroscopic lavage or debridement in OA patients of the knee is no greater than that of placebo surgery, the billions of dollars spent on such procedures annually might be put to better use.

Barry, P. Drug industry spends huge sums guarding prices. AARP Bulletin; 2002 (May): 3, 13, 14, 15. The drug industry wages its battles with money. The sheer volume of their expenditures gives drug makers so much weight, they are able to thwart legislation they don't like. The industry's expenditures in Washington in 1999-2000 was documented by an investigation by Public Citizen which revealed the drug industry spent \$177 million lobbying members of Congress & \$20 million on campaign contributions – more than any other industry. The industry employed 625 lobbyists, more than 1 for each member of Congress & paid each lobbyist on average >\$12,000/month. Critics say this perpetuates the high cost of drugs. The pharmaceutical industry's influence concerns lawmakers. "The amount of money they spend & the number of lobbyists they hire is really a problem in a democracy," says Tom Allen, D-Maine. The drug industry disagrees. "I'd say we are actively participating in the democratic process," responds a spokesman for the Pharmaceutical Research & Manufacturers of America (PhARMA), its trade group. The industries' major issues: lobby for: bills maintaining & extending patent rights, bills shortening approval time for new drugs. Lobby against bills encouraging the use of generics to curb costs, bills allowing drugs to be imported from Canada. For years the pharmaceutical industry has been, by far, the richest industry in America. This year's Fortune 500 list it had an average 18.5% profit margin, more than 4X that of all other industries. Economic analysis shows that the drug industry makes large profits way above the average 13% of revenue it spends on R&D. It spends an average of 35% on advertising & administration including lobbying costs.

Zoellner, T. America's other drug problem. Men's Health 2001; Oct: 118-123. The AMA supplies pharmaceutical manufacturers with the "physician's master file," a database that contains detailed biographies of member MDs as well as their individual DEA (drug enforcement agency) numbers. Combine an MDs DEA number with the prescription records that drug companies purchase from pharmacies & suddenly you're looking at every medication an MD is prescribing. Last year sales of the physician's master file to drug companies made the AMA an estimated \$20 million.

Wiesel, S., MD. Multimillion dollar treatments. Backletter; 2002 17(7): 84, Vioxx (Merck) & Celebrex (Pharmacia) are the most heavily promoted treatments for BP in history. In 2000 Merck spent \$161 million promoting Vioxx & Pharmacia \$78 million for Celebrex. Pepsi spent \$125 million advertising Pepsi & Budweiser spent \$146 million for beer. (NoFreeLunch.org). There are currently about 80,000 drug reps in the US. The drug industry gave out \$7.2 billion in free samples in 2000. Free samples are a strong selling point. Older NSAIDs are no longer available in sample packets. The marketing system is promoting more expensive care.

Elder, MD, et al. A cyclooxygenase-2 inhibitor impairs ligament healing in the rat. Am J Sports Med 2001; 29(6): 801-5. Study used surgical transection of medial collateral ligaments of 50 rats as a model for acute ligamentament injuries to investigate the effects of Celebrex (celecoxib) on ligament healing. Post-op, half the rates were given celecoxib for first 6 days of recovery, others were not. At 14 days after the operation, both injured & uninjured medial collateral ligamentaments were mechanically tested to failure in tension. The strength of

celecoxib-treated injured ligaments was 32% less than that of untreated injured ligaments. In addition, the energy absorbed to failure was 41% less & stiffness was 21% less than in untreated injured ligaments. This is the first study to deal with the effects of COX-2 inhibitors on soft tissue healing. Our results suggest that caution should be used when prescribing COX-2 inhibitors for the treatment of human ligament injuries.

