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IN THE SUPREME COURT OF THE STATE OF NEVADA

VERONICA JAZMIN CASTILLO, AN INDIVIDUAL,

Appellant,

vs.

ARMANDO PONS-DIAZ, AN INDIVIDUAL,

Respondent.

Supreme Court Case No. 82267

District Court Case No.A-19-789525-C

APPELLANT'S APPENDIX VOLUME 2

Appellant VERONICA JAZMIN CASTILLO submits the following Appellant's Appendix in the Appeal from the Eighth Judicial District Court of the State of Nevada in and for the County of Clark, Department 4, the Honorable Nadia Krall

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Appellant VERONICA JAZMIN CASTILLO, by and through her counsel of record, Desert Ridge Legal Group, hereby submit its Appellant's Appendix in compliance with Nevada Rules of Appellate Procedure 30(b)(4).

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The Appendix satisfies NRAP 30(c)(3) (2013), with each volume containing no more than 250 pages.

DATED: September 21st 2021.

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CERTIFICATE OF SERVICE

I HEREBY CERTIFY that on this 21st day of September 2021, I served a true and complete copy of the foregoing **APPELLANT'S APPENDIX VOLUME 2** **addressed** to the parties below as follows:

[X] by placing a true and correct copy of the same to be deposited for mailing in the U.S. Mail, enclosed in a sealed envelope upon which first class postage was fully prepaid; and /or

[ ] via facsimile; and or

[ ] by hand delivery to parties listed below; and or

[X] by electronic service via E Flex through the Supreme Court of the State of Nevada.

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I. OVERVIEW

An instrument is a clinical tool that yields a measure. As such it may take on various forms. They all are intended to give one of three kinds of information about patient status or response to treatment. In general, they are: 1) perceptual measurements (e.g., reports of pain severity, satisfaction with life style); 2) functional measurements (e.g., range of motion, strength, activities-of-daily-living); and 3) physiological measurements (e.g., neurological assessment, serological changes).

The case history coupled with a discerning physical examination typically supplies most of the information necessary to make a diagnosis and determine a prognosis. Instrumentation serves to confirm a differential diagnosis, assess the severity of a condition or to monitor progress from a pre-established baseline. In order for the results from any instrument to be clinically useful, they must be appropriately applied and interpreted by the clinician, and the patient must be sincere and cooperative in performance.

Appropriate Use of Instruments

Instruments are all designed with various levels of sophistication and make use of underlying assumptions. Sapega[144] has observed that many clinical tools available today are capable of generating more measurements than can be meaningfully understood. The technological explosion in health care delivery has advanced far beyond valid clinical utility. Although the instruments themselves are not able to be validated, the application of the information they supply can be evaluated for their validity and usefulness.

The meaningful interpretation of changes in a subject's test results requires the reliability and validity of the procedures. The most effective means to ensure reliability is through test standardization and close attention to the correspondence of test conditions to those of the actual demands that the patient's lifestyle makes on his performance. The test clearly must be relevant to the individual's activities that have been impaired or to normative data, and should be able to discriminate healthy from unhealthy people.

Evaluating Instruments

Several qualities are found in common for instruments that ultimately prove to be clinically useful. Focusing on these qualities rather than on specific named instruments simplifies the task of evaluating instruments individually. They include the following:

1) Validity is the most clinically important quality. A test is valid when it accurately measures the desired function, and when that function is pertinent to the patient's condition.

2) Discriminability is determined by the ability to distinguish healthy from unhealthy individuals. In order to accomplish this, a normative data base consisting of studies of people from both groups is required. The relative frequency of false-positive (i.e., healthy persons who test positive) and false-negative tests (i.e., unhealthy persons who test negative) occurring for each group also helps to define a test's discriminability.

3) Accuracy of a measure is determined by comparison to a known value. Repeated use of some devices and the simple effects of passing time may cause loss of calibration which will alter accuracy.

4) Precision describes the variation of a measure across the range over which it is intended to be used. Both accuracy and precision can change over the possible ranges of test applications.

5) Reliability of a measure depends both on the accuracy of the instrument and the characteristics of the variable being measured.

For each category of instrument discussed below, knowledge of how each performs with respect to the above test qualities is presumed. Information of this kind is the minimum necessary, but may not be sufficient to achieve a rating above the classification of "Investigational."

Patient Motivation

Test results should be interpreted in conjunction with observations of the quality of patient performance and cooperation made while the test is being performed. As a result, only adequately trained personnel who can integrate clinically meaningful observations should perform most tests. Quality of patient performance, repeated measures testing [43, 82, 192] and correlation of findings with other clinical information [189] permit an accurate evaluation of patient motivation. Specific reasons for poor test performance include legitimate reduced capability, misunderstood instructions, apprehension of the test setting, fear of pain arising from the test, and questions of secondary gain.

II. DEFINITIONS

Accuracy: The property of a measurement which determines how closely the result will approximate the true value.

Anthropometry: The study of proportional relationships between the shape, weight and size of body segments.

Calibration: Periodic adjustment/maintenance of instrument components to yield minimum variation of measurements in contrast to a "Gold Standard" over a specified range of measurement.

Discriminability: The property of information derived from a test or a measurement that allows the practitioner to

discern between groups of subjects: for example, healthy from unhealthy.

Gold Standard: A known value or attribute used to test veracity of instrumented measures to define the true state of the patient.

Instrument: A clinical tool that yields a measurement. For purposes of this section, standard diagnostic instruments used in the conduct of routine physical examination are omitted.

Motivation: Conscious or subliminal factors of attitude and belief which contribute to the rationale for a person to choose between self-reliance (coping), patient and claimant behaviors in contending with health related predicaments.

Physician Dependence: Patient behavior which transfers responsibility for health status to the care-giver.

Precision: The ability to obtain the same measurement of a function or structure repeatedly within a set margin of error across the possible range of test applications.

Reactivity: A test interaction effect causing an unintentional change in a patient's response when exposed to the repeated application of a test.

Reliability: The ability to obtain the same measurement of a stable function or structure upon repeated tests. Reliability depends both upon accuracy and precision which, for instruments, may be separately evaluated and adjusted for calibration.

Sensitivity: The ability to correctly identify positive test results among subjects who truly have a specific disorder. The likelihood of a positive test result in a person with a disorder (also true-positive rate, TPR).

Somatization: One of several contemporary terms (e.g., psychological overlay, supratentorial overlay, etc.) indicating that the patient's symptoms may be aggravated by or may arise from non-organic factors.

Specificity: The ability to correctly identify negative test results among subjects who truly do not have a specific disorder. The likelihood of a negative test in a patient without disorder (also true-negative rate, TNR).

Validity: The property of information derived from a test or a measurement that assures that it represents the function or structure that is intended.

III. LIST OF SUBTOPICS

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IV. LITERATURE REVIEW

Perceptual Measurements

A. Questionnaires as Instruments:

Physical signs can be rather insensitive measures of a patient's disability.[192-202] Standardized rating scales and questionnaires afford a simple means of appraising many aspects of patient life and health.[111] Instruments commonly used in the chiropractic community assess pain, activities-of-daily-living

(ADL), somatization, depression, and anxiety. Generally, questionnaires may be divided into two categories, self-reporting and practitioner-administered. Self-reporting questionnaires are often self-normalizing but suffer from reactivity which may result in an unintentional change in the patient's response when exposed to the same questions repeatedly.[111] Practitioner-administered questionnaires benefit from the involvement of a trained observer whose skill can help in interpreting the patient's response. In administering either format, several error sources should be considered including 1) patient motivation; 2) acquiescence to positively worded items; and 3) patient's seeking social approval.[169] Overall, functional questionnaires offer standardization of measurement, comprehensiveness, and generally good reproducibility and validity.[169]

There is no consensus on the use of a particular questionnaire for a specific clinical problem. For the measurement of the same clinical problem, different questionnaires may not yield interchangeable findings. Screening questionnaires may be used to obtain a broad patient overview in a comprehensive and timely manner.[221] With the recent intensive development in the outcome measurement field, future field standardization on use of questionnaires is to be expected.

Pressure Algometry

Pressure algometry is a comparatively new procedure which uses a pressure manometer to estimate pain threshold from applied pressures to the myofascial structures. Normative data[38, 39] shows that pressure pain thresholds are highly symmetrical and are generally lower in females than in males. Reeves et al.[220] have reported reliability coefficients ranging from 0.71 to 0.97. Pressure pain threshold levels are sensitive to a variety of treatment interventions.[220, 303b] Good inter-rater and test-retest reliability has been shown.

Functional Measurements

A. Measurement of Position/Clinical Anthropometry

1. Posture

Studies in ergonomics have shown that trunk, head and joint positions adopted during work can be used as an objective index for evaluating the intensity of physical work stress, mental concentration or manual dexterity.[8, 122] The choice of a particular position may be the most important factor contributing to whether an attempted physical activity is risky or safe. Individual instruments and automated measures are available to quantify posture or body segment position.

2. Plumbline analysis

The plumbline was one of the first tools to be used in chiropractic to analyze posture. The plumbline provides a visual frame of reference for the influence of the centers of gravity from each body segment, enabling the clinician to detect postural deviation, asymmetry, and suspect areas of postural stress. Patients are observed in the anterior, posterior, and lateral stances.[186] Effects of diurnal variations and differences in test methods on the interpretation of results have not been well studied.

3. Scoliometry

Various instruments are available to quantify the physical signs of scoliosis and may include a form of plumbline analysis. The most important measurement quantifies the deformity of the rib cage associated with axial rotation of the vertebrae. The prominence of the rib hump correlates with the severity of the curvature and may presage its progression.[146] The differences from side to side are measured in millimeters or in degrees of deformity. Pelvic and shoulder girdle unleveling may also be quantified with bubble level devices.

4. Photogrammetry

Photographic evidence is most often used to quantify postures selected by persons during specific tasks. Methods of measurement include static, video and opto-electronic systems. Three principal applications are made in clinical practice. They are: 1) recording of structural or topographical anomalies as a part of the baseline assessment data collected during the patient examination; 2) quantification of typical postures adopted by patients during functional performance tests for post-injury severity and return-to-work evaluations; and 3) work site ergonomic risk factor evaluations performed for industry.[30, 195] Quantitative knowledge of posture and velocities of motion are important to understand the physical stresses on musculoskeletal structures during work and recreational activities.

The main technical concerns that must be addressed in order to maintain confidence in the measures obtained from photogrammetry are similar to those considered in setting up radiographic equipment. They include calibrated alignment of the camera, image contrast, standardized postures for repeated measures and distortion effects. For static images, most may be resolved by standardizing camera distances, heights and lighting. For video and opto-electronic methods, more complex computerized methods are required to obtain reliable data. (See review on given distortion factors given in Chaffin and Andersson 1984.[30])

5. Moire topography

Moire topography is a static photographic technique modified to highlight body contours for the purpose of quantifying structural deformity, in the same manner as the methods of map making to denote elevation.[137, 213] Photographs are obtained of interference patterns cast onto the body surface by an angled light source passing through a grid. The relative number of resulting concentric contour lines on a Moire photograph are proportional to the elevation of a landmark with respect to a reference surface. Patient positioning is very important with this method of postural analysis, as the grid-to-patient distance relationship must be kept constant in order to

achieve accurate follow-up evaluations. It is performed quickly and is reproducible, but the results are difficult to quantify and no good correlation to physical findings exists. Adequate interpretation is therefore lacking.

6. Bilateral weight distribution

Asymmetric posture and weight-bearing have been proposed as contributing factors in the development of degenerative joint disease, sacroiliac instability, chronic lumbar strain and other conditions.[36, 68, 87, 97, 136] Validity of these assumptions, including subtle postural asymmetries, remains to be demonstrated. The simplest means employed to determine if the loads transmitted throughout the skeleton are asymmetrical is through the use of bilateral weight scales or load cells positioned under each foot.[36, 91, 204] Recent biomechanical studies[83] suggest that postural balance may be useful in evaluating sacroiliac joint status and treatment. Inherent measurement variability and offset of postural sway necessitates careful attention to protocol.

7. Automated measurements of posture

Quantifying position in three dimensional space has been used as a research tool for several years. Several methods of spatial measurement are available including sonic, magnetic, photoelectric and electrogoniometric systems that locate the position of a point in space with respect to an arbitrary fixed reference point. Discussion of each is beyond the scope of this chapter primarily because they are not available for, nor useful in, general practice. Physical measurement systems that are available, for example three dimensional digitizers,[70] do not resolve fundamental problems of accuracy in landmark identification, characteristic of manual methods and can amplify them.[146]

B. Measurement of Movement

In the general course of patient care, range of motion is examined using goniometers, inclinometers and optical based systems. Most devices quantify the regional movement of a part and express it as an angular displacement about some center of rotation.

1. Goniometers

The degree of peripheral joint movement can be measured throughout active or passive ranges. Its usefulness is greatest in the extremities, particularly the small joints of the hands and feet. The reference point for measurement is the long axis of the part being measured and is determined by judgment. Accuracy is limited to a range of 10 to 15 degrees.[30] Usage for spinal measurements is no longer considered acceptable practice because of the advent of better methods.

2. Inclinometers

Inclinometers use the constant vertical direction of gravity as a reference and require only that a side rests against the body segment surface. Digital or analog and mechanical or electronic versions are available. Greater accuracy of measurement is available with ranges of 3 to 5 degrees being possible under typical clinical conditions.[177] Inclinometers are the more suitable instrument for assessing spinal function and are capable of separating components of motion, e.g., pelvic versus lumbar.

3. Optically based systems

Aside from research applications, the most prevalent clinical use of opto-electronic systems is in conjunction with the use of force plates for assessing gait abnormalities.[84, 156] Video-monitoring is often used in industrial practice to capture the salient features and at least semi-quantify motions and postures at the work station. Work related spine injuries, carpal tunnel syndrome and other cumulative trauma disorders are frequent areas of concern where these methods are used. The primary parameters of importance are joint angle, angular velocity and angular acceleration. Coupled with appropriate software and external load measurements, joint loads and patterns of behavior can provide information on relative risk of work related tasks.

C. Measurement of Strength

The term strength denotes the capacity for active development of muscle tension and through the resulting muscle force generates joint torque. Computerized muscle dynamometer systems quantify more variables than the average physician can properly interpret.[166] In the case of employment-related tests, the evaluation must closely simulate critical job tasks.[3]

The emphasis on computerized muscle-dynamometry systems (isometric, isokinetic, isotonic and isoinertial) has overshadowed earlier isometric and psychophysical testing methods. No single method of strength evaluation is decidedly superior or more valid for measuring muscular strength.[166] Each method also has a number of advantages and disadvantages. For valid interpretation of test results, the unique characteristics of each must be kept in mind. It has yet to be shown conclusively that testing can clearly predict that a patient can return to a certain activity level and will have less risk of reinjury under actual functional conditions. Only continued research and development of broader normative data bases than are now available will finally test the underlying assumptions currently used in these clinical applications.

1. Manual hand-held strength testing

Manual muscle strength testing provides only a rough approximation of capability[13, 66, 167, 207] and its use is limited. Accuracy in manual assessment requires differences in strength of 35% or more.[166] Hand-held dynamometers, while not eliminating all the problems of manual testing, provide greater degrees of accuracy and reliability.[19, 36, 177]

2. Instrumented strength measurement testing

Diagnostic assessment naturally falls into three categories: 1) preventative evaluation (as in employee job-matching); 2)

post-injury evaluation; and 3) outcome monitoring following treatment.[5, 16, 31, 127, 149, 152, 166, 172, 193] Significant clinical information can be obtained toward these objectives, but careless interpretation of test data can result in inappropriate clinical decisions. Acute disorders are a contraindication to strength test protocols. The average discrepancy between symmetrical muscle groups for healthy populations has been reported as much as 12%.[71, 123, 155, 166, 217] When evaluating an individual's performance, differences of 20% or more may be needed to discriminate abnormalities.

a. Isometric testing

There are several technical concerns in the performance of isometric tests: 1) the inertial effects at the onset of the test; 2) patient fatigue; 3) patient posture; and 4) patient motivation. The objective of the test is to identify and record the maximum voluntary contraction force that can be sustained.[206] At this time, the tasks that can be adequately represented with isometric tests are sagittally symmetric. Up to 70% of work postures can be approximated symmetrically. Normative data for occupational classifications of lifting activities[29, 214] as well as for reciprocal trunk strength ratios[113, 131, 193] are available. Normative data is used to evaluate extremity strength for post-injury assessment or seasonal sports fitness.[146] Bilateral differences greater than 15-20% indicate abnormality.

The patient's motivation to supply a maximum effort can be assessed by repeated measurement and acceptable maximum effort protocols.[112, 161, 181] Quantitative knowledge of the patient's posture during the performance of the strength task is critical to any effort to relate the test result to joint loads or NIOSH standards.[3, 30, 166, 212]

b. Isokinetic testing

The primary measurement obtained is the torque generated which is only valid during the controlled part of the motion. The maximum voluntary effort will coincide with the greatest mechanical advantage of the joint for the motion that is being attempted.[101] There are two technical concerns with isokinetic measurements. They are: 1) gravitational effects; and 2) torque overshoot. Both may be corrected through computerized correction routines and damper settings. Standard isokinetic measurements are commonly taken at increments of 30 degrees per second using 2-6 repetitions with the maximum single torque value used as the measure of performance. As with isometric evaluation, the normal extensor/flexor trunk ratio falls when impairment is present.[18, 124, 128, 130, 188, 193] Kannus,[109] Nunn and Mayhew [144] feel the side-to-side comparison of extremity testing has some importance.

c. Isoinertial testing

While no testing method yet devised allows an assessment of free dynamic motion such as would occur at a work site or in sports, isoinertial equipment may come closer than others. Several authors have examined the ability to predict performance by controlling torque during movement.[99, 104, 185, 120, 121, 140, 183] Isoinertial systems can be made capable of monitoring position, velocity and torque simultaneously. Measures of regional coupled motions appear to hold promise in discriminating fatigue effects from healthy movement.[144] Likewise, velocity measurements appear to be sensitive to lumbar spine disorders. Normative data is available for a number of occupational subgroups including sedentary workers.[74]

Physiologic Measurements

A. Thermographic Recordings

Body heat loss to the environment takes place passively by convection, conduction and radiation. Regional body temperature is governed by the interaction of central autonomic control mechanisms[183] and multisegmental spinal vasomotor reflexes.[67] Regional variations of sympathetic thermoregulation produce a complex pattern of temperature distribution including cephalocaudal, diurnal and circadian patterns.[78] Accurate measure requires accommodation of the skin to room temperature, which should be kept at between 33.5 to 34 C.[93] For reproducible measures, the patient needs to establish constant patterns of work and rest and follow-up testing should be performed at the same time of day.[139] Measurements of skin temperature and the amount of heat radiated from anatomically symmetrical regions yields useful information about the relative circulatory volume to each part. Areas of increased cutaneous temperature have been ascribed to vasodilation occurring during a migraine headache,[203] inflammation[1, 32, 99, 114, 115, 118, 146] or muscle spasm.[40, 51, 110] Decreased cutaneous temperature may reflect vasoconstriction, vascular obstruction, or fibrous and fatty replacement.[106] An abundance of literature is available documenting employment of thermography as a screening tool; e.g., detection of deep vein thrombosis, identification of allergic reactions,[91] qualification of vascular phenomena, and the identification of pain.[151, 153] The clinical value of the data, however, remains uncertain.

1. Thermocouple devices

Several thermocouple devices have been marketed to be used for the manual determination of local paraspinal temperature variations.[43, 135, 197] While sometimes still used, these types of paraspinal measures have not been shown to have good discriminability, and both their validity and reliability of measurement is highly doubtful.[51, 197]

2. Telethermography

Measurement of skin temperature differences across the torso, head and extremities is a highly controversial procedure that has been proposed as a means of evaluating functional

changes from somatic lesions. Various forms of "gold standard" comparison have been used including surgical confirmation of disc herniation and percentage agreement or statistical correlation with other more widely accepted diagnostic procedures. Normative data are available; for example, see Chang et al., 1985,[31] Feldman and Nickolff [53] 1984, Goodman et al., 1986,[73] and Uematsu et al., 1988.[195] A number of efforts to evaluate diagnostic truth from telethermographic measures have been made.[77, 94, 198, 199] Unfortunately, a high proportion of the writings on the topic reflect opinion or fail to account for sample population factors such as prevalence, bias or experimental blinding procedures.

The results of comparative studies of thermography and other diagnostic procedures for nerve root entrapments are quite varied.[92, 93, 137] Where some studies claim that thermography has little diagnostic and uncertain prognostic value in the evaluation of low back pain and radiculopathy,[134, 183] others praise its sensitivity and positive predictive value.[28, 198] Thermographic images have been used in the diagnosis of myofascial pain syndromes and their respective pain referral zones. Perhaps the strongest evidence for use of telethermography is for cases of suspected neurodystrophy.[120,20] There has been a high correlation between the thermographically defined referral zones and those as described in the literature. Additional zones, not previously identified, have also been recognized.[47] Meta-analysis attempting to resolve the question of clinical utility for thermography has concluded that the procedure cannot be recommended as routine since its role remains unclear.[65]

Hubbard[94a] has written an interesting commentary on various criticisms of the thermography literature for lumbar radiculopathy concluding with the need for more studies published in the "mainstream" literature with attention to the political climate and valid criticism.

B. Galvanic Skin Response (GSR)

Devices to detect differences in paraspinal regional electrical skin resistance have been employed by the chiropractic profession for many decades. Loci of lowered skin resistance were thought to be related to areas of cutaneous hyper or hyposympathetic activity which, themselves, would be due to a putative vertebral subluxation. Other devices have been employed to detect punctate areas to lowered skin resistance putatively corresponding to acupuncture points (i.e., "point finders"). A final category consists of an apparatus designed to measure digital (hand) GSR, thought to reflect global levels of sympathetic nervous system activity, and, by influence, general levels of arousal.

These devices are subject to a high degree of intra- and inter-subject variability calling into question their reliability. Older class II studies are seriously in need of update and replication with modern instrumentation and more rigorous research methodology. Recent Class II studies have cast serious doubt on the reliability and validity of GSR in assessment of spinal dysfunction.[70,148]

C. Electrophysiologic Recordings

Several variables affect all electrophysiologic recordings: 1) the size and location of the recording electrode; 2) the configuration of the electrode position relative to the structure being recorded; 3) characteristic resistance of the tissues; 4) the pathophysiology of the patient's problem and 5) artifacts.

1. Electrodiagnosis

Several specialized procedures are available to evaluate select neuromuscular functions. These include measures of myoelectric activity during muscular loading, fatigue studies, conduction velocity tests, H-wave and F-wave responses, and evoked potentials. Generally these studies can be simply grouped as either 1) stimulation studies; or 2) electromyography (EMG).[37] The clinical procedures are sometimes divided according to whether needle or surface electrodes are used.

Surface electrode studies may be used in many cases, but are traditionally applied to the examination of nerve conduction velocities, reflex studies and kinesiological evaluations.[22,120] In kinesiologic applications, up to 16% of the surface recordings from the upper leg muscles, for example, is from co-contraction activity.[69] Surface electrodes may be used with repetitive stimulation to examine suspected myoneural junction disorders. Somatosensory evoked potentials (EP) are performed with surface electrodes. EP serve to discern between peripheral and cord (dorsal column) lesion sites.[79] Needle electrode studies are classically termed electromyography. This technique may be used in all varieties of electrodiagnostic studies, but it is required to detect denervation, myoneural junction disorders, cerebellar and brainstem tremors, anterior cord disease and motor unit potentials. To obtain accurate information about single motor units, needle electrodes are necessary.

a. Nerve stimulation studies

Nerve stimulation studies can be performed using either surface or needle electrodes. Basic information may be gained about the neuromuscular peripheral sensory and motor components using conduction velocity and reflex responses of the nerve (i.e., H-reflex and F-waves). Practically, this information may be used to evaluate the nerve trunk integrity as well as significant compression, or temporal dispersion from entrapment or metabolic neuropathy. Both sensory and motor studies permit analysis of wave form, amplitude and duration of the impulse.[99] Nerve compression from lumbar root lesions can be quantified.[44,33,79,211] While nerve conduction velocity is a poor index for radicular syndromes, F-waves and H-reflexes are more useful. Similar use can be made for study of complaints from the upper extremity.[79,193] Sensitivity and specificity for each of the following electrodiagnostic procedures are well studied. Se-

quencing of tests often increases the diagnostic yield. Timing of tests performed with respect to the onset of symptoms is important since their appearance and disappearance can be temporally dependent.[79]

Evoked, transforaminal responses (surface or needle): Peripheral motor nerve fibers of major nerve trunks from the extremities may be evaluated by use of the F-wave of Magladery. Adequate assessment requires a sequence of supramaximal stimuli with measure of several response latencies. These signals may be absent in diseases of compression affecting the anterior horn or peripheral nerve.

For lesions involving the peripheral motor or sensory fibers from L5/S1 or S1/S2, the Hoffman reflex may be used. A series of progressively increasing subthreshold to suprathreshold stimuli are used to evaluate sensory and motor fiber responses.

Nerve conduction studies (surface or needle NCV): Motor nerves can be evaluated for site and severity of lesions from mechanical or pathological causes. Stimulation of major nerve trunks at a series of sites along their path can locate the region affected. Characteristic wave form and relative conduction velocity changes may also be important to differentiate between causes of nerve damage. Sensory nerve conduction is studied in a similar fashion.

Somatosensory evoked potentials (Surface or Needle SSEP): Similar to conduction velocities, these procedures stimulate the peripheral nerve either at accessible nerve trunks or by dermatomal sensory nerve endings. Responses may be monitored along the nerve pathway traversing the IVF, cord, brainstem and cortex.

b. Electromyography

Kinesiologic studies: A surface measurement that monitors myoelectric volitional responses can be used to examine superficial layer muscle recruitment and fatigue. When calibrated against known exertional efforts, biomechanical estimates of muscle tensions for simple isometric tasks can be made.[219] Clinical applications to the evaluation of spine related disorders has been proposed under the heading of surface paraspinal scanning EMG[69] using either post-style or adhesive tape-on electrodes. With the exception of flexion-relaxation[2, 176, 193] and spectral density parameters like mean/median frequency shifts[20, 54, 166] during isometric contraction using tape-on electrodes, clinical usefulness is limited because the discriminability of these procedures has not been fully evaluated. Myoelectric monitoring during simple postural tasks shows common patterns of behavior but these are easily influenced by subtle changes in posture and other sources of error.[99] Triano and Luttges[194] found that an ensemble of flexion and postural tasks might discriminate healthy subjects from unhealthy patients, whereas single postures alone were insufficient. Lumbar disc and nonspecific backache tend to have overall higher electrical activity but are confounded by a high sensitivity to positional variation.[4]

Comparison of right/left myoelectric amplitudes during static postures remain to be validated as being discriminable. Acute spinal symptoms may be associated with alterations in muscular tone (e.g., hypotonus, hypertonus, spasm). However, the meaning of measurements associated with them is uncertain and does not significantly contribute to therapeutic decision making.[44] In chronic back pain, matters are even worse with conflicting evidence as to whether changes in paraspinal muscle tone can be found.[1, 28, 30, 41, 123, 143, 174] Six other groups have found differences based only on more complex spine loading tasks and multiple testing procedures.[72, 118, 142, 184, 194, 195]

Motor unit potentials: Needle electrode EMG is used to measure single motor unit potentials. The characteristics of the duration, amplitude and phases of the action potential are examined for abnormalities suggesting disease including: synchronization; fibrillation potentials; positive sharp waves; fasciculation; and long duration, large amplitude polyphasic potentials. Appropriate interpretation can be conclusive for myopathies; radiculopathy; metabolic; myoneural junction; and central nervous system diseases.[114, 128, 178, 182, 187]

2. Electrocardiography

Electrocardiography (ECG) is very useful in the diagnosis of various heart diseases and the differentiation of noncardiac disorders such as thyroid, renal, pulmonary and electrolyte disorders. They also serve to differentiate spondylogenic symptoms that emulate heart disease, such as found in cervical angina.[210] Anecdotal and uncontrolled reports have been provided by many researchers and clinicians about improvement within patients having both ischemic and arrhythmic disorders of the heart following correction of spinal lesions.

D. Clinical Laboratory Procedures

For the present purposes, laboratory procedures will be arbitrarily sectioned into three hierarchical concerns: 1) the differential diagnosis of symptoms produced by somatic lesions from referred symptoms; 2) testing for contraindications to manipulative therapy in conjunction with evidence from other physical and examination findings; and 3) nutritional evaluation and monitoring.

1. Differential diagnosis of somatic and referred symptoms

Disorders with somatic reference of pain in the spinal region include peptic ulcer, aneurysm, pylorospasm, colitis, diverticulitis, abdominal carcinomas, prostatic carcinoma and obstructive uropathy, among others.[121] Appropriate laboratory

procedures encompass the full set of services including hematology, serology, and urinalysis.[111, 209]

2. Contraindications to manipulative treatment

Under certain pathologic circumstances undue manipulative force may result in increased joint irritation, nerve compression, vertebral collapse, or hemorrhage. It is doubtful that absolute contraindications to manipulation of pathologic tissues/structures would be disagreed upon by many. They include vertebral malignancy, tuberculosis, osteomyelitis, infectious arthritis, acute vertebral fracture, extreme osteoporosis, metabolic bone disease, and extensive disc prolapse with evidence of severe nerve damage.[102, 171, 186] Common laboratory tests used for some of these conditions have been reported[60, 189] and are detailed in the chapter on clinical laboratory.

3. Nutritional evaluation and monitoring

The clinical usefulness of nutrition and the rational approach of nutritional counselling as therapy for malnutrition, chronic undernutrition,[83] overnutrition,[179] functional disease and some organic disorders has historically been of interest to chiropractors. Variance of individual nutritional needs are hotly contested issues.[3, 15, 27, 33, 64, 83, 117, 179, 188, 189, 218] Periodic laboratory testing becomes valuable as a means of monitoring patient response and affirming diagnosis. The outcome of nutritional and pharmaceutical therapies prescribed for certain conditions is monitored by laboratory analysis. These include infection, cardiovascular disease, arteriosclerosis, anemia, osteoporosis, renal disease, and diabetes.[21, 48, 50, 1, 72, 90, 100, 101, 107, 119, 147, 153, 161, 170, 171, 215]

Functional disorders are often misunderstood and misdiagnosed entities. A few of these have been found to have measurable biochemical alterations that allow easier diagnosis and monitoring but remain poorly described. Examples of the types of functional disorders for which laboratory evaluation is found to be useful include hypoglycemia, carbohydrate malabsorption, hypothyroid, and functional hypoadrenia.[24, 98, 103, 180, 209] Further validation studies and statistical analyses are needed.

E. Other Instrument Measures

Several other types of examining instruments are in use within the chiropractic profession. As none of these are widespread, only the fundamentals of their use will be described.

1. Non-invasive vascular measures

Both plethysmography and doppler ultrasonic measures allow objective evaluation of vascular disorders by quantifying segmental limb blood pressures, velocities or pulse wave forms.

Doppler ultrasound:

Doppler ultrasound is the most simple and versatile method available for screening examinations of suspected vascular disease.[13, 123] Frequency shifts of ultrasound reflected from moving blood cells are detected. Simple hand held devices are adequate to screen peripheral vessels; however, doppler spectral analysis (Duplex scanning) is more accurate for cerebrovascular and visceral arterial disease.

For lower extremity claudication, doppler will identify significant occlusive arterial disease with a high degree of reproducibility.[216] Special procedures of value include the ankle/arm index[137] and lower extremity, multi-segmental pressure analysis. The latter examines for a pressure gradient greater than 30 mm Hg across appropriate intervals[66] Hemodynamic deficit may be further evaluated using hyperemia procedures.

Plethysmography:

The plethysmograph quantifies the relative tissue volume of the distal extremities. This method has been used by Figar and Krausova[36, 37] to portray improvement in manipulative treatment of radicular syndromes involving the sixth to eighth cervical segments.

2. Spirometry

Estimation of vital capacity, total lung capacity, expiratory flow rate, maximum voluntary ventilation and forced expiratory volume are important in the evaluation and clinical follow-up of lung disorders.[63] It also serves to assess the severity of pulmonary involvement in patients with severe scoliosis. Monitoring of pulmonary function in patients with asthma, upper respiratory infection and chronic pulmonary disease[7, 17, 18, 22, 42, 73, 143, 156, 208] has periodically been reported as being responsive to change from treatment of the related spinal lesions. Good controlled studies are needed to evaluate the nature of manipulative therapy for these conditions.

V. ASSESSMENT CRITERIA

Procedure Ratings (System I)

Established: Accepted as appropriate by the practicing chiropractic community for the given indication in the specified patient population.

Promising: Given current knowledge, this technology appears to be appropriate for the given indication in the specified patient population. As more evidence and experience accumulates, this interim rating will change. This connotes provisional acceptance but permits a greater role for the level of current clinical use.

Equivocal: Current knowledge exists to support a given indication in the specified patient population, though value can neither be confirmed or denied. As more evidence and experience accumulates, this interim rating will change. Expert opinion recognizes a need for caution in general application.

Investigational: Evidence is insufficient to determine appropriateness. Further study is warranted. Use for a given indication in the specified patient population should be confined largely to research protocols. As more evidence and experience accumulates this interim rating will change.

Doubtful: Given current knowledge, this appears to be inappropriate for the given indication in the specified patient population. As more evidence and experience accumulates this interim rating will change.

Inappropriate: Regarded by the practicing chiropractic community as unacceptable for the given indication in the specified patient population.

Quality of Evidence

The following categories of evidence are used to support the ratings.

Class I:
Evidence provided by one or more well-designed controlled clinical trials; or well-designed experimental studies that address reliability, validity, positive predictive value, discriminability, sensitivity, and specificity.

Class II:
Evidence provided by one or more well-designed uncontrolled, observational clinical studies such as case control, cohort studies, etc.; or clinically relevant basic science studies that address reliability, validity, positive predictive value, discriminability, sensitivity and specificity; and published in refereed journals.

Class III:
Evidence provided by expert opinion, descriptive studies or case reports.

Suggested Strength of Recommendations Ratings

Type A. Strong positive recommendation. Based on Class I evidence or overwhelming Class II evidence when circumstances preclude randomized clinical trials.

Type B. Positive recommendation based on Class II evidence.

Type C. Positive recommendation based on strong consensus of Class III evidence.

Type D. Negative recommendation based on inconclusive or conflicting Class II evidence.

Type E. Negative recommendation based on evidence of ineffectiveness or lack of efficacy based on Class I or Class II evidence.

Safety and effectiveness

Safety: a judgment of the acceptability of risk in a specified situation, e.g., for a given health problem, by a provider with specified training (at a specific stage of the disorder, etc.).

Effectiveness: producing a desired effect under conditions of actual use.

VI. RECOMMENDATIONS

All recommendations are made based upon the assumptions that the operator/examiner is appropriately trained, versed in the technical issues affecting the qualities of safety, validity, discriminability, accuracy, precision and reliability of the measures. Standardized test protocols and periodic instrument calibration is important to ensure clinical utility of the information. Interpretation should be made by the attending clinician in all cases.

Perceptual Measurements

A. Questionnaires as Instruments

Questionnaire instruments are safe and effective. Several instruments have been fully validated, are widely used and well established. Their use is supported by both Class I (modified to the discipline of measurement) and Class II evidence.

3.1.1 Strength of recommendation: Type A.
Consensus Level: 1

B. Screening Questionnaire

Their use is safe and effective, supported by Class II and III evidence.

3.1.2 Strength of recommendation: Type C.
Consensus Level: 1

C. Pressure Algometry

Pressure algometry is safe and effective when contrasted with normative values for region and gender. It is a new procedure that is not yet in wide use but is promising. Its use is supported by Class II and Class III evidence.

3.1.3 Strength of recommendation: Type B.
Consensus Level: 1

Functional Measurements

A. Measurement of Position/Clinical Anthropometry (Posture)

1. Plumbline Analysis

Plumbline analysis is safe and effective when used to assess upright posture. It can be administered by persons with mini-

mal training but should be interpreted by a professional health care provider. The procedure is widely used, established and supported by both Class II and Class III evidence.

3.2.1 Strength of recommendation: Type B.
Consensus Level: 1

2. Scoliometry

Scoliometry is safe and effective and can be administered by persons with minimal training but should be interpreted by a professional health care provider. The procedure is well established and supported by both Class I and Class II evidence.

3.2.2 Strength of recommendation: Type A.
Consensus Level: 1

3. Photogrammetry Methods

Photogrammetry methods are safe and effective means to quantify topographical or structural anomaly and work postures. Training is necessary to avoid error sources and assure reliability of measures. The procedures are well established and supported by evidence in Classes I, II and III.

3.2.3 Strength of recommendation: Type A.
Consensus Level: 1

4. Moire Topography

Moire topography is safe and can be administered by persons with minimal training but requires oversight on technical procedures. It is of limited effectiveness. The procedure is promising only as a qualitative screening method supported by Class II and Class III evidence.

3.2.4 Strength of recommendation: Type B.
Consensus Level: 1

5. Bilateral Weight Distribution

Bilateral weight scales are safe but their effectiveness is unknown and are rated as equivocal. Class II & III evidence is available.

3.2.5 Strength of recommendation: Type C.
Consensus Level: 1

6. Automated Measurements of Posture

Automated methods have received limited acceptance and are rated as promising. They are safe to administer but their effectiveness is limited by the training and practice of the operator. Fundamental difficulty in landmark identification and limited information on reliability restricts the use to screening purposes. Their use is supported by Class II and Class III evidence.

3.2.6 Strength of recommendation: Type B.
Consensus Level: 1

B. Measurement of Movement

1. Goniometers

Goniometers are widely used, safe and effective. They are established to measure peripheral joint motion although the margin of error remains high. Class I and Class II evidence supports their use.

3.3.1 Strength of recommendation: Type A.
Consensus Level: 1

2. Inclinometers

Inclinometers are established for measurements of spinal motion. Their common use is supported by Class I and Class II evidence and is safe and effective.

3.3.2 Strength of recommendation: Type A.
Consensus Level: 1

3. Optically Based Systems

Optically based systems are established for evaluating specific gait abnormalities or risky positions related to work tasks. They are safe and effective when evaluated by specially trained personnel and are supported by Class II evidence.

3.3.3 Strength of recommendation: Type B.
Consensus Level: 1

4. Computer Assisted Range of Motion Systems

Computer assisted range of motion systems provide improved levels of precision and reproducibility. They are safe, effective and non-invasive. They require specialized training and should be interpreted by a qualified health care provider. Clinical applications are promising. Class II & III evidence is available.

3.3.4 Strength of recommendation: Type B.
Consensus Level: 1

C. Measurement of Strength

1. Manual Strength Testing

Manual strength testing is widely used, safe and largely ineffective for strength differences less than 35%. Hand held loed cells may assist in finding smaller differences in extremity muscle strengths. It is established as a screening procedure and is supported by Class I and Class II data.

3.4.1 Strength of recommendation: Type A.
Consensus Level: 1

2. Isometric Strength Testing

Isometric strength testing is an established procedure that is effective for limited applications involving employment evaluation and post-injury assessment where relevant standards can be determined. The methods are safe when performed by trained personnel who can make appropriate clinical judgments with respect to patient limitations during the procedure and when contraindications are observed. Class I and Class II data are available.

3.4.2 Strength of recommendation: Type A.
Consensus Level: 1

3. Isokinetic Strength Testing

Isokinetic strength testing is widely used, safe for non-acute disorders and effective for making bilateral comparisons or

contrasting performance to normative data. The procedures are well established in sports applications and promising for post-injury use after the acute phase of treatment has passed. Class II and Class III evidence supports its use.

3.4.3 Strength of recommendation: Type B.
Consensus Level: 1

4. Isoinertial Strength Testing

Isoinertial strength testing is a promising procedure for employment selection and post-injury applications. It is safe for non-acute disorders when carried out by trained personnel. Class II and Class III evidence has been reported.

3.4.4 Strength of recommendation: Type C.
Consensus Level: 1

Physiologic Measurements

A. Thermographic Recordings

1. Thermocouple Devices

Thermocouple devices are still in use. While they are safe, there is no evidence to support a claim of effectiveness. Their use is rated doubtful and is supported by Class II and Class III evidence.

3.5.1 Strength of recommendation: Type D.
Consensus Level: 3
(See Section IX [3.10.1] for minority opinion)

2. Infrared Thermography

Infrared thermography is a safe procedure of intense controversial effectiveness. Its use requires specially trained personnel and specially adapted surroundings. Its rating as equivocal/promising is supported by continuing controversy from Class II and Class III evidence.

3.5.2 Strength of recommendation: Type C because of the controversy.
Consensus Level: 3
(See Section IX [3.10.2] for minority opinion)

B. Galvanic Skin Response

These types of measurement are safe, but generally ineffective as a result of questions remaining on reliability and validity from Class II and Class III types of evidence. For general arousal studies they are considered investigational.

3.6.1 Strength of recommendation: Type D.
Consensus Level: 1

For acupuncture point finding and for assessing spine related disorders, they are considered as doubtful.

3.6.2 Strength of recommendation: Type E.
Consensus Level: 1

C. Electrophysiologic Recordings

All of the electrodiagnostic methods are safe when carried out by specially trained personnel. Interpretation should be carried out only by physicians with extensive training in the technical and clinical considerations that can readily confound the findings.

1. Kinesiologic Surface (Scanning) EMG

Kinesiologic surface (scanning) EMG is a rapidly proliferating, safe procedure that has not been shown effective with the exception of limited use for flexion/relaxation and mean/median frequency shifting measures. Generally, its use remains investigational. Specific procedures of flexion/relaxation and mean/median frequency shift evaluation are considered promising based on Class II and Class III evidence.

3.7.1 Strength of recommendation - scanning surface EMG: Type C.
Consensus Level: 2

3.7.2 Strength of recommendation - flexion/relaxation and mean/median frequency shift measures: Type B.
Consensus Level: 1

2. Surface Electrodiagnostic Procedures (NCV, F-Wave, H-Reflex, SSEP)

Surface electrodiagnostic procedures (NCV, F-wave, H-reflex, SSEP) are established procedures effective for examination of peripheral nerve disorders and are supported by Class I and Class II evidence. Somatosensory evoked potentials are established for limited applications to peripheral nerve disorders and lesions affecting the long sensory tracks of the spinal cord.

3.7.3 Strength of recommendation: Type A.
Consensus Level: 1

3. Needle Electrodiagnostic Procedures (EMG, NCV, F-wave, H-reflex, SSEP)

Needle electrodiagnostic procedures (EMG, NCV, F-wave, H-reflex, SSEP) are widely used, established procedures that are affective in assessing functional effects of pathology affecting the central and peripheral nervous system and muscle. Class I and Class II evidence is available.

3.7.4 Strength of recommendation: Type A.
Consensus Level: 1

4. Electrocardiography

ECG is a widely used, safe, effective and established procedure for aiding in the differential diagnosis of complaints that may be cardiopulmonary in origin. Interpretation requires specialized training. Class I and Class II evidence is available.