Wiesel, S., MD. Cox-2s and Bone Healing. Backletter; 2002 17(7): 73, 82, 83. Editorial in J Bone & Mineral Research suggests MDs stop using Cox-2 inhibitors & other NSAIDs for patients undergoing bony healing (spine surgery, stress or spine Fx, receiving dental implants, or joint arthroplasty) because new animal studies suggest these meds inhibit bone formation. Vioxx & Celebrex had a particularly negative impact on bone formation. It's not clear whether older patients with low bone density & history of Fx should also avoid Cox-2 inhibitors & NSAIDs. Study: NSAIDs delayed healing of femoral Fx in rats & Cox-2 inhibitors appeared to prevent nl healing altogether. Cox-2 inhibitors can stop nl fracture healing & induce the formation of incomplete unions & nonunions. (Simon et al Cyclooxygenase-2 function is essential for bone fracture healing. J Bone & Mineral Res 2002; 17(6):963-76). Created femoral Fxs in 253 rats. Group 1: no meds, Group 2: indomethacin, Group 3: Celebrex (at nl dose) & Group 4: Vioxx (at 4X nl dose). Results: Indomethacin group healed, but healing delayed: 25% to 50%. No rats treatment with Celebrex exhibited complete healing. Conclusion: Celebrex at nl daily dose delayed & inhibited bony healing. Vioxx at higher dose (4X) completely inhibited bony healing.

Wiesel, MD. Are drug companies shading the truth about Cox-2 inhibitors? Backletter 2001; 16(12): 136-7. The FDA arthritis advisory committee reports Vioxx & Celebrex provide no more effective analgesia than older NSAIDs. Celebrex is comparable in efficacy to naproxen. Vioxx is comparable to ibuprofen or diclofenac. GI safety profile of Celebrex is no better than ibuprofen or diclofenac. "There is not a proven clinically important safety advantage in upper GI events globally." Vioxx has a significantly lower cumulative incidence of GI perforations, ulcers, & bleeds compared to naproxen (2.08% & 4.49%). But, FDA has not eased its GI warning on the Vioxx label. Cardiovascular safety: (CLASS trial), patients taking Celebrex & those taking diclofenac & ibuprofen had a virtually identical incidence of cardiovascular events (@1%). Patients on Vioxx (VIGOR trial) had a 4 to 5 fold increase in myocardial infarctions compared to patients on naproxen & more than twice as many serious CV events overall (2.5% vs 1.1%).

Mukherjee, D et al. Risk of cardiovascular events associated with selective COX-2 inhibitors. JAMA 2001; 286(8):954-9. A lit search on the use of COX-2 inhibitors published between 1998 & 2001 yielded 2 major randomized trials, the Vioxx Gastrointestinal Outcomes Research Study (VIGOR: 8076 patients) & the Celecoxib Long-term Arthritis Safety Study (CLASS: 8059 patients), & 2 smaller trials with approximately 1000 patients each. Results from VIGOR showed that the relative risk of developing a thrombotic cardiovascular event (myocardial infarction, unstable angina, cardiac thrombus, cardiac arrest, sudden death, ischemic stroke, and TIA) with rofecoxib compared with naproxen was 2.38. There was no significant difference in cardiovascular events between celecoxib & NSAIDs in CLASS. The myocardial infarction rates for COX-2 inhibitors in both VIGOR and CLASS were significantly higher than in the placebo group of a recent meta-analysis of 23,407 patients. The data raise a cautionary flag about the risk of cardiovascular events with COX-2 inhibitors.

Growth in Prescription Drug Sales – 1998 (nacds.org/news/releases/retail.html). For the first time, retail sales of prescription drugs will exceed \$100 billion, according to projections released by the National Association of Chain Drug Stores (NACDS) which estimates year end sales for 1998 will reach \$102 billion, an increase of 15% over 1997. Additionally, sales of over-the-counter meds in chain pharmacies will reach over \$28 billion, an increase of >10% over sales in

1997. NACDS also announced projected increases in the total number of prescriptions dispensed by retail pharmacies for 1998 will reach nearly 2.8 billion, an increase of 6% from 1997. NACD subjects projects continuing growth in prescription volume will lead to nearly 4 billion dispensed by 2005.