3.7.5 Strength of recommendation: Type A.
Consensus Level: 1

D. Clinical Laboratory Procedures

Clinical laboratory testing is an established approach that is widely used, safe and effective when used in differential diagnosis. Test procedures require appropriate technical instrumentation operated by specially trained and certified staff as determined by law. Equipment must be kept calibrated and standardized. Quality assurance procedures must be followed to ensure accuracy and reliability. Class I, II and III evidence is available.

3.8.1 Strength of recommendation: Type A.
Consensus Level: 1

E. Other Instrument Measures

1. Doppler Ultrasound

Doppler measures are well established, safe and effective as means to quantify the presence of vascular disease. Special training is necessary and results should be interpreted by a trained health care provider. Both Class II and Class III data are available.

3.9.1 Strength of recommendation: Type B.
Consensus Level: 1

2. Plethysmography

Plethysmography is used on occasion. It is safe and effective when tissue volume changes and a symptom or peripheral vascular differential diagnosis is needed. Use for these purposes is well established. Special training is necessary and results should be interpreted by a trained health care provider. Its effectiveness as a monitor of treatment of spine disorders is not determined and use for this purpose should be considered investigational. Class II and Class III data are available.

3.9.2 Strength of recommendation - differential diagnosis: Type B.
Consensus Level: 1

3.9.3 Strength of recommendation - monitor spine disorders: Type D.
Consensus Level: 1

3. Spirometry

Pulmonary function testing is established as a method to assess effect of severe scoliosis and the differential diagnosis of lung disease. These uses are backed by Class I and Class II evidence. The procedures are safe and effective when performed by appropriately trained personnel.

3.9.4 Strength of recommendation: Type A.
Consensus Level: 1

VII. COMMENTS, SUMMARY OR CONCLUSION

Measurement instruments used in chiropractic practice are important not only in the initial assessment of the patient but also in the ongoing evaluation of their response to a particular intervention. The instrument used, therefore, must be applicable, appropriate, reliable, and valid. This necessitates that the clinician utilizing a particular instrument clearly understand the intended use and the limitation of the selected instrument.

This paper attempts to outline the instruments available to the practitioner and rates them according to the results of studies and reports in the scientific and clinical literature. It is expected that many of the aforementioned recommendations may in fact change as a result of ongoing investigations.

In order for the interpretation of changes in a subject's test results to be meaningful, the reliability and validity of the procedures used must be high. The test clearly must be relevant to the individual's activities that have been impaired, to normative data, or both, and should be able to discriminate healthy from unhealthy people. Careful attention to standardized test protocols is essential if replication of meaningful results is to occur.

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IX. MINORITY OPINIONS

Physiologic Measurements

Thermographic Recordings

Thermocouple Devices

Thermocouple devices are commonly used in chiropractic practice. They are safe in a clinical setting. Their use is rated as equivocal and this rating is supported by Class II evidence.

3.10.1 Strength of recommendation: Type C.
(For majority recommendation, see 3.5.1.)

Physiologic Measurements

Thermographic Recordings

Infrared Thermography

Infrared thermography is a safe and effective procedure. Its use requires specially trained personnel, specially adapted surroundings and explicit protocols. Its use is considered to be promising as supported by Class II and Class III evidence.

3.10.2 Strength of recommendation: Type B.
(For majority recommendation, see 3.5.2.)

4

Clinical Laboratory

Chapter Outline

I. OVERVIEW

A chiropractic practitioner who accepts a patient for any professional reason has a duty and responsibility to perform an appropriate clinical evaluation on that patient for the purpose of assessing the patient's current health status and identifying if the patient is a proper subject for chiropractic care. Such a clinical evaluation necessarily involves diagnostic procedures which aid in arriving at a clinical impression.

The purpose of this chapter is to identify and provide guidelines for the appropriate use of clinical laboratory procedures in chiropractic practice. The role of the clinical laboratory in diagnosis, screening, and patient management is discussed as well as the principles of appropriate test selection and use. Guidelines for clinical laboratory test interpretation are presented and recommendations for appropriate use of commonly requested clinical laboratory tests are described.

Definitions useful to the practitioner as applied to laboratory testing are provided in Section II. Section III lists all topics covered in the Recommendations section. Section IV reviews literature relevant to clinical application of laboratory procedures for the doctor of chiropractic.

Additionally, investigational procedures are briefly discussed.

Literature for well-established standard procedures are listed in the references, but detailed test descriptions are not possible in the space available. The bulk of this information appears in the Section VI recommendations. It has been divided for the purposes of clinical relevance into four sections:

A. General recommendations regarding use of laboratory procedures in chiropractic practice.
B. Detailed guidelines for ordering commonly used tests.
C. Investigational laboratory procedures.
D. Inappropriate laboratory procedures.

The Reference Section (Section VIII) is organized by topic to allow the reader to access relevant material upon which this chapter is based.

Lastly, this chapter contains an appendix that characterizes useful examples of clinical laboratory guidelines for the investigation of spinal disorders, common visceral pain disorders, as well as examples of focused organ/health problem profiles.

II. DEFINITIONS

Screening: The application of a test to detect a potential illness or condition in a person who has no known signs or symptoms of that illness or condition. Screening is performed on "at risk" populations in order to determine appropriate intervention(s).

Case Finding: Laboratory testing of health care seeking patients for disorders that may be unrelated to their chief complaint.

Accuracy: The property of a measurement which determines how closely the result will approximate the true value.

Precision: A measurement of the agreement between repeated measurements; an indication of the random error. The term may be interchanged with the term "reliability."

Prevalence: The total number of cases of a disorder in existence at a certain time in a designated area.

False-Negative Rate (FNR): The likelihood of a negative test in a patient with a disorder.

False-negative rate =

$$\frac{\text{number of patients with a disorder with negative test}}{\text{number of patients with a disorder}}$$

False-Negative Result: A negative result in a patient with a disorder.

False-Positive Rate (FPR): The likelihood of a positive test in a patient without a disorder.

False-positive rate =

$$\frac{\text{number of patients without a disorder with positive test}}{\text{number of patients without disorder}}$$

False-Positive Result: A positive result in a person who does not have the disorder.

"Gold Standard" Test: An accepted reference test or procedure that is used to define the true state of the patient's health.

Likelihood Ratio: A measure of discrimination by a test result. A test result with a likelihood ratio of greater than 1.0 raises the probability of a disorder and is often referred to as a "positive" test result. A test result with a likelihood ratio of less than 1.0 lowers the probability of a disorder and is often called a "negative" test result.

Likelihood ratio =

$$\frac{\text{probability of result in person with disorder}}{\text{probability of result in person without disorder}}$$

LIKELIHOOD RATIO FOR A POSITIVE TEST RESULT:

$$\text{Likelihood ratio (+)} = \frac{\text{sensitivity}}{1\text{—specificity}}$$

LIKELIHOOD RATIO FOR A NEGATIVE TEST RESULT:

$$\text{Likelihood ratio (–)} = \frac{1\text{—sensitivity}}{\text{specificity}}$$

Negative Test Result: A test result that occurs more frequently in patients who do not have a disorder than in patients who do have the disorder.

Odds: The odds of an event is another way to express its probability.

$$\text{Odds} = \frac{\text{probability of event}}{1\text{—probability of event}}$$

Positive Test Result: A test result that occurs more frequently in patients with a disorder than in patients without the disorder.

Post-Test Probability: The probability of disorder after the results of a test have been learned (also posterior probability or post-test risk).

Predictive Value Negative: Probability of a disorder being absent if a test is negative.

Predictive Value Positive: Probability of a disorder being present if a test is positive.

Pretest Probability: The probability of disorder before a test is done (also prior probability or pretest risk).

Probability: An expression of opinion, on a scale of 0 to 1.0, about the likelihood that an event will occur.

Sensitivity: The likelihood of a positive test result in a person with a disorder (also true-positive rate, TPR).

Sensitivity =

$$\frac{\text{number of patients with disorder with positive test}}{\text{number of patients with disorder}}$$

Specificity: The ability to correctly identify negative test results among subjects who truly do not have a specific disorder. The likelihood of a negative test in a patient without the disorder (also true-negative rate, TNR).

Specificity =

$$\frac{\text{number of patients without disorder with negative test}}{\text{number of patients without disorder}}$$

True-Negative Result: A negative test result in a patient who does not have a disease.

True-Negative Rate: See specificity.

True-Positive Rate: See sensitivity.

III. LIST OF SUBTOPICS

A. General Recommendations

1. The Role of Clinical Laboratory Procedures in Chiropractic Practice
2. Laboratory Selection
3. Office Laboratories
4. Proper Patient Preparation
5. Specimen Collection and Preservation
6. The Need for Laboratory Testing
7. Laboratory Test Selection in Diagnosis
8. Laboratory Test Selection in Screening
9. Laboratory Test Selection in Patient Management
10. Interpretation of Laboratory Reference Values
11. Integration of Clinical Laboratory Data with Other Examination Findings
12. Communication of Laboratory Procedures to the Patient
13. Recording Laboratory Procedures
14. Consultation on Laboratory Procedures
15. Use of Focused Organ/Health Problem-Oriented Test Profiles
16. Use of Investigational Laboratory Tests
17. Novel Application of Established Laboratory Procedures in Chiropractic Practice

B. Guidelines for Ordering Commonly Utilized Laboratory Tests

1. Routine Urinalysis
2. Complete Blood Count
3. Erythrocyte Sedimentation Rate
4. Biochemical Profiles
5. Plasma Glucose
6. Serum Urea Nitrogen and Creatinine
7. Serum Calcium
8. Serum Inorganic Phosphorus
9. Serum Total Protein and Albumin
10. Serum Cholesterol
11. Serum Alkaline Phosphatase
12. Serum Prostatic Acid Phosphatase
13. Serum Prostate-Specific Antigen
14. Serum Aspartate Aminotransferase
15. Serum Creatine Kinase
16. Thyroid Function Tests
17. Serum Uric Acid
18. Rheumatoid Factor
19. Anti-Nuclear Antibody Test
20. HLA-B27 Test
21. C-Reactive Protein Test
22. Serum Potassium Test
23. Serum Sodium Test
24. Serum Iron and Total Iron-Binding Capacity Test
25. Fecal Occult Blood Test
26. Serum Ferritin Test

C. Investigational Clinical Laboratory Procedures

1. Analysis of Trace Minerals in Hair
2. Live Cell Analysis
3. Biochemical Biopsy
4. Determination of "Optimal" Reference Values

D. Inappropriate Clinical Laboratory Procedures

1. Cytotoxic Testing for Food Allergies
2. Reams Testing and Interpretation of Urine

E. Appendix

IV. LITERATURE REVIEW

The literature search for this topic utilized the MEDLINE database on CD-ROM from 1980 to the present for articles using the medical subject heading terms relevant to guidelines for the selection and interpretation of laboratory tests. In addition, the CHIROLARS database was searched for articles related to the use of laboratory diagnosis in chiropractic practice. A manual search of the *Chiropractic Research Archives Collection* was also accomplished. From these sources bibliographies were compiled which contained both journal articles and textbooks.

Materials were selected for inclusion if they contained information on the usefulness of clinical laboratory tests in patient care. Included was information on the principles of test selection and interpretation of procedures commonly used in chiropractic practice. Priority was given to well-designed studies published in peer-reviewed journals. Second priority was given to review articles and textbooks.

Role of Laboratory Diagnosis

The role of clinical laboratory diagnosis in chiropractic has evolved since the inception of the profession to where currently, laboratory diagnosis courses are taught at all accredited chiropractic colleges. In addition, the majority of jurisdictions in North America allow some form of access to laboratory tests (Lamm 1989).

The chiropractic practitioner, as a portal of entry health care provider, has the responsibility to perform an appropriate clinical examination for the purpose of assessing a patient's current health status and identifying if the patient is a proper subject for chiropractic care. The clinical laboratory can, at times, provide useful information when the findings from the clinical examination are insufficient to answer the questions at hand. The decision to order a test is made on the assumption that the results will appreciably reduce the uncertainty surrounding a given clinical question and significantly change the pre-test probability that a disorder is present.

Use of Laboratory Tests

Laboratory procedures can be used as screening devices to identify "at risk" patients who may be prone to illness that can be prevented or diminished by early detection and care. For example, routine measurement of cholesterol can be useful in determining which patients should start on preventive management for atherosclerotic cardiovascular disease. The problem with screening, though, is the number of false-positive results it produces. As the prevalence of a disorder in a population falls, the percentage of false-positive results rises dramatically, so there are five to ten false-positive results for every true-positive one. In order to deal with this situation, many attempts have been made to develop guidelines for selection of appropriate patients and tests for early detection (Eddy, 1991).

A second reason for using clinical laboratory tests is to provide assistance in establishing diagnostic hypotheses. The laboratory may be particularly helpful in sorting out whether a patient's clinical complaints are due to a functional or organic disorder.

To rule out a disorder, very sensitive tests are most effective in reducing the probability of that disorder. Very specific tests are most effective in raising the probability of the presence of a disorder and thus are useful for ruling in diagnoses. Such tests when abnormal can confirm the presence of a disorder.

The intelligent selection of an appropriate laboratory test depends on choosing the proper test for the purpose intended. The purpose of the test is affected by the practitioner's estimate of the pretest likelihood that a disorder is present based on an assessment of the available clinical information. The use of a test to exclude or confirm a diagnosis should indicate that the practitioner's best estimate after a careful evaluation of the patient's problem is that the diagnosis in question is either relatively unlikely or probable, respectively. When these principles are followed, the conclusions reached from laboratory test results are likely to be correct and lead to appropriate action (Panzer 1991).

Laboratory tests are used for patient management which includes monitoring patient's response to care, the need for care, and determination of prognosis. Compared with tests for screening and diagnosis, tests used for monitoring are more likely to have abnormal results, show a change from previous test values, cause a change in patient care, and be followed up with repeat testing. Determining the optimal frequency for monitoring patients with repeat tests or procedures cannot be based solely on the presence of the disorder but requires the application of principles of normal physiology, knowledge of the tests or procedures used to monitor the disorder, and awareness of factors other than the disorder that may influence the test result.

Laboratory Test Characteristics

Each laboratory test or procedure possesses a set of characteristics that reflects the information expected in patients with and without the disorder in question. These test characteristics provide clinicians with answers to two fundamental questions: 1) If the disorder is present, what is the likelihood that the test result will be abnormal (positive)? And, 2) if the disorder is not present, what is the likelihood that the result will be normal (negative)? The answer to the first question defines the sensitivity of the test and the answer to the latter defines its specificity.

An ideal test is one for which there is no overlap in the range of results among patients with and without the disorder in question. Few tests are ideal. Usually there is an overlap of results among patients with or without a specific disorder. Each point along the distribution of results that overlap defines a set of operating characteristics for the test. As the point used to define an abnormal result (cutoff point) is moved in the direction of patients with the disorder, the sensitivity decreases. As it is moved in the direction of patients without the disorder, the reverse is true. Some tests may be used both to exclude or to confirm a disorder by altering the criteria for a positive test according to the purpose of the test.

Knowledge of test characteristics is important in deciding which test to select for a given purpose. The process of confirming a disorder requires a test whose specificity is high. When two or more tests are available for this purpose, the one with the highest specificity is ordinarily preferred. When a test is used either for the purpose of screening or to exclude a diagnostic possibility, it must be sensitive. When two or more such tests are available, that with the highest sensitivity is ordinarily preferred. Multiple tests are most helpful when: 1) all are normal, thus tending to exclude the disorder, and 2) when all are abnormal thus tending to confirm the presence of the disorder. Multiple tests are least helpful when one is positive and the others are normal. If two or more tests are highly sensitive and the primary purpose of the test is to exclude a disorder the gain in sensitivity obtained by ordering more than one test may be offset by the increase in false-positive results.

Reference Ranges for Tests

The limits of normal for most analytical tests are determined by measurements done on a large number of subjects and defined as the range encompassed by two standard deviations from the mean value. There are several limitations inherent in this conventional definition. First, the definition excludes approximately 2.5 percent of the subjects whose values lie at the extremes of the distribution curve, rendering them abnormal but presumably not ill. Second, for most measurable biological substances, the distribution curve of test results is skewed rather than symmetric and the method used to express the reference range does not precisely define the central 95 percent of subjects. Third, the reference population used to calculate the limits is not necessarily free of illness. It is assumed that with a large enough sample, the impact of subjects with disease will be diluted. This assumption has been shown to be invalid for many chemistry determinations. The result is often the reporting of reference limits that are too broad. Fourth, few laboratories adjust the reference range for the many factors that may influence the test results other than disease; these include age, sex, weight, diet, time of day, activity, and position of the subject when the specimen is drawn. Last, and most important, the uniform method used to define the reference range does not recognize the many purposes that the test may serve. This range will differ according to whether the clinician is concerned with confirming a condition or excluding one. Although this traditional approach suffers from the above limitations, alternative approaches which create narrower reference ranges should follow acceptable methods in determining those ranges.

Laboratory Test Interpretation

To ensure proper interpretation of the results of laboratory tests, it is important to consider a prior estimate of the likelihood of the presence of a disorder suspected to be present from the history and clinical examination. This is referred to as a pretest probability or prevalence. When the pretest probability is high, a positive result tends to confirm the presence of a disorder, but an unexpected negative result is not particularly helpful in ruling the condition out. When the pre-test probability is low, a normal result tends to exclude the condition, but an unexpectedly positive result is not particularly helpful in confirming the disorder.

If the sensitivity, specificity, and prevalence of the condition are known, then one may easily calculate the effect of the test result on the probability of a correct diagnosis. This is referred to as predictive value or post-test probability (Gottfried, 1982).

Commonly Utilized Laboratory Procedures

This chapter contains information on commonly utilized laboratory tests. These tests were selected based upon an informal survey of test utilization by a representative sample of doctors of chiropractic. Each test is described as it relates to its usefulness in screening, diagnosis and patient management. A critical review of the literature on the utility of each test was performed to provide a basis for guideline recommendations.

V. ASSESSMENT CRITERIA

Procedure Ratings (System I)

Established: Accepted as appropriate by the practicing chiropractic community for the given indication in the specified patient population.

Promising: Given current knowledge, this appears to be appropriate for the given indication in the specified patient population. As more evidence and experience accumulates, this interim rating will change. This connotes provisional acceptance but permits a greater role for the current level of clinical use.

Equivocal: Current knowledge exists to support a given indication in a specified patient population, though value can neither be confirmed or denied. As more evidence and experience accumulates this interim rating will change. Expert opinion recognizes a need for caution in general application.

Investigational: Evidence is insufficient to determine appropriateness. Further study is warranted. Use for a given indication in a specified patient population should be confined to research protocols. As more evidence and experience accumulates this interim rating will change.

Doubtful: Given current knowledge, this appears to be inappropriate for the given indication in the specified patient population. As more evidence and experience accumulates, this interim rating will change.

Inappropriate: Regarded by the practicing chiropractic community as unacceptable for the given indication in the specified patient population.

Quality of Evidence:

The following categories of evidence are used to support the ratings.

Class I:
Evidence provided by one or more well-designed, controlled clinical trials; or well-designed experimental studies that address reliability, validity, positive predictive value, discriminability, sensitivity, and specificity.

Class II:
Evidence provided by one or more well-designed uncontrolled, observational clinical studies such as case-control, cohort studies, etc.; or clinically relevant basic science studies that address reliability, validity, positive predictive value, discriminability, sensitivity, and specificity; and are published in refereed journals.

Class III:
Evidence provided by expert opinion, descriptive studies or case reports.

Suggested Strength of Recommendation Ratings:

Type A. Strong positive recommendation. Based on Class I evidence or overwhelming Class II evidence when circumstances preclude randomized clinical trials.

Type B. Positive recommendation based on Class II evidence.

Type C. Positive recommendation based on strong consensus of Class III evidence.

Type D. Negative recommendation based on inconclusive or conflicting Class II evidence.

Type E. Negative recommendation based on evidence of ineffectiveness or lack of efficacy based on Class I or Class II evidence.

VI. RECOMMENDATIONS

A. General

1. The Role of Laboratory Prucedures in Chiropractic Practice

The appropriate use of clinical laboratory procedures in chiropractic practice is for diagnosis, screening, and patient management.

Comment: Clinical laboratory tests are used by the practitioner to (1) aid in the diagnostic process; (2) screen for early recognition of preventable health problems ; and (3) monitor patient progress and outcomes. It is inappropriate to utilize clinical laboratory procedures for other purposes (e.g., for defensive testing or economic gain).

4.1.1 Rating: Established
Evidence: Class III
Consensus Level: 1

2. Laboratory Selection

It is recommended that the practitioner who uses the services of a clinical laboratory should be aware of the laboratory's scope of services, recognition (licensure and accreditation), and reputation.

4.1.2 Rating: Established
Evidence: Class III
Consensus Level: 1

3. Office Laboratories

The practitioner who performs office laboratory procedures should carry out testing in a manner which meets state and/or federal regulations, and is consistent with quality laboratory practice.

Comment: State and federal regulations define the scope of testing, qualification of laboratory personnel, and the need and extent of quality assurance and proficiency testing.

4.1.3 Rating: Established
Evidence: Class III
Consensus Level: 1

4. Proper Patient Preparation

The practitioner should make sure the patient is adequately prepared for laboratory testing, verifying that the patient understands any special instructions to assure adequate specimens necessary to generate valid laboratory results.

4.1.4 Rating: Established
Evidence: Class III
Consensus Level: 1

5. Specimen Collection and Preservation

The practitioner should assure that in-office laboratory specimens are appropriately collected and preserved.