Wiesel S, MD. Drug Ads, Consumer Wrath. Backletter 1999; 14(2):24. HCFA predicts that expenditures on prescription drugs will almost triple between 1996 & 2007 – from \$62 billion in 1996 to \$171 billion in 2007. Direct-to-consumer advertising is expected to play a significant role in that growth. A November 1998 press release from a pharmaceutical consulting firm that drug companies spent more than \$722 million on Direct-to-Consumer advertising in the first 6 months of 1998 alone. Over half of the MDs surveyed said patients were requesting increasingly more drugs that were advertised directly to them.

Lurie, MD, MPH, Wolfe, MD. FDA Medical Officers (Mos) report lower standards permit dangerous drug approvals. 1998, Dec. 2. After criticism from the drug industry that the drug approval process was too slow, the US Congress passed the **Prescription Drug User Fee Act** in 1992 which authorized drug companies to pay fees to the FDA so it could hire more months–MDs responsible for coordinating the reviews of New Drug Applications by FDA employees, to speed up the review of new drugs. One result: larger numbers of drugs are now being approved. In 1995, 28 new drugs were approved, similar to previous years, in 1996, 53 new drugs were approved & 39 more new drugs were approved in 1997. In 1997 Congress passed the **FDA Modernization Act**, which permits drug approval based on a single clinical trial (instead of two). It also included mechanisms for speeding FDA review. A survey of FDA months in Sept/Oct 1998 found that many say the safety & efficacy standards for approving new drugs have been lowered in the past few years, allowing many drugs to be approved which should not have been. The study was conducted following the setting of 2 all time FDA records. First, the largest number of drugs ever approved in any 2-year period (92 in 1996 & '97). Second, a record 3 new prescription drugs were banned in a 12 month period because they were too dangerous to be allowed to stay on the market. For all 3: (1) **dexfenfluramine (Redux – 3/98)**. (2) **mibefradil (Posicor – 6/98)** & (3) **bromfenac (Duract – 10/98)** – data available prior to approval raised significant safety concerns. 19 months identified 27 new drugs in the past 3 years that they reviewed & thought should not have been approved but were. 17 months described the current standards as “lower” or “much lower” than in the past. 1 month stated: “My feeling, after more than 20 years at FDA, is that unless drugs cannot be shown to kill patients outright then they will be approved with revised labeling & box warning.” 34 months stated that the pressure on them to approve new drugs was “somewhat greater” or “much greater” compared to prior to 1995. Inappropriate pressure from Congress, drug companies, & senior FDA employees create an atmosphere in which the likelihood of drug approval is maximized & takes the form of 1) Inappropriate phone calls, 2) Pressure to withhold data or personal opinions unfavorable to a drug from FDA Advisory Committees, & 3) Pressure from supervisors to change their opinion in the direction of approving the drug.

Stolberg, SG. The Boom in Medications Brings Rise in Fatal Risks. New York Times 1999; June 3. Doctors are having a difficult time keeping abreast of FDA warnings about possible risks. “There are just so many new drugs available,” says Dr. Kenneth W. Kizer, Under Secretary for health in the Depart of Veterans Affairs, “And keeping current with the information that goes with each drug has become almost impossible.” FDA officials are convinced the danger is growing. FDA, long criticized as moving too slowly on drug applications, is now approving products at a record-setting pace. More prescriptions are being written not only because there are more drugs but also because the population is aging; elderly people take more than 1/3 of all drugs that are prescribed.

Consumer-Direct Broadcast Advertisements. Draft Guidance for industry. 1997 August. The Federal Food, Drug, & Cosmetic Act requires that manufacturers advertising prescription (treatment (prescription)) drugs disclose information about the product's uses & risks. For treatment (prescription) drugs, the Act requires broadcast ads to contain "information in brief summary relating to side effects, contraindications, & effectiveness." Ads broadcast through television, radio, or phone systems must disclose the product's major risks. This is called the "**major statement**" which conveys the product's most important risk information in consumer friendly language. Sponsors of broadcast ads may present a brief summary or, may make "adequate provision. . .for dissemination of the package labeling in connection with the broadcast presentation" via toll free phone number, web page, print ads. The major statement, together with adequate provision for dissemination of the product's labeling, provide the information disclosure required for broadcast advertisements.