4.1.5 Rating: Established
Evidence: Class III
Consensus Level: 1

6. The Need for Laboratory Testing

Laboratory procedures may be appropriate when the information available from the history, clinical examination, and previous evaluation is considered insufficient to address the clinical questions at hand.

Comment: The decision to order and/or perform a given test or procedure is made on the assumption that the results will appreciably reduce the uncertainty surrounding a given clinical question and significantly change the pre-test probability that the disorder is present.

4.1.6 Rating: Established
Evidence: Class I, II, III
Consensus Level: 1

7. Laboratory Test Selection in Diagnosis

The practitioner should select a laboratory test(s) appropriate for the purpose of ruling out a specific condition(s) or confirming a strong clinical suspicion by considering the sensitivity and specificity of the test(s) and estimating the likelihood of the condition(s) (pretest probability) based on his or her assessment of the available clinical information.

4.1.7 Rating: Promising
Evidence: Class I, II, III
Consensus Level: 1

8. Laboratory Test Selection in Screening

The use of laboratory tests for screening purposes should include selection of a highly sensitive laboratory test(s) and the appropriate application of the test(s) to health problem(s) which are common, have significant morbidity/mortality and are preventable and/or amenable to effective care.

4.1.8 Rating: Established
Evidence: Class I, II, III
Consensus Level: 1

9. Laboratory Test Selection in Patient Management (Monitoring)

The reproducibility (precision) of the test is the most important characteristic when selecting laboratory tests for monitoring.

Comment: The optimal frequency for monitoring patients cannot be predicted solely on the basis of knowledge of the disorder or the effectiveness of chiropractic care. It requires the application of normal physiology, knowledge of the natural history of the underlying disorder, tests or procedures used to monitor the disorder and awareness of factors other than the disorder that may influence the test results.

4.1.9 Rating: Established
Evidence: Class II, III
Consensus Level: 1

10. Interpretation of Laboratory Reference Values

The practitioner should have an understanding of "normality" as it applies to conventional laboratory reference values in order to appropriately interpret laboratory results.

4.1.10 Rating: Established
Evidence: Class I, II, III
Consensus Level: 1

11. Integration of Clinical Laboratory Data with Other Examination Findings

Clinical laboratory data should be integrated with results from other examinations as part of the clinical decision-making process when monitoring the patient's clinical status.

4.1.11 Rating: Established
Evidence: Class I, II, III
Consensus Level: 1

12. Communication of Laboratory Procedures and Results to the Patient

The practitioner should effectively discuss with the patient the purposes, possible complications, and clinical significance of the results of laboratory studies conducted or ordered.

4.1.12 Rating: Established
Evidence: Class III
Consensus Level: 1

13. Recording Laboratory Results:

Clinical laboratory results should be recorded in the patient case record.

4.1.13 Rating: Established
Evidence: Class III
Consensus Level: 1

14. Consultation on Laboratory Procedures

The practitioner should seek assistance when uncertain about appropriate test selection, patient preparation, and/or interpretation of laboratory results.

4.1.14 Rating: Established
Evidence: Class III
Consensus Level: 1

15. Use of Focused Organ/Health Problem-Oriented Test Profiles

The use of profiles which focus on an organ system and/or health problem in a symptomatic patient can be considered a cost-effective and efficient procedure for generating appropriate laboratory data to help confirm or rule out a diagnosis or clinical impression.

4.1.15 Rating: Established
Evidence: Class I, II, III
Consensus Level: 1

16. Use of Investigational Laboratory Tests

Laboratory tests which are considered to be investigational should be used in clinical settings only when part of an acceptable research protocol which is supervised by the staff of a recognized research institution.

Comments: Research protocols for the evaluation of investigational clinical laboratory tests should take into consideration the actual need for the tests, the inherent properties of the tests, the population characteristics to which the tests are applied, the existence of gold standard tests, the required study

population size, and the tests' discrimination abilities relative to sensitivity, specificity, and predictive value (Adams, 1990). Research protocols should be approved by an institutional review board.

4.1.16 Rating: Established
Evidence: Class I, II, III
Consensus Level: 1

17. The Novel Application of Established Laboratory Procedures in Chiropractic Practice

Novel application of established laboratory procedures should not be used in chiropractic practice as a substitute for conventional application of laboratory procedures in the clinical decision-making process.

Comment: Novel applications of established tests should be evaluated by appropriate research methods. If used in a patient care setting, informed consent is necessary.

4.1.17 Rating: Established
Evidence: Class I, II, III
Consensus Level: 1

B. Guidelines for Ordering Commonly Utilized Laboratory Procedures

1. Guidelines for Ordering a Urinalysis
   a. Outpatient Screening/Case-Finding
      i. A urinalysis is not indicated in asymptomatic individuals whose history and physical examination findings are within the normal ranges for age and sex.
      ii. In specific subsets of the population with higher prevalence of renal disease, urinary tract infections, liver disease, and diabetes mellitus, the urinalysis may be useful to identify those who are significantly at risk, including but not limited to the following:
         - Pregnancy
         - Elderly (> 60 years) men and women
         - Obese individuals with a positive family history of diabetes mellitus
         - Individuals taking hepato- or nephrotoxic drugs
         - Individuals routinely exposed to toxic chemicals in the work or home environment
   b. Diagnosis
      i. The urinalysis is indicated in patients where there are clinical findings suggestive of urinary tract infections, renal disease, diabetes mellitus, and liver disease. The urinalysis should include physical, chemical, and microscopic evaluation.
      ii. The urinalysis may be useful in patients with previous positive findings for proteinuria, microhematuria, bacteriuria, pyuria, or diabetes mellitus.
   c. Monitoring
      i. Repeat urinalysis is not indicated in patients in whom no abnormality is suspected.
      ii. Repeat urinalysis may be useful in the following:
         - Documenting evidence of response to treatment for urinary tract infections, renal disease, and diabetes mellitus
         - Patients in whom there is concern that treatment has not been effective
         - Patients taking medications which are hepato- or nephrotoxic
         - Individuals routinely exposed to toxic chemicals
         - Pregnancy

4.2.1 Rating: Established
Evidence: Class I, II, III
Consensus Level: 1

2. Guidelines for Ordering a Complete Blood Count (CBC)
   a. Outpatient Screening/Case-Finding
      i. CBCs are not indicated in asymptomatic individuals whose history and physical examination findings are within reference for age and sex.
         - Routine use of CBCs in populations of low disease prevalence have a low diagnostic yield
      ii. In specific subsets of the population with higher prevalence of anemia, the CBC may be useful to identify those who are significantly anemic because of poor nutrition or undiagnosed chronic illness, including but not limited to the following:
         - Pregnant women in whom there is a suspicion that iron supplementation or nutrition has not been adequate
         - The elderly (> 75 years old)
         - Recent immigrants from Third World countries, especially persons at increased risk of malnourishment
         - Individuals on diets which are nutritionally unbalanced
   b. Diagnosis of Suspected Abnormality
      i. The CBC is useful in the diagnosis of infection or primary hematological disorders.
         - The CBC is indicated in patients in whom there are clinical findings suggestive of anemia, including fatigue, mucous-membrane pallor, sore tongue, peripheral neuropathy, abnormal bleeding, or findings suggestive of polycythemia
      ii. The CBC may be useful in conditions that may be associated with anemia and/or abnormal leukocyte counts, such as rheumatoid arthritis, ma-

lignancy (e.g., lymphoma)and renal insufficiency.

iii. The CBC may be useful when fever is present or when infection is suspected, especially when other confirmatory findings are absent.

c. Monitoring

i. Repeat CBCs are not indicated in patients in whom no abnormality is suspected.

ii. Repeat CBCs may be useful in the following:

- Patients in whom there is concern that treatment has not been effective
- Documenting evidence of response to treatment for anemia
- Patients with infection not improving clinically under collaborative care
- Patients with leukopenia (leukocyte count is less than 4,500/μl)
- Patients taking cytotoxic medications

4.2.2 Rating: Established
Evidence: Class I, II, III
Consensus Level: 1

3. Guidelines for Ordering the Erythrocyte Sedimentation Rate (ESR) Test

a. Outpatient Screening/Case-Finding

i. The ESR is not indicated in asymptomatic persons.

ii. An ESR should be ordered/performed selectively and interpreted with caution in patients whose symptoms are not adequately explained by a careful history and physical examination.

- Significant infections or inflammatory or neoplastic disease are unlikely in such patients, and the ESR must be markedly elevated to be diagnostically useful.
- Extreme elevation of the ESR seldom occurs in patients with no evidence of serious disease.

b. Diagnosis

i. The ESR is useful for the diagnosis of temporal arteritis (giant cell arteritis) and polymyulgia rheumatica.

- A normal ESR virtually excludes the diagnosis of temporal arteritis in most patients who are suspected of having the disease.
- When there is strong clinical evidence for temporal arteritis and the ESR is normal, further efforts to diagnose temporal arteritis are required.

ii. A careful history and physical examination are the most reliable means of making a diagnosis of rheumatoid arthritis. In patients with an equivocal examination, an ESR may be indicated and an abnormal result is a clue to the presence of this disease.

iii. The ESR may be indicated in the differential diagnosis of solitary bone lesions.

iv. The ESR may be indicated in the diagnosis of metastatic breast cancer.

v. The ESR may be indicated as a means of excluding suspected vertebral osteomyelitis.

vi. The ESR may assist in the differential diagnosis of certain infectious, inflammatory, and malignant disorders.

vii. The ESR may provide assistance in distinguishing spinal pain of organic origin from mechanical origin.

c. Monitoring

i. The ESR is useful for monitoring temporal arteritis and polymyalgia rheumatica.

ii. The judicious use of the ESR combined with other clinical and laboratory observations may be of value in patients with rheumatoid arthritis and systemic lupus erythematosis.

iii. The ESR may be indicated for monitoring patients with Hodgkin's disease.

iv. The ESR may be indicated for monitoring patients with acute rheumatic fever.

4.2.3 Rating: Established
Evidence: Class I, II, III
Consensus Level: 1

4. Guidelines for Ordering Biochemical Profiles

a. Outpatient Screening/Case-Finding

i. Biochemical profiles are not routinely indicated for screening asymptomatic patients.

ii. Selected components of biochemical profiles may be indicated for screening and/or case-finding in adults: serum glucose, cholesterol and creatinine.

iii. Specific components of biochemical profiles that are not indicated for screening include the following: serum calcium, alkaline phosphatase, uric acid, sodium, potassium, chloride; AST, lactic dehydrogenase (LDH), total protein, albumin, and total bilirubin.

iv. In cases where current technology and/or cost prohibit selective test ordering, biochemical profiles should be used with caution because of a greater likelihood of false-positive findings in low disease-prevalent populations.

4.2.4 Rating: Established
Evidence: Class I, II, III
Consensus Level: 1

5. Guidelines for Ordering a Serum or Plasma Glucose Test.

a. Outpatient Screening/Case-Finding

i. A serum or plasma glucose test is not routinely indicated to screen for diabetes mellitus in asymptomatic, nonpregnant adults.

ii. A serum or plasma glucose test may be indicated in individuals who are at increased risk for diabetes mellitus.
- Risk factors for diabetes mellitus include age (> 50 years), family history in a first degree relative, personal history of gestational diabetes, body weight that exceeds generally accepted standards by at least 25 percent, or membership in an ethnic group that has a high prevalence of diabetes.

iii. A serum or plasma glucose test is recommended for all pregnant women to screen for gestational diabetes.
- A serum or plasma glucose test obtained after a 50-gram glucose load is the preferred screening procedure.

b. Diagnosis
i. A fasting or random plasma glucose measurement is useful for the diagnosis of diabetes mellitus in persons who present with symptoms of hyperglycemia (rapid weight loss, polyuria, polydipsia) and/or diabetes (for example, peripheral neuropathy or peripheral vascular disease).
- An oral glucose tolerance test may be indicated to confirm equivocal tests.

ii. In patients with clinical findings of hypoglycemia, a serum or plasma glucose should be ordered.
- The true hypoglycemia syndrome refers to the presence of adrenergic (sweating, tremor, tachycardia, anxiety, and hunger) or neuroglycopenic (dizziness, headache, clouded vision, blunted mental acuity, confusion, abnormal behavior, coma) signs and symptoms in the presence of a low serum or plasma glucose concentration.

c. Monitoring
i. A plasma or serum glucose test is not optimal as the primary modality for monitoring glycemia in insulin-dependent (Type I) diabetic patients with diabetes.
- Daily self-monitored blood glucose measurement, along with periodic (3-4 times per year) measurement of glycated hemoglobin (glycosylated hemoglobin) are appropriate monitoring evaluations

ii. In non-insulin dependent (Type II) diabetes, laboratory performed plasma or serum glucose testing may be indicated every three months.
- Self-monitored blood glucose measurement may be indicated one or two times per day to assess glycemia
- Glycated hemoglobin measurements are indicated at least two times per year to provide an index of mean glucose levels as a measure of overall chronic glucose control

iii. Laboratory performed fasting and postprandial plasma glucose measurements are indicated in diet-treated gestational diabetes every one to two weeks from time of diagnosis until 30 weeks' gestation, and once or twice weekly thereafter.

4.2.5 Rating: Established
Evidence: Class I, II, III
Consensus Level: 1

6. Guidelines for Ordering Serum Urea Nitrogen and Creatinine Test

a. Outpatient Screening/Case-Finding
i. Serum urea nitrogen and creatinine tests are not indicated in asymptomatic individuals whose history and physical examination findings are within reference ranges.

ii. Individuals who have a higher likelihood of developing renal dysfunction may benefit from measuring serum urea nitrogen and creatinine concentrations
- Patients with hypertension, diabetes mellitus, congestive heart failure, cirrhosis, prostatic hypertrophy, exposure to nephrotoxic agents, taking diuretics, eating a high-protein diet, and over 75 years of age, are candidates for these tests.

b. Diagnosis
i. Serum urea nitrogen and creatinine tests are useful in the diagnosis of renal disorders.
- These tests are indicated in patients with clinical findings suggestive of renal dysfunction, such as pallor, anemia, anorexia, unexplained weight loss, polyuria, urinary hesitancy, nocturia, renal colic, dehydration, retinopathy, hypertension, skin lesions of vasculitis, and/or an abnormal urinalysis (high specific gravity, proteinuria, hematuria, pyuria, presence of crystals and/or casts).

ii. Measuring serum urea nitrogen and creatinine concentration, or creatinine alone, may be useful in hypertension or diabetes patients.

iii. Conditions in which both the serum urea nitrogen and creatinine concentration may be indicated include but are not limited to the following:
- Gastrointestinal bleeding, complicated by some degree of renal insufficiency
- A suspected diagnosis of water intoxication
- Syndrome of inappropriate antidiuretic hormone secretion

c. Monitoring
i. Measuring serum urea nitrogen and serum creatinine concentration, or creatinine alone, may be useful for the following conditions and at the following frequencies:

- Uncomplicated hypertensive patients, every one to two years
- Chronic renal disease, every four to six months
- Patients in acute renal failure, every one to two days

4.2.6 Rating: Established
Evidence: Class I, II, III
Consensus Level: 1

7. Guidelines for Ordering a Serum Calcium Test

a. Outpatient Screening/Case-Finding

i. The serum calcium test is not indicated in asymptomatic individuals whose history and physical examination findings are within reference limits for age and sex.

ii. The use of serum calcium as a screening test for occult metabolic bone disease or malignancy will result in a low diagnostic yield.

- For most of these conditions, the post-test probability of disease after abnormal calcium results is not sufficiently high to warrant the inclusion of calcium determinations in a screening profile.

b. Diagnosis

i. The serum calcium test is useful in the evaluation of patients who present with clinical evidence of hypercalcemia (anorexia, nausea, constipation, polyuria, polydipsia, bone pain, and mental or neurologic aberrations) or hypocalcemia (paresthesia, muscle cramps, tetany, weakness, convulsions).

ii. The serum calcium test may be useful in the evaluation of patients with hypertension, renal calculi, peptic ulcer disease, metabolic bone disease, malignant disorders, history of previous neck surgery, alcoholism, and acid-base imbalance.

c. Monitoring

i. Repeat serum calcium measurement is not indicated in patients in whom no abnormality is suspected.

ii. Serum calcium may be used to follow the course of hypercalcemia and hypocalcemic disorders and their response to care.

- A serum calcium level should be interpreted with knowledge of the serum albumin level

4.2.7 Rating: Established
Evidence: Class II, III
Consensus Level: 1

8. Guidelines for Ordering a Serum Inorganic Phosphorus Test

a. Outpatient Screening/Case-Finding

i. The serum inorganic phosphorus test is not indicated in asymptomatic individuals whose history and physical examination findings are within reference limits for age and sex.

ii. The use of serum inorganic phosphorus as a screening test for various malignant, inflammatory, bony, renal and metabolic disorders will result in a low diagnostic yield.

- For most of these conditions, the post-test probability of disease after abnormal inorganic phosphorus results is not sufficiently high to warrant the inclusion of inorganic phosphorus determinations in a screening profile.

b. Diagnosis

i. The serum inorganic phosphorus test is useful in the evaluation of patients suspected of having metabolic bone disease, renal disorders, endocrine disorders, and acid-base imbalance.

c. Monitoring

i. Repeat serum inorganic phosphorus measurement is not indicated in patients in whom no abnormality is suspected.

ii. Serum inorganic phosphorus may be used to follow the course of hyperphosphatemic and hypophosphatemic disorders and their response to care.

- A serum inorganic phosphorus level should be interpreted with knowledge of the serum urea nitrogen level.

4.2.8 Rating: Established
Evidence: Class II, III
Consensus Level: 1

9. Guidelines for Ordering Serum Total Protein and Albumin Test

a. Outpatient Screening/Case-Finding

i. The serum total protein and albumin tests are not indicated in asymptomatic individuals whose history and physical examination findings are within reference limits for age and sex.

ii. The use of serum total protein and albumin as screening tests for malnutrition, protein loss or breakdown, and impaired protein synthesis will result in a low diagnostic yield.

b. Diagnosis

i. The serum total protein and albumin tests may be useful in the evaluation of patients with suspected malnutrition, liver disorders, renal disease, malabsorption, recurrent infections, blood dyscrasias, and malignancies such as multiple myeloma.

- Results which fall outside the reference range for these tests may require a protein electrophoresis determination and/or immunoelectrophoresis.

c. Monitoring
   i. Repeat serum total protein and albumin measurements are not indicated in patients in whom no abnormality is suspected.
   ii. Serum total protein and albumin determinations have limited value in monitoring disorders associated with changes in serum protein levels.

4.2.9 Rating: Established
Evidence: Class II, III
Consensus Level: 1

10. Guidelines for Ordering a Serum Cholesterol Test
   a. Outpatient Screening/Case-Finding
      i. A total serum cholesterol measurement is recommended at least once in early adulthood and at intervals of five or more years up to age 70.
         - The LDL and HDL cholesterol and serum triglyceride levels should be measured in persons with an elevated total serum cholesterol.
      ii. In patients who demonstrate risk factors for coronary artery disease, a serum total cholesterol is indicated to assess cardiac risk.
         - Risk factors for coronary artery disease include: being male or postmenopausal female, positive family history, smoker, hypertension, history of hyper-cholesterolemia, low HDL-cholesterol levels, diabetes mellitus, previous stroke, peripheral vascular disease, or severe obesity.
   b. Diagnosis
      i. The total serum cholesterol is useful in the diagnosis of patients with coronary artery disease and peripheral vascular disease.
      ii. The total serum cholesterol may be useful in the diagnosis of nephrotic syndrome, pancreatitis, and liver disease.
   c. Monitoring
      i. Total serum cholesterol may be used to follow up hypercholesterolemic related disorders and their response to care.

4.2.10 Rating: Established
Evidence: Class I, II, III
Consensus Level: 1

11. Guidelines for Ordering a Serum Alkaline Phosphatase Test
   a. Outpatient Screening/Case-Finding
      i. The serum alkaline phosphatase test is not indicated in asymptomatic individuals whose history and physical examination findings are within reference limits for age and sex.
      ii. The use of serum alkaline phosphatase as a screening test for unsuspected skeletal and hepatobiliary diseases provides a low diagnostic yield.
         - The pretest probability is low in the general population for those disorders most strongly associated with an elevated alkaline phosphatase.
         - The serum alkaline phosphatase test is not specific for any particular disorder or sensitive enough to identify most patients with any single disease.
   b. Diagnosis
      i. The serum alkaline phosphatase may be useful in the evaluation of patients who present with clinical evidence of a skeletal disorder with increased osteoblastic activity, and are suspected of having either Paget's disease of bone (osteitis deformans), osteomalacia, primary bone tumors, metastatic bone tumors or primary hyperparathyroidism.
         - Clinical evidence may include backache, bone pain, bone swelling, abnormal plain film bone radiographs, and bone scans.
      ii. The serum alkaline phosphatase test may be useful in the evaluation of patients who present with clinical evidence of a hepatobiliary disorder such as cholelithiasis with obstruction, drug-induced cholestasis, metastatic tumor or space-occupying lesion in the liver, cirrhosis, hepatitis, and alcoholism.
         - Clinical evidence may include fever, nausea, vomiting, abdominal pain, jaundice, certain medication use, and abnormal liver function tests.
      iii. The serum alkaline phosphatase test may exhibit abnormal results in a number of other disorders.
         - These conditions include intestinal disorders, malignancy, malnutrition, congestive heart failure, renal disorders, thyroid dysfunction, diabetes mellitus, and physiological influences (age, pregnancy, non-fasting patient).
   c. Monitoring
      i. Repeat serum alkaline phosphatase measurement is not indicated in patients in whom no abnormality is suspected.
      ii. Periodic determinations of serum alkaline phosphatase may be used to follow the course of a disorder and its response to care.

4.2.11 Rating: Established
Evidence: Class I, II, III
Consensus Level: 1

12. Guidelines for Ordering Serum Prostatic Acid Phosphatase
   a. Outpatient Screening/Case-Finding
      i. The serum prostatic acid phosphatase test is not indicated in asymptomatic individuals whose history and physical examination findings are within reference limits for age and sex.

ii. The use of serum prostatic acid phosphatase as a screening test for unsuspected cancer of the prostate provides a low diagnostic yield.
- Assays for serum prostatic acid phosphatase are not sufficiently sensitive to detect prostatic carcinoma in 70 to 80 percent of patients with localized disease (Stage A or B) or 5 to 15 percent of patients with metastatic prostatic disease.
- Specificity is low because nearly every method devised for detecting prostatic acid phosphatase exhibits cross-reactivity with other acid phosphatase isoenzymes found widely in human tissues.

b. Diagnosis
i. The serum prostatic acid phosphatase test may be useful in the evaluation of patients with clinical evidence of prostatic carcinoma.
- Patients may present with obstructive symptoms (hesitancy, diminished urine stream, dribbling, intermittency), lumbar and/or sacral pain, and have induration or nodular irregularities of the prostate discovered by digital rectal examination.

c. Monitoring
i. Repeat serum prostatic acid phosphatase measurement is not indicated in patients in whom no abnormality is suspected.
ii. Serum prostatic acid phosphatase measurement may be used to monitor cancer patients for recurrence after prostatectomy or other ablative care.

4.2.12 Rating: Established
Evidence: Class I, II, III
Consensus Level: 1

13. Guidelines for Ordering Serum Prostate-Specific Antigen (PSA)

a. Outpatient Screening/Case-Finding
i. The serum prostate-specific antigen (PSA) test is not indicated in asymptomatic individuals whose history and physical examination findings are within reference limits for age and sex.
ii. The use of serum PSA as a screening test for unsuspected cancer of the prostate provides a low diagnostic yield.
- Serum PSA measurements are not sufficiently sensitive to be used alone as a screening test.
- The specificity of PSA is limited, due to elevations of the antigen occurring in men with benign prostatic hyperplasia or prostatitis.
- Serum PSA measurement is a useful addition to rectal examination and ultrasonography in the detection of prostate cancer.
- PSA is more sensitive but less specific than prostatic acid phosphatase for prostatic cancer.

b. Diagnosis
i. The serum prostate-specific antigen is a useful test in the evaluation of patients with clinical evidence of prostatic carcinoma.

c. Monitoring
i. Repeat serum prostate-specific antigen measurement is not indicated in patients in whom no abnormality is suspected.
ii. Serum PSA measurements may be useful to detect recurrences of prostate cancer.
iii. Serum PSA measurements may be useful in monitoring the response to care for prostate cancer.

4.2.13 Rating: Established
Evidence: Class I, II, III
Consensus Level: 1

14. Guidelines for Ordering a Serum Aspartate Aminotransferase (AST) Test

NOTE: This test was formerly known as glutamic-oxaloacetic transaminase (SGOT).

a. Outpatient Screening/Case-Finding
i. The serum AST is not indicated in asymptomatic individuals whose history and physical examination findings are within reference limits for age and sex.
ii. The use of serum AST as a screening test for liver disorders, cardiac disease, and skeletal muscle disorders will result in a low diagnostic yield.

b. Diagnosis
i. The serum AST test may be useful in the evaluation of patients with suspected liver disorders.

c. Monitoring
i. Repeat serum AST measurement is not indicated in patients in whom no abnormality is suspected.
ii. Serum AST may be used to follow the course of various liver disorders and their response to care.

4.2.14 Rating: Established
Evidence: Class I, II, III
Consensus Level: 1

15. Guidelines for Ordering Serum Creatine Kinase (CK)

NOTE: This test was formerly known as Creatine Phosphokinase (CPK).

a. Outpatient Screening/Case-Finding
i. The serum creatine kinase (CK) test is not indicated in asymptomatic individuals whose history and physical examination findings are within reference limits for age and sex.

ii. The use of the serum creatine kinase (CK) as a screening test for cardiac, skeletal muscle, and central nervous system disorders will result in a low diagnostic yield.

b. Diagnosis
   i. The serum creatine kinase (CK) test is useful in the evaluation of patients who present with clinical evidence of acute myocardial infarction.
      - Fractionation and measurement of CK isoenzymes (CK-MB primarily) augments total CK results.
   ii. The serum creatine kinase (CK) test may be useful in the differential diagnosis of chest pain, hypothyroidism and in the detection of skeletal muscle disorders that are not of neurogenic origin, such as Duchenne Muscular Dystrophy.

c. Monitoring
   i. Measurement of serial levels of serum CK and CK-MB isoenzymes are used to monitor care in acute myocardial infarction.
   ii. Total serum CK may be used to follow patients with certain primary myopathies.

4.2.15 Rating: Established
Evidence: Class I, II, III
Consensus Level: 1

16. Guidelines for Ordering Thyroid Function Tests
a. Outpatient Screening/Case-Finding
   i. Routine testing for thyroid disorders is not indicated in asymptomatic individuals.
   ii. Case-finding is indicated in women over 50 years of age who have general symptoms that could be associated with thyroid dysfunction.

b. Diagnosis
   i. The sensitive thyrotropin assay (sTSH) is useful in the evaluation of patients of either sex who present with clinical evidence of thyroid dysfunction.
      - If sTSH is not available, the Free T3, Free T4, or Free T4 Index can be used in the evaluation of suspected hyperthyroidism.
      - For the diagnosis of hypothyroidism, the Free T4 or Free T4 Index, followed by a serum thyrotropin (TSH) test, is acceptable. For patients suspected of having thyroiditis, antithyroid antibody studies may be useful.

c. Monitoring
   i. The sTSH test is indicated for monitoring patient response to care.

4.2.16 Rating: Established
Evidence: Class I, II, III
Consensus Level: 1

17. Guidelines for Ordering a Serum Uric Acid Test
a. Outpatient Screening/Case-Finding
   i. The serum uric acid test is not indicated in asymptomatic individuals whose history and physical examination findings are within reference limits for age and sex.
   ii. The use of serum uric acid as a screening test for gout will provide a low diagnostic yield.
      - On the basis of established prevalences, if asymptomatic individuals were screened, those with an elevated uric acid have only a 5 percent chance of having gout
   iii. For case finding, with a pretest probability of 10 percent (prevalence of gout in the U.S. is estimated at 0.3%), the probability that a correct diagnosis will be derived from a positive test is less than 50%.

b. Diagnosis
   i. The serum uric acid test is useful in the evaluation of patients who present with clinical evidence of monoarticular arthritis and are suspected of having gout.
      - Gout is a disorder of purine metabolism where the presence of an elevated serum uric acid level is but one of several criteria necessary for diagnosis.
   ii. The serum uric acid test may be elevated in a number of disorders other than gout which affect urate production or excretion, or both.
      - These conditions include: (1) increased nucleic acid turnover related to hematological disorders, malignancy and psoriasis; (2) reduced excretion due to renal dysfunction, certain drugs, and organic acidosis, and (3) miscellaneous causes such as arteriosclerosis and hypertension.
   iii. Serum uric acid measurement is not useful as a test for renal function because the reference range is wide and the rise in uric acid in renal dysfunction is not constant.

c. Monitoring
   i. Repeat serum uric acid measurement is not indicated in patients in whom no abnormality is suspected.
   ii. Periodic determinations of serum uric acid may be useful in monitoring patients under care for gout.
   iii. Serial serum uric acid analyses are sometimes of value in estimating prognosis in toxemia of pregnancy.

4.2.17 Rating: Established
Evidence: Class I, II, III
Consensus Level: 1

18. Guidelines for Ordering a Rheumatoid Factor Test
a. Outpatient Screening/Case-Finding
   i. The rheumatoid factor test is not indicated in asymptomatic individuals whose history and

physical examination findings are within reference ranges for age and sex.

ii. The use of rheumatoid factor as a screening test for rheumatoid arthritis will result in a low diagnostic yield.
- If the rheumatoid factor test is ordered when there is little likelihood of rheumatoid arthritis (e.g., low-back pain) and where the pretest probability is low (1 percent), the predictive value will be very low.

iii. For case finding, with a pretest probability of 10 percent (prevalence of rheumatoid arthritis in the U.S. is estimated at 0.5% to 3%), the probability that a correct diagnosis will be derived from a positive test is less than 50%.

iv. Many more false-positive results as compared to true-positive results will occur from screening.
- There is less than a one in five chance in a screening program that an individual with a positive rheumatoid factor test will have rheumatoid arthritis.

b. Diagnosis of Rheumatoid Arthritis and Related Disorders

i. The rheumatoid factor test is useful in the evaluation of patients who present with clinical evidence of symmetric polyarthritis and are suspected of having rheumatoid arthritis.
- Seronegative patients suspected of having rheumatoid arthritis should be retested in six months.

ii. The usefulness of the rheumatoid factor test among patients already known to have rheumatoid arthritis is primarily prognostic. Patients with high titers of rheumatoid factor tend to have more severe disease, subcutaneous nodules, vasculitis, and poorer long-term prognosis. However, individual patients will vary with these manifestations.

iii. Rheumatoid factor is positive in a significant subset of patients with other rheumatic and nonrheumatic diseases, but its presence or absence weighs little in the diagnosis of the majority of such diseases.
- The disappearance of the rheumatoid factor in a patient with Sjogren's syndrome may herald the onset of lymphoma.
- The rheumatoid factor is frequently positive in cryoglobulinemia.

c. Monitoring

i. Repeat rheumatoid factor tests are not indicated in patients in whom rheumatoid arthritis is not suspected.

ii. The use of the rheumatoid factor test to guide treatment in patients with rheumatoid arthritis is not recommended. There is little evidence to suggest that an individual rheumatoid arthritis patient with a highly positive rheumatoid factor test will fare better if treated earlier or more aggressively.

iii. The rheumatoid factor test is not a generally accepted measure of improvement in rheumatoid arthritis.

4.2.18 Rating: Established
Evidence: Class I, II, III
Consensus Level: 1

19. Guidelines for Ordering the Anti-Nuclear Antibody Test (ANA)

a. Outpatient Screening/Case-Finding

i. The ANA test is not indicated in asymptomatic individuals whose history and physical examination findings are within reference ranges for age and sex.

ii. The use of the ANA as a screening test for systemic lupus erythematosus, drug-induced lupus, or mixed connective tissue disease where a moderate pretest probability is low will result in a low diagnostic yield.

b. Diagnosis

i. The ANA test is useful in the evaluation of patients suspected of having systemic lupus erythematosus, drug-induced lupus, or mixed connective tissue disease where a moderate pretest probability is estimated based on the clinical criteria present.

ii. A positive test, while nonspecific, increases the post-test probability of disease.
- A positive ANA test (titer > 1:40) should be followed up with more specific tests such as anti-nDNA and precipitating antibodies (against RNP, Sm, Ro/SS-A).
- However, in a patient over 70 years of age, a titer of 1:40 may be insignificant, and repeat measurement should be obtained to see if the titer increases or is stable.

iii. A negative ANA test result is extremely powerful in reducing the probability of these diseases.
- In patients who have high probability of systemic lupus erythematosus based on clinical criteria but who have a negative antinuclear antibody assay, a determination for anti-Ro or antiphospholipid antibodies may be helpful.

c. Monitoring

i. Repeat measurements of antinuclear antibodies were not indicated in patients in whom connective tissue disease is not suspected.

ii. The ANA test can be used as an aid in the assessment of systemic lupus erythematosus disease activity and as a guide for treatment.

4.2.19 Rating: Established
Evidence: Class I, II, III
Consensus Level: 1

20. Guidelines for Ordering the HLA-B27 Test
a. Outpatient Screening/Case-Finding
i. The HLA-B27 test is not indicated in asymptomatic individuals whose history and physical examination findings are within reference ranges for age and sex.
ii. The use of the HLA-B27 as a screening test for ankylosing spondylitis in patients presenting with low-back pain will result in a low diagnostic yield.
b. Diagnosis
i. The HLA-B27 test is not useful for confirmation of the diagnosis of spondyloarthropathies (e.g., ankylosing spondylitis and Reiter's syndrome) when adequate clinical and radiologic criteria are present.
ii. However, the HLA-B27 test may be useful in patients with low-back pain of insidious onset, minimal tenderness over the sacroiliac joints, normal spinal movement and chest expansion and equivocal radiographic findings where the pretest probability is close to 50 percent for ankylpsing spondylitis.
- A positive HLA-B27 test increases the likelihood of ankylosing spondylitis significantly and a negative result lowers the likelihood.
iii. The HLA-B27 test may be useful in children with spondyloarthropathy, especially those with a history of juvenile chronic polyarthritis, to help establish the diagnosis of ankylosing spondylitis.
iv. The HLA-B27 test may be useful in helping to differentiate incomplete Reiter's syndrome from seronegative rheumatoid arthritis and gonococcal arthropathy.
c. Monitoring
i. The HLA-B27 test is not useful for monitoring spondyloarthropathies including the establishment of prognosis, genetic counseling, and patient management.

4.2.20 Rating: Established
Evidence: Class I, II, III
Consensus Level: 1

21. Guidelines for Ordering the C-Reactive Protein (CRP) Test
a. Outpatient Screening/Case Finding
i. The CRP is not indicated in asymptomatic persons.
ii. The CRP test should be used selectively and interpreted with caution in patients with symptoms that are not explained by a careful history and physical examination.
- Significant infections or inflammatory or neoplastic disease is unlikely in such patients, and the CRP must be markedly elevated or positive to be diagnostically useful.
b. Diagnosis
i. Measurement of CRP by quantitative methods provides the most clinically useful information.
ii. The CRP is useful for the diagnosis of temporal arteritis (giant cell arteritis) and polymyalgia rheumatica.
iii. A CRP test may be indicated in patients suspected of rheumatoid arteritis where clinical examination findings are equivocal.
iv. Measurement of CRP may be useful in the differential diagnosis of peripheral joint pain.
v. The CRP may be indicated in the differential diagnosis of solitary bone lesions.
vi. The CRP may be indicated in the diagnosis of metastatic breast cancer.
vii. The CRP may be indicated as a means of excluding suspected vertebral osteomyelitis.
viii. The CRP may assist in the differential diagnosis of certain infectious, inflammatory, and malignant disorders.
ix. The CRP may provide assistance in distinguishing spinal pain of organic from mechanical origin.
c. Monitoring
i. Measurement of CRP by quantitative methods provides the most clinically useful information.
ii. The CRP is indicated for monitoring temporal arteritis and polymyalgia rheumatica.
iii. The judicious use of the CRP test combined with other clinical and laboratory observations may be of value in patients with rheumatoid arthritis and systemic lupus erythematosis.
iv. The CRP may be indicated for monitoring patients with Hodgkin's disease.
v. The CRP may be indicated for monitoring patients with acute rheumatic fever.

4.2.21 Rating: Established
Evidence: Class I, II, III
Consensus Level: 1

22. Guidelines for Ordering a Serum Potassium Test
a. Outpatient Screening/Case-Finding
i. A serum potassium test is not indicated in asymptomatic individuals whose history and physical examination are within reference limits for age and sex.
ii. Measurement of serum potassium levels is not useful in general screening of ambulatory care patient populations.

b. Diagnosis
   i. Serum potassium measurement is useful in patients with chronic renal disease, including diabetic renal insufficiency.
   ii. Serum potassium measurement is useful in patients with hypertension to detect primary hyper-aldosteronism.
      - Measurements should be made at time of diagnosis and before initiation of care.
   iii. Serum potassium measurement is useful in patients with symptoms or signs suggestive of renal tubular acidosis.
   iv. Serum potassium measurement is useful in patients with signs and symptoms suggestive of altered serum potassium concentration, including generalized or proximal weakness, new atrial tachyarrhythmias, nocturia, polyuria, or ileus.

c. Monitoring
   i. Serum potassium measurement is indicated one to two times a year in patients with diabetic renal disease.
   ii. Serum potassium measurement is indicated in hypertensive patients receiving diuretic therapy.
   iii. Serum potassium measurement may be useful every six months in diuretic-treated patients concurrently receiving digitalis.
   iv. Serum potassium measurements may be useful in patients with renal dysfunction, cardiac arrhythmias, diarrhea, dehydration, and metabolic acidosis in whom there is a change in clinical status.

4.2.22 Rating: Established
Evidence: Class I, II, III
Consensus Level: 1

23. Guidelines for Ordering a Serum Sodium Test

a. Outpatient Screening
   i. A serum sodium test is not indicated in asymptomatic individuals whose history and physical examination are within reference limits for age and sex.
   ii. Measurement of serum sodium levels is not useful in general screening of ambulatory care patient populations.

b. Diagnosis
   i. Serum sodium measurement may be indicated in patients with the following signs or symptoms:
      - Rapid change in weight
      - Rapid change in fluid balance (severe vomiting, diarrhea, polyuria)
      - Rapid change in mental status
      - Clinical evidence of dehydration or volume depletion
   ii. Serum sodium concentration is not indicated in hypertensive patients to identify primary aldosteronism.

c. Monitoring
   i. Serum sodium measurement may be useful as an index of hydration, especially in elderly persons or others who may fail to ingest adequate quantities of water to maintain water balance.
   ii. Serum sodium measurement may be useful in patients with chronic renal insufficiency at the following frequencies:
      - At the time of change in clinical status
      - When serum creatinine reaches 7 to 8 mg/dL; thereafter, every two to three months
   iii. Serum sodium measurement may be indicated in most patients at the time of change in clinical status, especially change in mental or neurologic status, fluid balance, weight, or dehydration or volume depletion.

4.2.23 Rating: Established
Evidence: Class I, II, III
Consensus Level: 1

24. Guidelines for Ordering Serum Iron and Total Iron Binding Capacity (TIBC) Tests

a. Outpatient Screening/Case-Finding
   i. The serum iron and total iron binding capacity (TIBC) tests are not indicated in asymptomatic individuals whose history and physical examination findings are within reference limits for age and sex.
   ii. In individuals with a moderate to high pretest probability of iron deficiency (e.g., pregnant women, premenopausal female with hemorrhagia, premature infants, and the malnourished) a serum iron and TIBC may be useful.
   iii. Measurement of serum iron and TIBC may be useful in screening for iron overload.

b. Diagnosis
   i. Measurement of serum iron and TIBC are useful in patients whose complete blood count results are consistent with a microcytic hypochromic anemia.
      - Calculation of transferrin saturation from the serum iron and TIBC may provide additional diagnostic information.
   ii. Patients who present with clinical features of iron deficiency may benefit from measurement of serum iron and TIBC tests.
   iii. Serum iron and TIBC measurements may be useful in the differential diagnosis of microcytic hypochromic anemias.
   iv. Measurement of serum iron and TIBC may be useful in the confirmation of iron overload.

c. Monitoring
   i. Measurement of serum iron and TIBC have limited value in monitoring the management of patients with iron deficiency anemia.
      - A complete blood count (CBC) and an absolute reticulocyte count are useful tests to monitor the management of iron-deficiency anemia.

4.2.24 Rating: Established
Evidence: Class I, II, III
Consensus Level: I

25. Guidelines for Ordering a Fecal Occult Blood Test
   a. Outpatient Screening/Case-Finding
      i. Screening with fecal occult blood tests is not indicated for asymptomatic patients under 40 years of age.
      ii. For persons 40 years and older who have familial polyposis coli, inflammatory bowel disease, or a history of colon cancer in a first-degree relative, screening with fecal occult blood tests is recommended annually.
         - Due to the nature of gastrointestinal bleeding, it is recommended that three consecutive samples be obtained.
         - Screening for colorectal cancer with air-contrast barium enema or colonoscopy in addition to annual fecal occult blood tests is recommended every 3 to 5 years.
      iii. Screening with fecal occult blood tests is recommended annually for persons 50 years of age and older.
         - Every 3 to 5 years, in addition to the annual fecal occult blood test, a sigmoidoscopic examination should be performed.
   b. Diagnosis
      i. Patients with significant colorectal symptoms (abdominal pain, localized tenderness, diarrhea or constipation, gastrointestinal bleeding) should have a fecal occult blood test performed as part of a colorectal examination.
      ii. A fecal occult blood test result should be interpreted with caution.
         - The influence of diet and nutritional supplements (Vitamin C and iron) should be considered as possible causes of false-positive and false-negative results.
         - Further evaluation of patients with a positive occult blood test may include an air contrast barium enema plus colonoscopy.

4.2.25 Rating: Established
Evidence: Class II, III
Consensus Level: I

26. Guidelines for Ordering a Serum Ferritin Test
   a. Outpatient Screening/Case-Finding
      i. The serum ferritin test is not indicated in asymptomatic individuals whose history and physical examination findings are within reference limits for age and sex.
      ii. In individuals with a moderate to high pretest probability of iron deficiency and with CBC and serum iron/TIBC levels within reference ranges, the serum ferritin test may be useful in detecting the early stages of iron depletion.
   b. Diagnosis
      i. Measurement of serum ferritin is useful in anemic patients who are suspected of having iron depletion but have equivocal serum iron and TIBC test results.
      ii. Serum ferritin measurements may be useful in the differentiation of anemia of chronic disease from iron deficiency anemia.
         - A CRP determination should be performed along with serum ferritin to identify possible effects of chronic disease state on ferritin results.
      iii. Measurement of serum ferritin may be useful in the detection of iron overload.
   c. Monitoring
      i. Serum ferritin measurement may be useful in the determination of the end-point to oral iron therapy.
      ii. Measurement of serum ferritin may be useful in monitoring iron status of patients with chronic renal disease.
      iii. Serum ferritin measurement may be useful in monitoring the rate of iron accumulation in iron overload.