The Nat'l Inst for Health Care Management Res & Ed Foundation. Factors affecting the growth of prescription drug expenditures 1999; July 9. Spending on treatment (prescription) drugs increased twice as fast as national care health spending from 1992 & '97 (>11% growth per year vs 5.5%). 1997-1998 growth rate will exceed 18%: a \$42.7 billion (84%) increase in retail drug expenditures between 1993 (\$50.6 billion) & 1998 (\$93.4 billion). Spending growth is concentrated in the heavily advertised drugs. Antihistamines: such as Claritin*, Zyrtec*, Allegra* increased by 612% between '93 & '98 (these 3 drugs accounted for 90% of sales for treatment (prescription) antihistamines.) Antidepressants such as Prozac*, Zoloft & Paxil increased by 240%; Cholesterol reducing drugs such as Lipitor, Zocor* & Pravachol* increased by 194%; Anti-ulcerant drugs such as Prilosec*, Prevacid, & Pepcid increased by 71%. When newer products are introduced & heavily marketed, they tend to rapidly dominate sales in their class. Direct to consumer (DTC) spending increased >20X from \$55.3 million in '91 to over \$1.3 billion in '98 & projected to increase another 54% in '99 reaching \$2 billion. Patients are becoming more likely to ask for treatment (prescription) drugs by brand name. A 1998 survey found 53% of MDs reported an increase in brand name requests, up 30% from mid-97 before TV ads. When patients ask a MD for a specific treatment (prescription) drug, evidence indicates that the Dr is likely to honor such requests. A '97 study found that 73% of consumers said their MD accommodated their request for a specific drug. Requests for Claritin were honored 86% of the time. Worldwide R & D expenditures increased >12X from \$2 billion in 1980 to \$24 billion in 1999. Pharm Res & Manufact Assoc (PhRMA) reports 316 new drugs are under development to treat cancer, 87 to treat cardiovascular diseases, 93 to treat other chronic problems such as arthritis, osteoporosis, DM & asthma, & 17 to treat Alzheimer's. Advances in genetic research will increase the number of targets for drug intervention exponentially in just a few years. There are 500 known targets for drug intervention & is expected to increase the number of potential targets to at least 3,000 & perhaps as many as 10,000. The single largest market for treatment (prescription) drugs is aging baby boomers. 54 to 64 age group will expand by 59% between 98 & 2010. Drugs used by middle age & elderly are expensive & often treatment conditions (HBP, cholesterol, DMD, arthritis) which require a steady regimen throughout the patient's life.

Medical Models, Patient Centered Care – Outcomes Assessment

Hawkins, PhD. T J of Mind-Body Health 1994; 10(1): 55-56. According to the **Biomedical Model**, disease is associated with changes at the microscopic level. This approach tends to ignore other significant factors associated with health & illness such as patients' attitude toward their work, health & disease. Such influences are dismissed or ignored because they don't fit within the biomedical model. This model doesn't account for the psychological state of the patient, the healing potential of caring & empathy, or the relationship between the patient & provider. Such factors are not seriously considered & have no part in the biomedical model. This

helps explain **the dehumanization & depersonalization in orthopedic medicine which places the disease rather than the patient at the center of its focus.**

Jamison, MD, PhD, EdD. J Chiropractic Humanities 1994; 4(1):26-35. The biomedical model is flawed because it is etiologically limited. It conceptualizes pathogenesis exclusively in terms of molecular biology & ignores the human role & social conditions of disease. The model inherently depersonalizes the doctor-patient relationship because the individual patient's perspective, experience of illness is dismissed as irrelevant to diagnosis & management.