4.2.26 Rating: Established
Evidence: Class I, II, III
Consensus Level: I

C. Investigational Clinical Laboratory Procedures

1. Analysis of Trace Minerals in Hair
   a. Outpatient Screening/Case Finding
      i. Hair analysis is not indicated for screening of nutritional status in asymptomatic individuals.
      ii. In specific subsets of the population who are at risk for nutritional imbalances, the use of hair analysis has not been found to be superior to traditional methods of assessing nutritional status.
   b. Diagnosis
      i. Hair analysis for trace minerals is not indicated in the determination of nutritional imbalances.
         - Measurement of some elements (e.g., iron) have not been found to be superior to traditional methods of assessment.

ii. Hair analysis suffers from many problems with interpretation of results
- Hair mineral content can be affected by shampoo, bleaches, hair dyes and other environmental factors.
- The level of certain minerals can be affected by color, diameter, rate of growth of an individual's hair and the season of the year.
- Most commercial hair analysis laboratories have not validated their analytical techniques.
- Reference ranges for hair minerals have not been adequately established.
- For most elements no correlation has been established between hair levels and other known indicators of nutritional status.

iii. Hair analysis may be useful in experimental studies of nutritional status.
- More human and animal studies are needed to validate this technique.

c. Monitoring

i. Repeat hair analysis for trace minerals is not indicated.

ii. The beneficial effects of nutritional therapy based on hair analysis have not been adequately documented.

4.3.1 Rating: Investigational
Evidence: Class I, II, III
Consensus Level: 1

2. Live Cell Analysis

a. Outpatient Screening/Case Finding

i. Live cell analysis is not indicated for screening health problems including nutritional imbalances in asymptomatic patients.

ii. In specific subsets of the population who are "at risk" for various health problems, the use of live cell analysis has not been found to be superior to traditional laboratory procedures utilized in case finding.

b. Diagnosis

i. Live cell analysis is not indicated in the determination of organ pathologies, infections, immune status or nutritional status.
- Blood indicators which live cell analysis claims are useful in diagnosing health problems have not been validated by adequate scientific studies

ii. Additional studies on the use of dark field microscopy for various diagnoses are needed.

c. Monitoring

i. Repeat live cell analysis for various health conditions is not indicated.

ii. The beneficial effects of patient care based on live cell analysis results have not been adequately documented.

4.3.2 Rating: Investigational
Evidence: Class III
Consensus Level: 1

3. Biochemical Biopsy: (Multiple Test Analysis Including Protein Electrophoresis and Isoenzyme Fractionation with Predictive Interpretation of Results)

Biochemical biopsy utilizes a comprehensive approach to laboratory testing where a multitest biochemical test profile is ordered along with isoenzyme fractionation of common enzymes and a serum protein electrophoresis. It may also include other serum protein analyses and complete blood count. The rationale behind the use of this approach is detection of early pathologies in the subclinical phase.

a. Outpatient Screening/Case Finding

i. Biochemical biopsy is not indicated for screening of health problems in asymptomatic patients.

ii. This approach has not met the criteria as an effective screening procedure. The biochemical biopsy may not be sensitive enough to detect early pathology and is indiscriminate as is currently applied to patients with health problems that don't fit the criteria for screening.
- This approach increases the probability of test results being outside the reference range and generates a significant number of false-positive results which leads the clinician to follow up on these laboratory abnormalities.

iii. Additional research is needed to determine the validity of this approach.

b. Diagnosis

i. The biochemical biopsy approach to testing is not useful for diagnosis of specific health problems and/or vague multisystem patient complaints.

ii. The role of the biochemical biopsy as an aid to diagnosis requires further scientific investigation.

c. Monitoring

i. Repeat determinations of the laboratory tests in the biochemical biopsy is not indicated.

ii. The beneficial effects of the biochemical biopsy approach to testing on patient management and health outcomes has not been documented.

4.3.3 Rating: Investigational
Evidence: Class I, II, III
Consensus Level: 1

4. Determination of "Optimal" Reference Values for Laboratory Tests without Following Acceptable Procedures for the Establishment of Reference Ranges.

a. Outpatient Screening/Case Finding

i. This approach to interpretation of lab reference values results is not recommended for screening and/or case findings in asymptomatic patients.

b. Diagnosis
   i. The optimal reference value approach to the interpretation of lab values is not useful in the diagnosis of specific health problems and nutritional imbalances because of its unusual way of determining reference ranges and because this approach does not take into consideration biological, analytical and statistical variations.
      - The reference ranges are determined by measurements performed on a large number of subjects and arbitrarily defined as the range encompassed by two standard deviations.
      - The distribution curve of test results is skewed rather than symmetric.
      - The population used to calculate reference ranges is not necessarily healthy.
   ii. Further research is necessary to determine the validity of this approach to the establishment of laboratory reference ranges.

c. Monitoring
   i. Utilizing the optimal value approach to laboratory interpretation is not useful in monitoring changes in patients' health status.

4.3.4 Rating: Investigational
Evidence: Class I, II, III
Consensus Level: 1

D. Inappropriate Clinical Laboratory Procedures

1. Cytotoxic Testing for Food Allergies
   a. Based on the data derived from controlled investigations, there is poor test reliability.
   b. This test has not been shown to produce results that can be consistently correlated with other examination findings.
   c. This test lacks an acceptable scientific rationale, lacks sensitivity and specificity and lacks evidence of clinical effectiveness.

4.4.1 Rating: Inappropriate
Evidence: Class I, II, III
Consensus Level: 1

2. Reams Testing and Interpretation of Urine
   a. There is no clinical or scientific evidence for the use of this procedure in chiropractic or other related health science literature.
   b. This test has not been shown to produce results that can be consistently correlated with examination findings.
   c. This test lacks an acceptable scientific rationale, lacks sensitivity and specificity and lacks evidence of clinical effectiveness.

4.4.2 Rating: Inappropriate
Evidence: Class III
Consensus Level: 1

VII. COMMENTS, SUMMARY OR CONCLUSION

This chapter attempts to provide a conceptual model for the appropriate use of clinical laboratory test in chiropractic practice. The application of this model takes place with the development of clinical practice guidelines which are explicit yet clinically adaptable.

The true test of the effectiveness of these guidelines will come with their ability to be implemented and cause a positive effect to occur on health practices and patient outcomes.

Finally, the recommendations suggested here must be subject to periodic review and revision.

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IX. MINORITY OPINIONS

None.

X. APPENDIX

A. Useful Guidelines for Clinical Laboratory Investigation of Spinal Disorders

1. Positive Health History for:
   - Previous malignancy
   - Striking weight loss
   - Persistent pain, more than 30 years old
   - Use of corticosteroids
   - Drug or alcohol abuse
2. Positive Clinical Examination for:
   - Systemic signs (i.e., fever)
3. Radiographic findings suggestive of pathology
4. Failure to improve with conservative care

(See Chapter 8, Frequency of Care)

B. Laboratory Procedures Which May Be Useful for Spinal Disorders

Cause/Dysfunction		Tests
Mechanical	Compression fracture	Serum alkaline phosphatase, Total protein, Albumin, Serum total calcium, Inorganic PO4
Inflammatory	Infective: TB of the spine	ESR or CRP CBC, Urine and sputum cultures
	Other infectious agents	ESR or CRP CBC Blood culture Agglutination titers
	Noninfective rheumatoid arthritis	ESR, CRP, Serum viscosity Rheumatoid factor (anti-IgG)
	Ankylosing spondylitis	ESR or CRP CBC, Alkaline phosphatase; HLA-B27
Metabolic	Nutritional Osteoporosis	Alkaline phosphatase, Calcium, Inorganic PO4, Total protein, Albumin, BUN, Creatinine, sTSH or FT4
	Osteomalacia	CBC, BUN, Creatinine, Calcium, Inorganic PO4,

		Alkaline phosphatase, Total protein, Albumin, Vitamin D assay
	Endocrine: Adrenal	Serum electrolytes, Urinary free cortisol
	Parathyroid	Calcium, Inorganic PO4, Ionized calcium, PtH assay, Alkaline phosphatase, Serum chloride (Cl/PO4 ratio)
Other	Paget's disease	Alkaline phosphatase, Calcium, Inorganic PO4, Urinary hydroxproline
Neoplastic	Multiple myeloma	Total protein, Albumin, CBC, Serum protein electrophoresis, Urinary protein electrophoresis, Uric acid, BUN, Creatinine, Immunoelectro-phoresis, Urinary light chain typing
	Metastatic tumors	Alkaline phosphatase Calcium, Inorganic PO4, Uric acid, Acid phosphatase, Prostate specific antigen (PSA), LDH, Serum protein electrophoresis, ESR or CRP
	Primary tumors	Same as metastatic tumors
Visceral Referred Pain	Myocardial infarction	Total CK, CK and LD isoenzymes
	Posterior peptic ulcer	CBC BUN Stool Occult blood test
	Acute pancreatitis	Glucose Calcium Serum and urine amylase Serum lipase Serum trypain
	Chronic pancreatitis	Glucose Serum amylase Serum lipase Stool fat Serum bilirubin Lunch test meal
	Carcinoma of the pancreas	Glucose AST Alkaline phosphatase T. bilirubin GGT Tumor marker assays ESR
	Cholecystitis	CBC T. bilirubin AST Alkaline phosphatase Serum amylase
	Pyelonephritis	Urinalysis Urine culture Colony count BUN and creatinine CBC ESR

C. Examples of Focused Organ/Health Problem Profiles

Utilization of these procedures requires clinical judgment and appropriateness.

Multisystem Involvement with Vague and Unexplained Physical Changes

- Serum Alkaline Phosphatase
- Serum LDH
- Serum Total Bilirubin
- CBC
- Serum Urea Nitrogen
- Serum HDL
- Serum AST
- sTSH or Free T4 Index
- Urinalysis
- Serum Creatinine
- Serum Calcium
- Serum Glucose
- Serum Inorganic Phosphorous
- Serum Cholesterol
- Serum Total Protein
- Serum Uric Acid
- Serum Albumin
- Serum Triglycerides

Urinary Tract Involvement

- Serum Urea Nitrogen
- Serum Creatinine
- Serum Uric Acid
- Routine Urinalysis
- Urine Culture and Colony Count

Hyperlipidemia and Lipid Transport Disorders

Serum Cholesterol	Serum LDL
Serum Triglycerides	Plasma Glucose
Serum HDL Cholesterol	Serum Uric Acid

Thyroid Involvement

T4	Thyroid Autoantibodies
Free T4 Index	(Anti-thyroglobulin antibody)
T3	(Anti-microsomal antibody)
sTSH	

Joint and Connective Tissue Involvement

ANA	RA Factor
ASO-T	Serum Uric Acid
CRP and/or ESR	CBC

Hepato-Biliary Involvement

Serum Alkaline Phosphatase	Serum ALT
Serum Total Bilirubin	Serum GGT
Serum Cholesterol	Serum Albumin
Serum LDH	Serum Protein Electrophoresis
Serum AST	

Anemia

CBC	Direct Coombs (Antiglobulin)
Reticulocyte Count	Serum B-12
Serum Iron	Serum Ferritin
Serum Iron Binding Capacity (IBC)	Hemoglobin Electrophoresis
RBC Folate	

Pregnancy

CBC	Indirect Coombs (Antiglobulin)
Blood Group (ABO)	Rubella
Blood Type (RH)	VDRL (RPR)

Hypertension

Serum Urea Nitrogen	Metanephrines 24-hour Urine
Serum Creatinine	Urinalysis
Serum Electrolytes	Urinary Free Cortisol
Plasma Aldosterone	
Cardiac Involvement (Chest Pain)	
Serum CK	Serum CK Isoenzymes
Serum LDH	Serum LDH Isoenzymes

Metabolic Bone Involvement

Serum Total Protein	Serum Calcium
Serum Albumin	Serum Phosphorus
Serum Alkaline Phosphatase	Urinary Hydroxyproline

Skeletal Muscle

Serum CPK	Serum Calcium
Serum Aldolase	Electrolytes
Urine Myoglobin	

Pancreatic Involvement

Serum Amylase	Serum Calcium
Urinary Amylase	Serum Creatinine
Serum Lipase	Serum Trypsin

5

Record Keeping and Patient Consents

"If it isn't written down, it doesn't exist."
—Anonymous and Ubiquitous

Chapter Outline

I. OVERVIEW

The health care record serves many important functions and is one of the critical components of the health care delivery system. The most important function is in the immediate care and treatment of the patient. The record also permits different members of a health care team, or successive health care providers, to have access to relevant data concerning the patient to see what procedures have been performed and with what results. The health care record is important for documenting the specific services received by the patient so that the provider can be reimbursed for them. Records should be maintained in a manner that makes them suitable for utilization review. The health record is helpful in the evaluation of practitioners, provides data for public health purposes, and may be used for the purpose of teaching and research. It is critical in a variety of legal contexts, including litigation by patients and malpractice claims.

Construction of an adequate patient chart involves the accumulation of essential information from the patient by interview, use of questionnaires, examination and special studies. There should also be transfer of pertinent information where available from previous or other care given to the patient. This chapter describes the documents, internal and external, that are used to arrive at a diagnosis, to determine and document necessity of care, and to provide a foundation for the chiropractic treatment plan. The chapter also discusses appropriate patient consents and other legal disclosures.

Once the initial patient work-up has been completed, all record/chart entries should be made in a systematic, organized and contemporaneous manner. Recommendations on what constitutes necessary information to be contained in the day-to-day patient record are offered. The information contained in such records provides a foundation for writing accurate reports to other health care providers, insurance companies, attorneys and other interested parties. The practitioner is encouraged to use a charting system that is effective and complete, yet practical and efficient.

The organization of the patient chart may be enhanced by using preprinted forms and by having proper identifying information on each page. Minimum recommendations for legibility and clarity of chart entries are offered. The importance of confidentiality and professional courtesy with respect to patient records is emphasized and guidelines are offered.

Patient consent may be implied or expressed, depending upon the circumstances. Where it is expressed, it may be obtained either verbally or in writing. Often the process is facilitated by the use of preprinted forms completed and signed by involved parties then kept as part of the health record as evidence of the consent process. The practitioner is encouraged to consult with legal counsel for proper document design and application. Less common forms of consent are diagnosis waiver and consent to participate in research.

II. DEFINITIONS

A. General Definitions

Chart Notes: General term indicating notes made on the patient's work chart.

Health Record: All documents and recorded information relating to the clinical management of a patient.

Peer Review: Evaluation by peers or colleagues of the quality, quantity, and efficiency of services ordered or performed by a practitioner.

POMR - Problem Oriented Medical Records.

Progress Notes: Generally brief notations recorded in the patient's file for each office visit once management has commenced.

SOAP: Acronym for Subjective symptoms, Objective signs, Assessment and Plan.

SORE: Acronym for Subjective, Objective, Rx (treatment) and Exercise (ergonomics).

Work Chart: The form that the practitioner and/or staff uses to record patient's chart notes.

B. Legal Definitions

Consent to Treatment: Permission to treat from the patient or, where the patient is a minor or otherwise without legal capacity to consent, from the patient's guardian. Valid consent must be voluntary, informed, and related to a specific act or set of acts. It may be oral or written if expressly given, or may be implied.

Consent to Participate in Research: As above, but with the additional requirement that the subject has adequate information regarding the research and the power of free choice to participate in the research or decline participation.

Rule of Confidentiality: The rule which requires that all information about a patient that is gathered by a practitioner as part of the provider/patient relationship be kept confidential unless its release is authorized by the patient or, in exceptional circumstances, serves some other overriding purpose.

III. LIST OF SUBTOPICS

A. Internal Documentation

- Patient file
- Doctor/clinic identification
- Misc. assessment & outcome instruments
- Clinical impression

- Patient identification
- Patient demographics
- Health care coverage
- Patient history
- Examination findings
- Special studies
- Treatment plan
- Chart/progress notes
- Re-examination/ reassessment
- Financial records
- Internal memoranda

B. External Documentation

- Direct correspondence
- Health records
- Diagnostic imaging
- External reports

C. Chart/File Organization

- General considerations
- Use of pre-printed forms
- Legibility and clarity
- Use of abbreviations/ symbols

D. Maintenance of Records

- Confidentiality
- Records retention
- Administrative records
- Records transfer
- Clinic staff responsibilities

E. Patient Consents

- Informed consent
- Consent to treat minor child
- Authorization to release patient information
- Financial assignments
- Consent to participate in research
- Publication/photo/ video consent
- Authority to admit observers

IV. LITERATURE REVIEW

The literature search for this topic was accomplished through the use of CLIBCON indexing, referencing subject headings pertinent to the scope of the chapter. Other information was obtained through retrieval from personal libraries of committee members and advisors, especially with respect to recently published papers and monographs.

Much of the published literature on health record documentation and patient consents is either found in guidebooks, usually with significant contribution from the legal profession, or in popular publications containing sections dedicated to legal advice. Since 1979 there has been little information published on these topics in the chiropractic peer reviewed journals. A notable exception is the *Journal of the Canadian Chiropractic Association* which is refereed but also serves as an important conduit of such information to association members.

In the general chiropractic literature, there are notable bound publications that have contributed to the knowledge-base. In 1973 Simmons[46] prepared a concise guide to assist the practitioner in maintaining daily records and recording elements of case history and consultation. Schafer[41,43] published procedural manuals through the American Chiropractic Association which underscored the importance of documenting necessity of chiropractic care through adequate record-keeping and the support of chiropractic paraprofessionals. In a publication of the International Chiropractors' Association Kranz[22] provides guidance for the practitioner in the hospital environment. There have been two recent publications promoting malpractice prevention or risk management strategies for practitioners. Campbell, Ladenheim, Sherman and Sportelli [5] identify many pitfalls of lax patient chart management and failure to obtain patient consents, and offer recommendations that can be implemented in office management systems. Harrison[18] crisply identifies shortcomings of patient records and the risks in the context of malpractice claims.

The Canadians lead the way in publishing contemporary articles in the chiropractic refereed journals relative to risk management, charting procedures and report writing. Authors such as Carey,[6] Cassidy,[7] Gotlib,[12,13] Nixdorf,[31] Vear and Vernon have contributed material that assists practitioners in management of patient records and obtaining appropriate consents. Elsewhere Reinke and Jahn[38] provide pointed commentary correlating the importance of the patient's health record and the practitioner's "legal well-being." Other direction has been offered by Turnbull[47] from New Zealand and Gledhill.[11] Bolton[4] adds to the published knowledge base on informed consent. Nyiendo and Haldeman[32] have analysed practice activities of student interns in a chiropractic college teaching clinic and summarize the need for standardized accountability in patient care.

Recently many monographs have been establishing guidelines for the management of chiropractic cases. These include a surge in efforts to publish standards of care in a number of state and provincial jurisdictions. Within these are position statements or "standards" on obtaining and documenting clinical information. Practitioners in Connecticut[36] were among the first to provide practice guidelines, noting that there must be adequate documentation of the necessity for chiropractic care. They established recommended formats for interval reporting. The workers' compensation guidelines produced by the Washington State Chiropractic Advisory Committee[18] adapted an outline proposed earlier by Vear, Haldeman and West citing six primary case management objectives supported by "standards." Vear[48] has subsequently republished these objectives and standards in a major text. Efforts by Olson,[34] LaBrot,[23] and state chiropractic organizations in Ohio,[33] Michigan[26] and Minnesota[27] have all produced practice guidelines that emphasize the need for better standards in record keeping. Similar efforts are underway in Or-

egon, Quebec, Manitoba, Oklahoma, Texas, South Carolina and other jurisdictions.

Chiropractic professional liability carriers have contributed to the information pool with monographs that are a part of their risk management program. Both the OUM Group and the National Chiropractic Mutual Insurance Company (NCMIC) have produced many articles through newsletters and booklets.[4-6, 42]

Chiropractic popular publications produced by the national and state associations periodically give guidance on efficient record keeping, risk management[4-6, 19-21] and report writing.[4-6, 7] Other popular publications that contribute articles include *The American Chiropractor*,[33] *Today's Chiropractic*,[28] *Digest of Chiropractic Economics*[4-6, 1-3] and *Dynamic Chiropractic*. Chiropractic specialty councils have contributed white papers[4-6, 14] on essential elements of the patient's case file, report composition and clinical workup. Popular publications outside the chiropractic field also contribute valuable knowledge that can be used in the development of guidelines.[4-6, 37, 40]

Probably the richest technical source of information relative to documentation and patient consents is found in legal publications.[4-6, 10, 13] The legal standard found in these publications is supported with citation of case law. Publications such as this are not easily accessed by the average practitioner in the field, nor are they available in all chiropractic college libraries. The profession must rely on its legal consultants to assist in review of such literature. Fortunately, publications such as *Legal Update* (formerly *Chiropractic Amicus*) edited by Ladenheim et al., and the *Chiropractic Report* edited by Chapman-Smith have emerged to fulfill this role and assist practitioners to understand legal ramifications of health care practice.

V. ASSESSMENT CRITERIA

Procedure Ratings (System II)

Necessary: Strong positive recommendation based on Class I evidence, or overwhelming Class II evidence when circumstances reflect compromise of patient safety.

Recommended: Positive recommendation based on consensus Class II and/or strong Class III evidence.

Discretionary: Positive recommendation based on strong consensus of Class III evidence.

Unnecessary: Negative recommendation based on inconclusive or conflicting Class II and Class III evidence.

Quality of Evidence

The following categories of evidence are used to support the ratings.

Class I:

A. Evidence of clinical utility from controlled studies published in refereed journals.

B. Binding or strongly persuasive legal authority such as legislation or case law.

Class II:

A. Evidence of clinical utility from the significant results of uncontrolled studies in refereed journals.

B. Evidence provided by recommendations from published expert legal opinion or persuasive case law.

Class III:

A. Evidence of clinical utility provided by opinions of experts, anecdote and/or by convention.

B. Expert legal opinion.

VI. RECOMMENDATIONS

Disclaimer — These guidelines may necessarily be superceded by statutory law in respective state or provincial jurisdictions. They do not purport to convey legal advice. It is recommended that each practitioner should obtain his/her own independent legal advice.

A. Internal Documentation

(Records generated within the chiropractor's office.)

1. The Patient File

When a new patient enters the office, a file is created which becomes the foundation of the patient's permanent record. Adequate systems may include personal patient data (e.g., name, address, phone numbers, age, sex, occupation); insurance and billing information; appropriate assignments and consent forms; case history; examination findings; imaging and laboratory findings; diagnosis; work chart for recording ongoing patient data obtained on each visit; the service rendered; health care plan; copies of insurance billings; reports; correspondence; case identification (e.g., by number) for easy storage and retrieval of patient's documents, etc.

5.1.1 **Rating:** Necessary
Evidence: Class I, II, III
Consensus Level: I

A folder is used to house most of the patient's records. This may also be part of the record, if the practitioner writes patient data on the folder, such as patient personal information or x-ray/examination/treatment plan data. The practitioner may attach a patient work chart to the inside of the folder along with the other items in the patient's file. On periodic file review, outdated portions may be removed and stored in an archive

file. A permanent note should be kept in the active file indicating that the patient has additional records.

5.1.2 Rating: Recommended
Evidence: Class II, III
Consensus Level: 1

2. Doctor/Clinic Identification

Basic information identifying the practitioner or facility should appear on documents used to establish the doctor-patient relationship. This can be preprinted on forms, affixed by rubber stamp or adhesive labels or typed or handwritten in ink. Basic information should include:

- practitioner's name/specialty
- specialty designation (if applicable)
- facility name (if different)
- legal trade name (if applicable)
- street address and mailing address (if different)
- telephone number(s)

5.1.3 Rating: Necessary
Evidence: Class I, II, III
Consensus Level: 1

3. Patient Identification

Clear identification of the patient with relevant demographic information (see item #4 below) is a necessary component of the chart. This information can be obtained with ease by using preprinted forms for completion by the patient. Identifying information may include:

- case/file number (if applicable)
- name (prior/other names)
- birthdate, age
- name of consenting parent or guardian (if patient is a minor or incapacitated)
- copy letter of guardianship (where appropriate)
- address(es)
- telephone number(s)
- social security number (if applicable)
- radiograph/lab identification (if applicable)
- contact in case of emergency (closest relationship name/phone number)

5.1.4 Rating: Necessary
Evidence: Class I, II, III
Consensus Level: 1

4. Patient Demographics

- sex (M or F)
- occupation (special skills)

5.1.5 Rating: Necessary
Evidence: Class I, II, III
Consensus Level: 1

- marital status
- race
- number of dependents
- employer, address, phone number
- spouse's occupation

5.1.6 Rating: Discretionary
Evidence: Class I, II, III
Consensus Level: 1

5. Health Care Coverage

Health care coverage information is important for the business function of a health care facility, and such records are a part of the health care record. However, the information obtained and the format used are at the discretion of the practitioner.

- current incident result of accident or injury?
- insurance company or responsible party (auto/work comp/health/other)
- group and policy numbers, effective date
- spouse's insurance company and policy information (if applicable)

5.1.7 Rating: Discretionary
Evidence: Class III
Consensus Level: 1

6. Patient History

(See Chapter 1 of this document)

This is the foundation of the clinical database for each patient. The practitioner may choose to enter this data on a formatted or unformatted page. There should be an adequate picture of the patient's subjective perception of the history. Important elements of the history may include:

- date history taken
- present complaint/chief complaint
- description of accident/injurious event or other etiology
- past history, family history, social history (work history and recreational interests, hobbies as appropriate)
- review of systems (as appropriate)
- past and present medical/chiropractic treatment and attempts at self-care
- signature or initials of person eliciting history

5.1.8 Rating: Necessary
Evidence: Class I, II, III
Consensus Level: 1

When possible, history questionnaires, drawings and other information personally completed by the patient should be included in the initial documentation.

5.1.9 Rating: Recommended
Evidence: I, II, III
Consensus Level: 1

7. Examination Findings
(See Chapters 1, 3, & 4)

Objective information relative to the patient's history is obtained by physical assessment/examination of the area of complaint and related areas and/or systems. Gathering and recording this information may be facilitated by use of preprinted and formatted examination forms. If abbreviations are used, a legend should be available. Such documentation should include the date of the examination and name or initials of the examining practitioner. If persons other than the primary examining practitioner perform and/or record elements of the objective examination, their names and/or initials should appear on the exam/data form. Such evaluations may include:

- vital signs
- physical examination
- neuromusculoskeletal examination
- instrumentation
- other chiropractic examination procedures

5.1.10 Rating: Necessary
Evidence: Class I, II, III
Consensus Level: 1

8. Findings of Special Studies
(See Chapters 2, 3, & 4)

Documented results of special studies become a component part of the contemporaneous file. This documentation should include date of study, facility where performed, name of technician, name of interpreting practitioner, and relevant findings. Special studies ordered by practitioner may include:

- diagnostic imaging (e.g., plain film radiography; tomography or computed tomography; magnetic resonance imaging; diagnostic ultrasound; radionuclide bone scan)
- neurophysiologic/ electrodiagnostic testing (e.g., nerve conduction velocities; electromyography; somatosensory evoked responses)
- other laboratory tests

5.1.11 Rating: Recommended
Evidence: Class I, II, III
Consensus Level: 1

9. Miscellaneous Assessment and Outcome Instruments
(See Chapters 3 & 10)

Various assessment and outcome instruments can contribute to clinical management and become part of the case record. Many of these instruments are used in a repeated or serial fashion, which makes it essential for the record to identify the date(s) of completion and name(s) of scoring practitioner/ technician. Measurement instruments currently in use include:

- visual analog scale
- pain diagrams
- pain questionnaires (e.g., McGill)
- pain disability instruments (e.g., Oswestry, Neck Disability Index)
- health status indices (e.g., SF-36, Sickness Impact Profile)
- patient satisfaction indices
- other outcome measures

5.1.12 Rating: Recommended
Evidence: Class I, II, III
Consensus Level: 1

10. Clinical Impression
(See Chapters 6, 9, & 12)

Upon completion of the subjective and objective data base, the practitioner formulates a clinical impression or diagnosis. This may be preliminary only, and may comprise more than one diagnosis. This clinical impression should be recorded within the file or in the contemporaneous visit record. As the clinical impression may change with new clinical information or in response to treatment, it is important that each clinical impression be dated. The record may include:

- primary, secondary and/or tertiary elements of diagnosis
- appropriate diagnostic coding (e.g., ICD-CM)

5.1.13 Rating: Necessary
Evidence: Class I, II, III
Consensus Level: 1

11. Treatment Plan
(See Chapters 6, 7, 8, 9 & 12)

This arises from the accumulation of clinical data and the formulation of the initial clinical impression. The plan may include further diagnostic work to monitor progress, or a therapeutic trial to test clinical impressions and assess appropriateness of treatment procedures selected. The treatment plan documents the approach to management by the practitioner and staff (e.g., spinal adjusting, therapy modalities, recommended exercise regime, lifestyle and dietary modifications). Any plan for referral to or consultation with other health care providers is appropriately listed in the record. The written treatment plan may appear on a form dedicated to the clinical work-up, or in the contemporaneous visit record, and may include:

- diagnostic/reassessment plan
- practitioner's treatment plan (modes and frequency of care)
- patient's education and self-care plan
- intra- or interdisciplinary referral or consultation

5.1.14 Rating: Recommended
Evidence: Class I, II, III
Consensus Level: 1

12. Chart/Progress Notes

Once the initial patient work-up has been completed, all record entries should be made in a systematic organized manner.

5.1.15 Rating: Necessary
Evidence: Class I, II, III
Consensus Level: 1

Clinical Information. The patient's records must be sufficiently complete to provide reasonable information requested by a subsequent health care provider, insurance company, and/or attorney (e.g., progress notes, SOAP notes, SORE notes). A dated record of what occurred on each visit, and any significant changes in the clinical picture or assessment or treatment plan need to be noted. The method in which chart notes are recorded is a matter of preference for each practitioner.

5.1.16 Rating: Necessary
Evidence: Class I, II, III
Consensus Level: 1

There are many different adjusting/manipulation/manual techniques. It is important to record what area was adjusted/manipulated/treated and the procedure used.

5.1.17 Rating: Necessary
Evidence: Class II, III
Consensus Level: 1

Anyone other than the attending practitioner who enters data into the contemporaneous chart must initial the entry.

5.1.18 Rating: Necessary
Evidence: Class I, II, III
Consensus Level: 1

13. Re-examination/Reassessment:
(See Chapter 9)
All relevant information from every reassesament and re-examination must be recorded in the patient file.

5.1.19 Rating: Necessary
Evidence: Class I, II, III
Consensus Level: 1

14. Financial Records
Financial records are important for the business function of a health care facility, and such data are part of the health care record:

- patient account ledgers
- billing statements
- explanation of benefits (EOB) from payers, proof of payment

5.1.20 Rating: Necessary
Evidence: Class I, III
Consensus Level: 1

The precise information obtained and the means of storage and retrieval are at the discretion of the chiropractor.

5.1.21 Rating: Discretionary
Evidence: Class III
Consensus Level: 1

15. Internal Memoranda Regarding Patient

- patient sign-in sheets
- staff messages (intra-office)
- phone messages and summaries/transcription of phone conversations

5.1.22 Rating: Discretionary
Evidence: Class I, III
Consensus Level: 1

B. External Documentation

External documentation includes all records arising from outside the practitioner's office, but also includes any communication with third parties.

1. Direct Correspondence
Correspondence in the form of letters or memoranda that leave the office should have information identifying the practitioner and/or clinic, address, and telephone number and be contemporaneouly dated. A copy must always be kept on file.

- introductory letter(s) to or from referring practitioner (DC, MD, etc.)
- general correspondence to or from other practitioners
- general correspondence to or from attorney(s)
- general correspondence to or from patient
- general correspondence to or from various payer groups

5.2.1 Rating: Recommended
Evidence: Class II, III
Consensus Level: 1

2. Health Records

- pertinent copies of health records from previous or concurrent health care providers
- special consultative reports
- reports of special diagnostic studies

5.2.2 Rating: Recommended
Evidence: Class II, III
Consensus Level: 1

3. Diagnostic Imaging
(See Chapter 2)

- When indicated, a reasonable attempt should be made to obtain recent x-rays (or copies) relevant to the presenting problem of the patient, and summarize and record pertinent information.
- Copies of external radiology reports.

5.2.3 Rating: Recommended
Evidence: Class II, III
Consensus Level: 1

4. External Reports

Frequently a practitioner will be required to write various reports. The information for these reports comes from patient records. Adequate reporting usually requires the practitioner to review the patient's history, examination findings, diagnosis, treatment procedures, progress notes/work chart and other reports that may have been written together with records from other health care providers that have treated or evaluated the patient. There are many types of reports that serve various needs. There are many acceptable styles and formats.

5.2.4 Rating: Recommended
Evidence: Class II, III
Consensus Level: 1

C. Chart/File Organization

1. General Considerations

Records should be kept in chronological order and entered as contemporaneously as possible. They should not be backdated or altered. Corrections or additions should be dated and initialled. The chart or file should be fully documented and contain all relevant, objective information; extraneous information should not be included. The record must be complete enough to provide the practitioner with information required for subsequent patient care or reporting to outside parties.

5.3.1 Rating: Necessary
Evidence: Class I, II, III
Consensus Level: 1

2. Use of Pre-printed Forms

The use of forms can assist in tasks such as obtaining case history, noting examination findings and charting case progress. Use of forms is at the discretion of the individual practitioner but should favor comprehensiveness and completeness rather than brevity.

5.3.2 Rating: Discretionary
Evidence: Class II, III
Consensus Level: 1

3. Legibility and Clarity

Health records should be neat, organized and complete. Entries in charts should be written legibly in ink. Entries must not be erased or altered with correction fluid (whiteout) or tape or adhesive labels, etc. If the contents of any document are changed, the practitioner should initial and date such changes in the corresponding margin.

5.3.3 Rating: Necessary
Evidence: Class I, II
Consensus Level: 1

4. Use of Abbreviations/Symbols

Use of abbreviations or coding can save record space and time. A legend of the codes or abbreviations should appear on the form or be available in the office in order that another practitioner or interested person can interpret and use the information. The legend can also be used for intra-office communications and as a dictation aid.

5.3.4 Rating: Recommended
Evidence: Class II, III
Consensus Level: 1

D. Maintenance of Records

1. Confidentiality

The rule of confidentiality requires that all information about a patient gathered by a practitioner as any part of the doctor-patient relationship be kept confidential unless its release is authorized by the patient or is compelled by law. The rule is an ethical responsibility as well as a legal one. Assurance of confidentiality is necessary if individuals are to be open and forthright with the practitioner. Patients rightly expect that such information as their health will remain private and secure from public scrutiny. Thus the principle that all doctor-patient communications are privileged and confidential.

5.4.1 Rating: Necessary
Evidence: Class I, II
Consensus Level: 1

2. Records Retention and Retrieval

Health records should be retained, and in a way that facilitates retrieval. To the extent possible, they should be kept in a centralized location. In most circumstances, recent records are maintained on premises either as hard copy or electronically, and after a period of time can be archived, microfilmed or microfiched and placed in storage. The length of time that records, in whatever form, must be kept varies. Many states/provinces have legislated minimum periods of time for retention of health records, usually between five to fifteen years. When the decision is made to dispose of health records, the manner of disposal must protect patient confidentiality. If a chiropractic office closes or changes ownership, secure retention of the health care record must be ensured.

5.4.2 Rating: Necessary
Evidence: Class I, II
Consensus Level: 1

Even when legal time limits have elapsed, it is advisable to continue to retain records because of the valuable information they contain.

5.4.3 Rating: Discretionary
Evidence: Class III
Consensus Level: 1

3. Administrative Records

Administrative records are primarily those relating to the non-clinical side of practice, but there is some overlap into the doctor/patient relationship. Examples of administrative records may include: telephone logs, schedule and record of

appointments, patient personal data information, insurance forms and billing, collection and patient billing, routine correspondence, a record filing system that makes for accurate retrieval of patient data. These records must be maintained in a legible and retrievable format.

5.4.4 Rating: Necessary
Evidence: Class I, II, III
Consensus Level: 1

4. Records Transfer

It is mandatory that health care data (excluding data and reports from outside sources) requested by another provider currently treating a present or former patient be forwarded upon receipt of an appropriate request and patient consent. In some jurisdictions, this duty to forward information to another treating health professional is imposed by statute also. However, even in the absence of a statutory requirement a practitioner has a responsibility to comply with such a request, and as expeditiously as possible.

5.4.5 Rating: Necessary
Evidence: Class I, II, III
Consensus Level: 1

5. Clinic Staff Responsibilities

The practitioner is responsible for staff actions regarding record keeping and consent forms, and for assuring that administrative tasks are handled correctly and promptly. Any employee involved in the preparation, organization, or filing of records should fully understand professional and legal requirements, including the rules of confidentiality.

5.4.6 Rating: Necessary
Evidence: Class I, II, III
Consensus Level: 1

E. Patient Consents

1. Informed Consent/Consent to Treatment - Generally (See also Chapter 12)

Patient consent to treatment is always necessary. It is often implied rather than expressed. However, where there is risk of significant harm from the treatment proposed, this risk must be disclosed, understood, and accepted by the patient. Such informed consent is required for ethical and legal reasons. The best record of consent is one that is objectively documented (e.g., a witnessed written consent or videotape).

5.5.1 Rating: Necessary
Evidence: Class I, II, III
Consensus Level: 1

2. Consent to Treatment - Competence

A patient must be competent to give consent to treatment. The treatment of minors (age of majority varies from 14 to 21 according to jurisdiction) and mentally incompetent adults requires the prior consent of a guardian in most circumstances.

5.5.2 Rating: Necessary
Evidence: I, II, III
Consensus Level: 1

3. Authorization to Release Patient Information

With the consent of a competent patient or guardian, records may, and in most situations must, be provided to third parties with a legitimate need for access. The patient consent should not be more than 90 days old, or as provided by law. Whenever health care information is released pursuant to authorization from a patient, documentation of the authorization should be requested and retained (except in some emergencies). If the request is for all or part of the health care record, the original record should never be released, unless compelled by law, only copies. Before the copy chart or other records are sent out, they should be reviewed to make certain they are complete.

5.5.3 Rating: Necessary
Evidence: Class I, II, III
Consensus Level: 1

4. Financial Assignments

While financial data is important for the business function of a health care facility, and such records are indeed part of the health care record, the information obtained and the method of acquiring such information is at the discretion of the practitioner. Any alteration of standard fees charged necessitates documentation (e.g. in cases of financial hardship).

5.5.4 Rating: Discretionary
Evidence: Class III
Consensus Level: 1

5. Consent to Participate in Research

When a practitioner engages in research, the ethical basis of the doctor-patient relationship changes to an investigator-subject interaction. The new relationship must meet a new set of criteria different from clinical practice.

If a patient is requested to participate in a research study or project the request must be accompanied by informed consent that meets the minimum request for the protection of human subjects as established by competent authorities (e.g., NIH/NSF or state/provincial law).

5.5.5 Rating: Necessary
Evidence: Class I, II, III
Consensus Level: 1

6. Publication/Photo/Video Consent

All records from which a patient may be identified (e.g., photographs, videotapes, audiotapes) should only be created once consent has been obtained. Such consents should identify the purposes of the record and the circumstances under which it will be released.

a. records for clinical management

5.5.6 Rating: Recommended
Evidence: Class I, II III
Consensus Level: 1

b. records for all other purposes (e.g., research, training, distribution)

5.5.7 Rating: Necessary
Evidence: Class I, II, III
Consensus Level: 1

7. Authority to Admit Observers

Persons not participating in the treatment of the patient should not be permitted to watch examinations or procedures without authorization from the patient. This principle is subject to some exceptions where the patient is a minor.

5.5.8 Rating: Necessary
Evidence: Class I, II, III
Consensus Level: 1

VII. COMMENTS, SUMMARY OR CONCLUSION

This chapter presents guidelines for the chiropractic profession in North America with regard to creation and maintenance of a patient chart/file. It is suggested in chiropractic literature [38] that the development of keener clinical awareness and improved patient care are the most important reasons to maintain competent records. Fundamental training of the practitioner in charting skills exists in the educational process, but reinforcement of the need for quality records must come through published literature, postgraduate seminars and risk management efforts.

However, there are additional administrative requirements in health care practice that underline the necessity for sound records maintenance. Today there is a heightened awareness of the need for good records because of accountability of all practitioners in managed care, intraprofessional peer review, and interactive claims management used by public and private sector purchasers. This rapid expansion of clinician accountability underscores the need for mature systems, and dissemination of information on recordkeeping throughout the chiropractic profession. It will be important for the sponsoring organizations of this consensus meeting on standards of practice to take the lead in the dissemination process.

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IX. MINORITY OPINIONS

None

6

Clinical Impression

Chapter Outline

I. OVERVIEW

This chapter will consider the use of the concepts of a "clinical impression," "diagnosis," and "analysis" in the practice of chiropractic.

The concept of diagnosis has been a matter of significant historical debate. The application of diagnosis in chiropractic practice, the perspective of the practitioner relative to diagnosis, and the diagnostic responsibility of the practitioner have varied with respect to state laws, board regulations, and court rulings.

While the exact language may vary, it is clear, however, that the practitioner is dealing with the process of conveying the salient findings of his or her examination relative to the patient in question. The consequence of the diagnosis, clinical impression, or analysis impacts directly on the management of the patient.

Guidelines for quality assurance and standards of practice are expressed and understood within historical, legal and professional perspectives of the profession. In addition, standards must be developed to reflect the advancement in the quality of chiropractic care, the protection of the patient and the continuing process of assessment of effectiveness.

II. DEFINITIONS

Diagnosis: A decision regarding the nature of the patient's complaint; the art or act of identifying a disease or condition from its signs and symptoms.

Clinical Impression: A working hypothesis formulated from significant items in the history and the physical findings; a tentative diagnosis; or a working diagnosis.

Differential Diagnosis: The determination of which one of two or more complaints or conditions a patient is suffering from by systematically comparing and contrasting their clinical findings.

Analysis: The act of separating into component parts the clinical evaluation of a condition or disease in order to identify the clinical impression or determine the diagnosis.

Utility: Significant benefit to both the patient and clinician resulting from a reduction in uncertainty of the diagnosis, clinical impression, or analysis.

Portal of Entry: First level of contact with and intake into the health delivery system.