Marketos SG, MD, Skiadas PK, MD. Spine 1999; 24(11):1159-1163. Advances in technology have changed the whole construction & philosophy of medicine. Interest has shifted from clinical evaluation of the patient to the interpretation of sophisticated procedures. This attitude tends to alienate physicians from the patient. Overspecialization has also contributed to broadening the gap between physician and patient. Fragmentation of medicine has created physicians who regard the patient as a disordered mechanism rather than a psychosomatic entity. . .Clinical medicine has been sidestepped by medical technology. There is a feeling that biomedical technology has ignored the psychosociologic aspect, treating the patient more or less as a disease, not as a unique human entity resulting in depersonalization and a lost sense of the patient's individuality.

What we want our patients to know: Chiropractic acknowledges & cares for the whole person. The Patient is the Center of Care: 1. His or her function, 2. Well being, 3. Quality of life, 4. General health and 5. Structural integrity – not a disease or symptoms.

Gatterman, MA, DC, EdD. Med. J Alternative Complementary Med 1995; 1(4):371-386. The medical reductionists narrow field of vision delays treatment until the pathological process can be identified. The holistic providers strive to improve function & enhance the body's own curative effort, its inherent capacity to heal.

Wilson, MD, MSc, **Cleary**, PhD. JAMA 1995; 273(1):59-65. **Health Related Quality of Life (HRQL)** model or functional status model: focuses on dimensions of functioning & overall well being. Research is to find ways to accurately measure complex behaviors & feelings. HRLQ includes: 1. Physical functioning, 2. .Role functioning, 3. Mental health, 4. General health, 5. Vitality (energy/fatigue) levels, 6. Pain, 7. Cognitive functioning.

An introduction to the Health Outcomes Institute's outcomes management system 1993 1-5. We don't know enough about how medical interventions affect patients' lives &, therefore, are unable to appraise the true value of health services. Information must be obtained from patients to learn about function & quality of life following treatment. Patients judge the effectiveness of care by its impact on their lives. They want to know whether the treatment will relieve pain, improve their ability to see, hear, walk, or function in other ways. Providers have not taken these outcomes seriously enough. To understand the true effects of health care, information must be obtained from patients to learn about function & quality of life following treatment.

Hufford, PhD. Alternatives Therapies 1995; 1(1): 53-61. Illness is the experience of being sick – the impact of disease on the patient's perceived quality of life. Illness is what concerns sick people most. Patients' problems are not bad laboratory values, anomalous CTs, nor abnormal findings on orthopedic or neurological exams. Their problems are pain, loss of function, & suffering. Illness is profoundly personal, & no one has better access to its central features than the sick person. Consumer changes in medicine are due to the perception that experts often omit

from decision making crucial factors available only to the patient. An MD has expertise to predict probable outcomes of treatment & risks, but, only patients can say what effect treatment has on their illness, on their quality of life. When the authority of patients to speak about their illness is ignored, medicine is extended beyond physicians' expertise. Such authority is not legitimate. Objectivity of data, the freedom from the influence of emotions & personal bias includes observations that are quantitative & can be made by mechanical instruments. This is the basis for the preference of signs over symptoms. It has contributed to a sharp focus on **physiological pathology** to describe sickness & the effectiveness of treatment. Objectivity can be a very useful value in investigation, but when it excludes the subjective dimension of sickness it becomes pernicious.

Lewis, MD, Amini, MD, Lannon, MD. A General Theory of Love. NY: Random House; 2000: 80-2, 220-3. In adults subjected to prolonged separation, their bodies respond to the loss: cardiovascular function, hormone levels, & immune processes are disturbed. Illness or death often follows the end of a marriage or the loss of a spouse. One study found that social isolation tripled the death rate following a heart attack. Another, that group psychotherapy doubled the postsurgical lifespan of women with breast cancer. A third noted that leukemia patients with strong social supports had 2 year survival rates more than twice that of those who lacked them. Dozens of studies demonstrate that solitary people have a vastly increased rate of premature death from all causes – they are 3 to 5 times likelier to die than people with ties to a caring spouse, family or community. However, connectedness is not a drug or an operation, that makes it nearly invisible to Western medicine. The prevailing medical paradigm has no capacity to incorporate the concept that a relationship is a physiological process, as real & as potent as any pill or surgical procedure. In medicine there has been a distancing of doctors from human affairs. The first half of the twentieth century brought antibiotics, vaccines, X-rays, anesthesia. The age ushered in was also one of estrangement from patients. The paradox of Western medicine has been the coexistence of technical excellence with unpopularity. Americans receive the world's most advanced treatments, yet patients complain fiercely – Drs don't listen, they are cold & busy technocrats. What Drs once knew, but cast aside for technology is that patients come looking for both expert & healer. Illness arouses the ancient attachment machinery; it awakens a limbic need. When they go to the doctor, patients hope not only for the correct diagnosis, the appropriate remedy, they also want someone who connects with them. They wish for a warm hand on their shoulder and the security of speaking with one who has been through this before. Western medicine dismissed these tools of healing as expendable hand-holding, a luxury that busy schedules could not permit. "Bedside manner" became a cursory interchange thought mildly reassuring but inessential, particularly when compared to the real science of pathophysiology. Medicine lost sight of this truth: attachment is physiology. Good Drs have always known that the relationship heals. Western medicine embraced effective machines and ceded its historic soul. In 1994 in *The Lancet*, a proposal advocated teaching acting techniques to medical students to provide physicians with the means to feign concern for patients since their incapacity to care is too embarrassingly evident. Here, our Drs endeavor, without irony or shame, to pass off a good relationship as a kind of performance art that be conveniently faked. Their proposal aptly captures the emptiness at the core of Western medicine. Patients sense the limbic void in American medicine & have deserted en masse. Even while traditional medicine has rejected emotional aspects of healing, multiple groups sprang up to accommodate them: chiropractors, acupuncturists, masseuses, & others. Alternative healers proliferate in response to the demand for a context of relatedness. These limbically wiser settings are friendlier to emotional needs – they involve regular contact with someone who participates in close listening, and often, the ancient reassurance of laying on hands.

Yeomans, S. DC, FACO. Manual: Quantitative Functional Capacity evaluation: 2000. Interest in functional testing & outcomes assessment (OAs) is growing because physicians, Ins companies, medico-legal reviewers & Managed Care Organizations are demanding a way to objectify pt status & document pt progress during the course of care. OAs are emerging as the tools for measuring treatment effectiveness regardless of treatment methods utilized. OAs are concerned with objectifying patient status & showing pt progress over time in order to: 1) Validate patient's subjective complaint & improvement (pain diagram, VAS); 2) Document functional loss & progress; 3) Document changes in activities of daily living; 4) Documenting psychosocial status; Documenting time off of work (days off work). OAs help establish objective baselines & show progress. Functional tests are concerned with isolating key functional deficits which in turn drive therapeutic planning & clinical decision making.

Yeomans, S., D.C. The Clinical Application of Outcomes Assessment. Stamford, CT, Appleton & Lange; 2000.

Hurwitz EL, DC, PhD et al. Am J Public Health 1998; 88 (5):771-776. **The number of DCs & the percent of the population using chiropractic have approximately doubled during the past 15 to 20 years.** There has been a 2 fold increase in the use of chiropractic services & this mirrors the increase in number of DCs as well. A random sample of 1,916 patient records from 131 DC offices for completed treatment episodes from 5 US sites & 1 Canadian site for pt consultation between Jan 1, 1985 & Dec 31, 1991 were evaluated. 1310 pt records were low back pain & 606 were patients with other conditions. 68% of those who sought care were for low back pain while 32% were for other reasons including: 40% reported complaints of the face or neck, 19% had symptoms of extremities, 7.5% had headache. Non- musculoskeletal conditions such as migraine headache, otitis media & asthma accounted for fewer than 1% of the diagnosis.

Grumbach, MD, Coffman, MPP. JAMA 1998; 280(9):825-826. For most of the 20th Century, MDs have enjoyed a privileged position in US society. This “**professional sovereignty**” was buttressed by regulations that shielded p physicians from competitors, restricting opportunities for others to practice medicine. Physicians exercised considerable latitude in setting their own fees & in practicing medicine with minimal external oversight. But managed care is ending this golden era by imposing fee schedules, authorizing clinical decisions & restricting practice opportunities. Between 1992 & 1997 there was a 2 to 4 fold increase in the annual number of grads of neck pain, CNM, & PA programs & a doubling or more of grads from chiropractic & acupuncture schools. Many welcome an expanded role for NPCs, arguing that restrictive practice laws functioned more as protectionism for a physician guild than as protection for patients against unqualified providers. Patients will benefit from wider options in health care & competition may drive down prices for services.

Institute for Alternative Futures. The Future of chiropractic: Optimizing Health Gains 1998. Funded by a grant from NCMIC & administered by FCER. There is dramatic growth among alternative providers. Acupuncturists will swell from 10,000 to 24,000 by 2010. **DCs will nearly double from 55,000 to 103,000 by 2010.** Currently 15% of DCs are underemployed. This expansion comes at a time when experts forecast massive surpluses of conventional providers: >100,000 or more MDs, 200,000 or more nurses, 40,000 pharmacists by 2010. Alternative providers could face tremendous increased competition from these provider populations. In this environment all health professionals will face significant challenges. The ability to be financially successful will be more challenging. A critical question: will CAA schools, including chiropractic colleges, “overshoot” & produce surpluses, as medical, nursing & pharmacy schools are thought to be doing now? The profession faces the serious possibility that by 2010, DCs may

experience underemployment or unemployment. If the figures are accurate, the chiropractic profession might be well advised to reduce the number of new graduates, & soon.

Outcome Measures

Anderson, MD. Spine letter 1994; 1(2):1-3, 8. Outcomes research: you attempt to determine if what you are providing the pt is beneficial or not. The focus has shifted to the patient: Is the pt satisfied with the operation? Is the patient's functional ability normalized? Thru outcomes research we are determining how helpful a procedure or program has been to the patient.

Nelson BW, MD et al. Arch of Phys Med Rehabil 1999; 80(Jan):20-25. Cost of lumbar laminectomy: \$30,300; cost of lumbar fusion: \$62,300; cost of cervical laminectomy: \$20,750; cost of cervical fusion: \$43,100.

Devo, MD, MPH et al. Spine 1998; 23(18):2003-2013. Measurements of patient outcomes of low back pain has been a vexing problem. In an effort to achieve objectivity, physiologic measures such as ROM & muscle strength were widely used, but such measures are only weakly associated with outcomes more relevant to patients such as symptom relief, daily functioning, & work status. The appropriate dimensions of outcomes for low back pain include: 1) Symptoms, 2) Functional Status, 3) Overall Well-being, 4) Work Disability

a. Charting. Today, Must Quantify & Document: 1) Severity of patient's condition at initial presentation including: a) Disability/Loss of function & activities of daily living; b) Pain intensity & distribution; c) Positive orthopedist/neuro & imaging findings; d) Range of motion; 2) Benefit of care to date; 3) Need for additional care.

Most Widely recommended Outcomes Measures: Disability scales (Activities of Daily Living Scales): Oswestry, Roland-Morris, Neck Disability Index. Pain Drawing & Quadruple Pain scale (using visual analog vs numerical rating scale). A new disability measure: Functional Rating Index. Feise, DC, Menke, musculoskeletal, DC. Functional Rating index: a new valid and reliable instrument to measure the magnitude of clinical change in spinal conditions. Spine 2001; 26(1):78-87. Health Status questionnaires: SF-36 or Rand 36 or SF-12.

Physical Impairment: anatomic or pathologic abnormality leading to loss of normal bodily ability.

Disability (aka Functional Impairment): diminished capacity for everyday activities & gainful employment. Waddell, MD. Clin Ortho 1987;;221:271-273.

The basic grading of the Oswestry Disability Index and the Neck Disability Index: have the patient follow the directions to check the box in each section that most closely describes them. Each section has 6 boxes.

The upper box in each section indicates no disability and is worth "0" points,
The next box indicates minimal disability and is worth "1" point
The next box indicates mild disability and is worth "2" points
The next box indicates moderate disability and is worth "3" points
The next box indicates severe disability and is worth "4" points
The last box indicates complete disability and is worth "5" points

Add up the scores of each of the 10 sections to get the “raw” score. Multiply the “raw” score by 2 to get the percent disability score. The highest possible raw score is 50 and when multiplied by 2 equals 100% functional disability. Take the patient’s percent disability score and apply it to the following grading scales:

Oswestry Disability Index: (see Fairbank. Physiotherapy 1981; 66(8):271-3. Hudson-Cook. In Roland, Jenner (eds). Back pain new approaches to rehabilitation & education. Manchester Univ Press, Manchester 1989: 187-204). Scoring: 0-5% none, 6-20% mild, 21-40% moderate, 41-60% severe, 61-80% crippled, 81-100 bed-bound or exaggerating

Neck Disability Index (see Vernon, Mior. JMPT 1991;14(7):409-15). Scoring: 0-8% none, 10-28% mild, 30-48% moderate, 50-68% severe, >70% complete.

For the **Roland-Morris Activity Scale** have the patient follow the directions. Add up the selections that are checked and subject them to the grading scale below. (Roland, Morris. Spine 1983; 8(2):144-50.

A raw score of over 14 of 24 is associated with a poor prognosis: 0-5 minimal, 6-10 moderate, 11-14 severe, 15-19 crippled, 20-24 bed bound or exaggerating

Frequency of Use for Outcome Assessment: The patient should complete disability scales, pain drawings, & pain scales at baseline (initial visit), once a week for acute patients & at least once a month for chronic patients. Some researchers suggest every other week for chronic patients. Others also recommend completing the forms at the time of flare-ups & at the time of discharge. Others suggest following up patients at 2 wks, 4 wks, 6 wks or 8 wks to see if the pt is maintaining his/her benefit or is unable to maintain therapeutic gains and may therefore need supportive care including supervised exercise.

Roland, MA, MRCS, Fairbank, FRCP. The Roland-Morris Disability Questionnaire and the Oswestry Disability questionnaire. Spine 2000; 25(24):3115-24. The authors recommend use of the Oswestry in BP patients who are likely to have persistent severe disability & the Roland-Morris in patients who have relatively little disability. However, for most pt groups, both instruments function satisfactorily in groups with severe disability The Roland is a short & simple method of self-rated physical function in BP patients. The ease of use makes it suitable for following the progress of patients & for combining with other measures of function. The Oswestry is also an effective method of measuring disability in BP patients with a wide range of severity & causes. Both instruments have stood the test of time & have been used in many countries. Both perform as well as most other currently available instruments & better than some. The Roland may be better suited to settings in which patients have mild to moderate disability & the Oswestry to situations in which patients have persistent severe disability.

Pietrobon, R., MD, R. R. Coeytaux, MD, et al. Standard scales for measurement of functional outcome for cervical pain or dysfunction: a systematic review. Spine; 2002 27(5): 515-22. The concept of functional measurement differs considerably from the traditional measurement of clinical signs & symptoms. Instead of focusing on signs & symptoms used for diagnostic purposes, functional scales measure the impact of a disease on the performance of activities of daily living. Assessment of the impact a traumatic injury or degenerative condition has on a patient’s life is necessary for proper follow-up to evaluate pt progress & outcomes. A systematic review to evaluate standard scales for assessing neck pain or dysfunction was done. 5 standard scales were found: The Neck Disability Index (NDI) has been revalidated the most times in different study populations. It has accumulated the most evidence to show that its psychometric characteristics should remain stable in different settings.