III. LIST OF SUBTOPICS

A. Necessity
B. Initial Responsibility
C. Subsequent Responsibility
D. Terminology
E. Content
F. Process
G. Dynamics
H. Communication

IV. LITERATURE REVIEW

Information regarding the evolution of concepts of diagnosis, clinical impression, or analysis has been available from the writings of early chiropractic pioneers [Palmer, D.D.,[2] Palmer, B.J.,[3] Firth[4]] through to current chiropractic experts.[1,5-13] It has also been described in a legislative framework.[22-30]

Chiropractic Analysis

The concept of chiropractic analysis as something unique and distinct from a diagnosis was expressed as early as 1910 by Palmer[2] and 1916 by Firth.[4] The term has continued to be used in this way by various members of the profession.[7,31] The commonality in its use is based on the concept that structure, primarily the spine, affects function.[1,4,5,6,7,9]

Chiropractic analysis can also be viewed in more general terms as the process of reaching a clinical impression or diagnosis. This incorporates the complete art of clinical decision-making.[1,34]

Diagnosis

Like chiropractic analysis, the term diagnosis has been defined in differing ways in chiropractic practice. As with many practitioners today, D.D. Palmer accepted the importance and necessity of making a diagnosis. His definition of diagnosis was not so dissimilar to that presented above, namely, "determining the character of disease; also the decision arrived at, is diagnosis."[32]

In earlier years, when legislation was not enacted, members of the chiropractic profession were accused of practicing medicine without a license when they treated patients after arriving at a diagnosis. Thus "diagnosis" was replaced with the term "analysis." This alteration may have been made for the following reasons: 1) to avoid prosecution; and 2) to make chiropractic a separate and distinct profession with no allegiance to medicine.[16]

As a portal of entry provider, the chiropractic practitioner is charged with certain responsibilities, legal and professional, and possesses certain rights and privileges shared by all doctors. The courts have not concerned themselves with which words a practitioner elects to use to describe a diagnostic situation but rather have strived to protect the public.[34,35] Therefore, the issue of diagnosis, clinical impression, or analysis is

paramount for the reason that it is necessary prior to the implementation of an appropriate plan of care.

The purpose of a diagnosis as described in legislative acts, government commission hearings and the literature is twofold: 1) to identify the problem to determine if it is amenable to chiropractic care, and 2) to determine if the patient should be referred. [1,13,18,20,21,24,39]

The process of arriving at a diagnosis depends upon logic and reasoning,[1,14] and includes the evaluation of information obtained from the interview, examination and diagnostic procedures. The methods used in the gathering and analysis of information are beyond the scope of this review but can be found in many sources among them are Jamison[1] and Weinstein and Fineberg.[37] (See also Chapter 5 of these guidelines.) This culminates in a clinical decision making process from which a diagnosis, clinical impression, or analysis is made concerning the disease or condition affecting the patient. Gitelman presents the concept of a double diagnosis. This double diagnosis takes into consideration firstly the articular dysfunction, secondly its influence upon the patient's general well-being and broader symptom complex.[15,30]

Regardless of the variety of views, the state of the art with respect to diagnosis is that which is currently described in the literature. This includes case reports published in reputable scientific journals, as an avenue by which chiropractic establishes the spectrum of conditions that its members are responsible for diagnosing.[32]

In perusing the standardized channels of literature review for the application of the concepts of diagnosis, it is important to note that case studies abound in chiropractic literature. In JMPT alone, over the last 14 years there have been 90 case reports. Although subluxation is mentioned in some of those reports as a portion of the diagnosis, additional diagnoses are used to describe the patients or conditions.

The significance of diagnostic responsibility is emphasized in statements contained within the Clinical Quality Assurance Guidelines of the CCE,[19] the Policy Guidelines of the International Chiropractors' Association,[40] the Consensus Report of the American Chiropractic Association Council on Technique[22] and the guidelines of the Canadian Chiropractic Protective Association, an agency of the Canadian Chiropractic Association.[35]

Application of Diagnostic or Analytical Concepts

Williams,[11] Slosberg,[10] Winterstein,[12] and Masarsky and Weber[38] have all attempted to address the question of the role of diagnosis from the point of view of the practicing chiropractor. Harrison[27] and Sportelli, et. al.,[28] have addressed the issue from the perspective of legal necessity as a component of legal defense. Herfert[39] has addressed the question from the perspective of the relationship with third party payers.

It is clear that all of these authors advocate acceptance of the diagnostic responsibility of the chiropractic profession. The concern remains for the appropriate use of language and the context of a diagnostic statement. Choice of language — diagnosis, clinical impression, analyses or assessment — reflects the clinician's philosophical constructs. There is, however, uniformity regarding the need for appropriate, responsible steps to be taken on the patients' behalf, regardless of the paradigm, to establish the clinical findings of each individual practitioner. It is the right of the patient to receive an appropriate evaluation and statement of their problem as a prerequisite for delivery of care.

The ethical, moral, legal and professional responsibility of a chiropractic practitioner does not change with the terminology used to express his or her clinical findings. The practitioner is required to assess the patient on presentation and respond to the clinical situation in a manner consistent with the best interests of the patient and the practitioner's clinical judgment.

V. ASSESSMENT CRITERIA

Procedure Ratings (System II)

Necessary: Strong positive recommendations based on Class I evidence, or overwhelming Class II evidence when circumstances reflect compromise of patient safety.

Recommended: Positive recommendation, based on consensus Class II and/or strong Class III evidence.

Discretionary: Positive recommendation, based on consensus of Class III evidence.

Unnecessary: Negative recommendation, based on inconclusive or conflicting Class II, III evidence.

Quality of Evidence

The following categories of evidence are used to support the ratings:

Class I:

A. Evidence of clinical utility from controlled studies published in refereed journals.
B. Binding or strongly persuasive legal authority such as legislation or case law.

Class II:

A. Evidence of clinical utility from the significant results of uncontrolled studies in refereed journals.
B. Evidence provided by recommendations from published expert legal opinion or persuasive case law.

Class III:

A. Evidence of clinical utility provided by opinions of experts, anecdote and/or convention.
B. Expert legal opinion.

VI. RECOMMENDATIONS

A. Necessity

Arrival at a clinical impression or diagnosis, or diagnostic conclusion or analysis, is a necessary outcome of the patient encounter.

Comment: The responsibility of a chiropractic practitioner does not change with the terminology used to describe clinical findings. The practitioner is required to assess the patient upon presentation and respond to the clinical situation in a manner consistent with the best interests of the patient, the practitioner's clinical judgment, and the law of the jurisdiction in question.

6.1.1 **Rating:** Necessary
Evidence: Class I, II, III
Consensus Level: 1

B. Initial Responsibility

The initial level of responsibility of the practitioner involves the immediate discernment as to the nature and status of the patient on initial presentation. A practitioner should be expected to recognize and respond to life-threatening situations in a manner consistent with the patient's best interest.

6.2.1 **Rating:** Necessary
Evidence: Class I, II, III
Consensus Level: 1

C. Subsequent Responsibility

After the initial evaluation has been completed the practitioner begins a series of differentiations that result in many clinical decisions being implemented. This process is not an end in itself, but merely designates suspected conditions that become the focus for prognostic judgments, further assessment and patient management. Initiation of chiropractic care, additional studies, referral with or without continuing chiropractic care and cessation of chiropractic care are possible.

6.3.1 **Rating:** Necessary
Evidence: Class I, II, III
Consensus Level: 1

D. Terminology

The terminology utilized to describe a clinical impression, diagnosis, diagnostic conclusion, or analysis should be consistent with appropriate usage in chiropractic (e.g., subluxation complex/fixation/misalignment) and related health care communities. If a practitioner is required to use specific terminology, or is prohibited from the use of such terminology by law, then that legal requirement is the guiding factor.

6.4.1 **Rating:** Recommended
Evidence: Class II, III
Consensus Level: 1

E. Content

1. Patients may have various conditions/symptoms/findings that result in a number of unrelated clinical impressions. The primary clinical impression, diagnosis, diagnostic conclusion, or analysis should address the chief complaint expressed by the patient. Secondary diagnoses should be prioritized and addressed as needed and may be of greater clinical consequence to the patient.

6.5.1 **Rating:** Recommended
Evidence: Class II, III
Consensus Level: 1

2. The clinical impression, diagnosis, diagnostic conclusion, or analysis should reflect a classification scheme that consists of statements reflective of severity, region, and organ/tissue involvement.

6.5.2 **Rating:** Recommended
Evidence: Class II, III
Consensus Level: 1

3. The clinical impression, diagnosis, diagnostic conclusion or analysis should be related to the subjective and/or objective findings of the patient, and be consistent with evidence-based criteria.

6.5.3 **Rating:** Established
Evidence: Class I, II, III
Consensus Level: 1

F. Process

1. When additional confirmatory tests are required to establish the clinical impression, diagnosis, diagnostic conclusion, or analysis it is the practitioner's responsibility to ensure that these studies are completed in as timely and efficient a manner as possible. Practitioners may perform such procedures consistent with their qualifications and the law, or they may seek to have such procedures performed by other qualified parties.

6.6.1 **Rating:** Necessary
Evidence: Class I, II, III
Consensus Level: 1

2. Where procedures relevant to a diagnosis, clinical impression, diagnostic conclusion, or analysis are not within the qualifications or competence of a practitioner, the practitioner should make appropriate consultations with others.

6.6.2 **Rating:** Recommended
Evidence: Class II, III
Consensus Level: 1

3. The clinical impression, diagnosis, diagnostic conclusion, or analysis should be recorded in the patient's record and qualified as to its certainty.

6.6.3 Rating: Necessary
Evidence: Class I, II, III
Consensus Level: 1

G. Dynamics

The clinical impression, diagnosis, diagnostic conclusion, or analysis should be a working hypothesis that may change over time, given additional information and/or changes in the condition of the patient.

6.7.1 Rating: Necessary
Evidence: Class I, II, III
Consensus Level: 1

H. Communication

The practitioner should communicate the diagnosis or clinical impression or diagnostic conclusion or analysis, and its significance, to the patient in understandable terms, and convey such findings to other providers or agencies as the patient requests and consents to, or as the law requires.

6.8.1 Rating: Necessary
Evidence: Class I, II, III
Consensus Level: 1

VII. COMMENTS, SUMMARY OR CONCLUSION

None.

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IX. MINORITY OPINIONS

None.

7

Modes of Care

Chapter Outline

I. OVERVIEW

This chapter provides a generic topical summary of typical chiropractic procedures in current use. Most chiropractic named technique procedures consist of a combination of various analytic and treatment components. This chapter does not serve to review and pass judgment on any particular named technique system as a whole. Rather, generic procedures are presented and ratings are made based on current available information and expert opinion. Clinical practice and scientific investigation are ongoing processes and it is understood that this document is a dynamic entity that will require modification as new knowledge becomes available.

Although this chapter does not include every possible chiropractic technique or procedure, an overall categorization of chiropractic approaches is presented. Chiropractic procedures are categorized according to the Bartol algorithm that has been recommended by the American Chiropractic Association's Council on Technique and has been adopted as a template for consensus development by the Consortium for Chiropractic Research. In addition, a more elaborate classification system is presented here for the non-manual chiropractic procedures.

II. DEFINITIONS

A. Chiropractic Adjustment

Chiropractic Adjustment: This term refers to a wide variety of manual and mechanical interventions that may be high or low velocity; short or long lever; high or low amplitude; with or without recoil. Procedures are usually directed at specific joints or anatomic regions. An adjustment may or may not involve the cavitation or gapping of a joint (opening of a joint within its paraphysiologic zone usually producing a characteristic audible "click" or "pop"). The common denominator for the various adjustive interventions is the concept of removing structural dysfunctions of joints and muscles that are associated with neurologic alterations. The chiropractic profession refers to this concept as a "subluxation." This use of the word subluxation should not be confused with the term's precise anatomic usage which considers only the anatomical relationships.

B. Manipulation and Mobilization

During joint motion, three barriers or end ranges to movement can be identified. The first is the active end range which occurs when the patient has maximally contracted muscles controlling a joint in a particular directional vector. At this point, the clinician can passively move the joint toward a second barrier called the passive end range. Movement up to this barrier is termed physiologic joint space. Beyond this point, the practitioner can move the joint into its paraphysiologic space. The third barrier encountered is the anatomic end range. Movement beyond this will result in rupture of the joint's ligaments.

Manipulation: Passive movement of short amplitude and high-velocity which moves the joint into the paraphysiologic range. This is accompanied by cavitation or gapping of the joint which results in an intrasynovial vacuum phenomenon thought to involve gas separating from fluid. Usually accompanied by an audible pop or click, manipulation has been shown to result in increased joint motion compared to mobilization alone. This increase in motion lasts for a 20-30 minute refractory period during which an additional cavitation of the same joint will not occur. Manipulation is a passive dynamic thrust that causes cavitation and attempts to increase the manipulated joint's range of motion.

Mobilization: Passive movement within the physiologic joint space administered by a clinician for the purpose of increasing overall range of joint motion.

C. Descriptors of Adjustment, Manipulation, Mobilization

Amplitude: Amplitude refers to the depth of, or distance traveled by, the practitioner's thrust. Most adjustment/manipulation is of low amplitude, minimizing total force applied to the patient. When placing a joint in position prior to treatment the practitioner pre-stresses the joint in the appropriate direction to take up soft-tissue slack (joint play). When joints are less accessible and/or involve a longer lever contact, or when inadequate pre-stress is obtained, amplitude will necessarily increase.

Dynamic Thrust (Thrust): The therapeutic force or maneuver delivered by the practitioner during manipulation and most adjustment techniques. It is typically a high-velocity, low-amplitude movement applied to a joint when all joint play has been passively removed. It may be applied with follow through, which means that the end amplitude of the thrust is briefly maintained, or it may be applied with recoil. This means that once the end amplitude is reached the thrust is immediately withdrawn. There are low-velocity thrust techniques, but all thrusts involve some element of rapid acceleration.

Force: The product of the amplitude and velocity applied during a thrust. An adjustment or manipulation may be very fast (high velocity) but of extremely low-amplitude, and in these circumstances the force will be relatively low.

Joint Play (Accessory Movement): The small, precise joint movements, not under the control of the voluntary muscles or patient, that are necessary to permit normal voluntary joint movement. Joint play may include spin, glide and roll of the articulation. The full range of active movement of a

joint without practitioner assistance is a combination of voluntary movement (voluntary muscles) and joint play.

Lever: During manual joint manipulation there are a variety of mechanical factors considered including the practitioner's contact points, stabilization points, fulcrums of movement, specific features of the joint to be manipulated, particular vectors, etc. Depending on which joint or motion segment is addressed, the stabilization and contact points selected, and a patient's position, biomechanical leverage considerations can become quite complex. For the sake of simplification and communication, descriptors of leverage can be defined as follows.

Long-lever Contacts: those in which joints and structures not primarily involved in the procedure are positioned between the practitioner's contact point and the adjusted or manipulated joint. For example, an adjustment of the right sacroiliac (SI) joint with a contact on the ischium is considered short-lever because there are no articulations between the contact point and the SI joint. However, an adjustment of the L5/S1 facet using the same contact is long-lever because the SI joint is located between the contact and the L5/S1 facet joint.

Short-lever Contacts: those which involve contacts and stabilizations on osseous structures directly involved in the joint being manipulated.

Line of Drive (Vector): The direction of thrust, usually described in terms of the three cardinal planes of skeletal motion: 1. Flexion/Extension, 2. Right/Left Rotation, 3. Right/Left Lateral Flexion. As manipulation of a joint may be both difficult and uncomfortable when a joint is in a compressed or close-packed position, nearly all adjustive or manipulative maneuvers include axial distraction as part of the pre-stress. For this reason, this vector is usually omitted but implied in descriptions of thrust.

Pre-Stress: The process in which, prior to manipulation, a joint is moved passively to its end range, controlling joint play. The joint is near the limit of its passive end range.

Velocity (Acceleration): The speed with which a thrust is delivered. This term is strictly incorrect because a thrust does not maintain a constant velocity but rather changes speed constantly. However, thrusts are commonly described as "high-velocity" or "low-velocity" and these relative terms are useful.

D. Soft Tissue Procedures

There are a variety of techniques for manual soft tissue procedures, some unique to chiropractic practitioners. As muscles and non-contractile structures lose function and elasticity, they have an effect on joint function. Most soft tissues are richly innervated with a variety of proprioceptive mechanisms, and often chiropractic application of soft tissue procedures will follow a traditional chiropractic rationale of attempting to improve a clinically identifiable aberrant neurologic reflex or pain pattern. Such work may be used in conjunction with other adjustive or manipulative approaches. Some chiropractors use a variety of soft tissue procedures for non-articular purposes as well. For example, abdominal pressure points may be stimulated in a constipated patient.

E. Descriptors of Some Common Soft Tissue Procedures

Contract-Relax: Application of a combination of active and passive muscle tightening and stretching.

Ischemic Compression (Acupressure, Shiatzu, Myotherapy): Application of a progressively increasing pressure on a pressure point, trigger point, or tight muscle. This typically reduces the point's tenderness and produces a flushing and a relaxation of tightness.

Massage: Application of pressure to a tight muscle in an attempt to relax it. Similar procedures may be used in other soft tissues. There are many specific procedures such as effluerage, petrissage, cross-friction, and J-stroking, along with certain techniques that may be used.

Passive Stretch (Spray and Stretch): Application of a lengthening force along a muscle by passive movement of the associated joint(s). Sometimes used with a distractor such as a coolant spray or ice prior to applying the stretch.

F. Neuromusculoskeletal Conditions:

For the purposes of this document, conditions which display symptoms and/or signs related to two or more of the nervous, muscular and skeletal body systems. Such conditions may be contrasted with those which produce advanced pathologic states (e.g., neurofibromatosis). Neuromusculoskeletal conditions are sometimes referred to as "type M disorders," and distinguished from "type O disorders," which refer to internal organ disorders.

III. LIST OF SUBTOPICS

A. Manual, Articular Manipulative and Adjustive Procedures
   1. Specific Contact Thrust Procedures
   2. Nonspecific Contact Thrust Procedures
   3. Manual Force, Mechanically Assisted Procedures
   4. Mechanical Force, Manually Assisted Procedures

B. Manual, Nonarticular Manipulative and Adjustive Procedures
   1. Manual Reflex and Muscle Relaxation Procedures
   2. Miscellaneous Procedures

C. Nonmanual Procedures
   1. Exercise and Rehabilitation
   2. Education Procedures
   3. Electrical Modalities
   4. Thermal Modalities
   5. Ultraviolet
   6. Ultrasound and Phonophoresis
   7. Bracing, Casts, and Supports
   8. Traction

D. Special Interest Areas
   1. Manipulation under Sedation/Anesthesia
   2. Acupuncture
   3. Homeopathic Remedies

IV. LITERATURE REVIEW

Specific literature on named chiropractic techniques has traditionally been proprietary and procedurally oriented. In addition, it has rarely been peer reviewed or indexed, which makes access difficult. This problem has been addressed in recent years by the chiropractic profession primarily through three vehicles.

Firstly, the *Journal of Chiropractic Technique* was established to provide a forum for articles relevant to chiropractic procedures. Secondly, a number of discussions, position papers and round tables have been sponsored by professional associations. The Consortium for Chiropractic Research, in collaboration with the Council on Technique and others, held a series of consensus conferences attended by technique teachers, academicians, chiropractic researchers, and private practitioners. See, for example, the proceedings of the 1990 Seattle Consensus Conference (Bergman 1990). Thirdly, a sophisticated standards of care project has been undertaken jointly by the RAND Corporation, the Consortium for Chiropractic Research, and the Foundation for Chiropractic Education and Research (Shekelle, et al., 1991a, Shekelle et al., 1991b).

These efforts have resulted in a number of helpful developments. At the state level, one of the first methodical publications attempting to describe chiropractic management in some detail was a set of standards of practice guidelines developed in Washington (Hansen, 1988). This provides a variety of recommended guidelines and practices for the delivery of chiropractic care in the management of industrial injuries in Washington state. Of particular note are the definitions regarding types of care, abstracts of literature relevant to manipulation, and clinical practice objectives.

Kaminski (1987) proposed an algorithm for the classification of chiropractic procedures, using the classifications "fully accepted," "provisionally accepted" and "unsubstantiated." This algorithm provides general guidelines for the review of procedures based on the reasonableness of the models, utility in practice and scientific investigation. This algorithm was adopted at subsequent consensus conferences and, in modified form, serves as the template for the rating of techniques in this chapter.

The organizational scheme for the classification of chiropractic techniques that is used here is based on Bartol's model (1991a, 1991b), which has been adopted by the ACA Council on Technique. The classification for nonmanual chiropractic approaches is expanded. There are some differences in specific categorization methods as well.

The reader is directed to Greenman (1989), Cox (1990), White & Anderson (1991), Schafer (1984), Haldeman (1992), and Grieve (1989) for in-depth discussions of particular manipulative approaches and more comprehensive references. With respect to information on ancillary procedures, Schafer (1984) provides a review of protocols adopted by the American Chiropractic Association.

Manipulative and adjustive procedures are currently in growing and widespread use, with the chiropractic profession having the most comprehensive training and practice in this field. Manipulative care has been shown to have value for a variety of ailments, but studies of patients seeking chiropractic care suggest that painful conditions of the spine and extremities are by far the leading symptoms presented (Nyiendo, 1989, Phillips, in press). Exact mechanisms of action in spinal adjustment and manipulation remain uncertain but result in mechanical, neurological, trophic and psychosocial effects (Mootz, 1992, Stonebrink, 1990).

There are over 30 randomized trials in the literature comparing manipulation and mobilization to other forms of treatment for low-back pain (Shekelle, et al. 1991a, Anderson, et al., 1992). The majority show manipulation to be more effective than the many interventions to which it has been compared. A few of the studies found no significant differences. In no studies has manipulation been shown to be less effective than other comparison approaches or a control group. There have also been a small number of trials on manipulation for other musculoskeletal conditions such as headache, neck pain, and thoracic pain, which have shown promising outcomes (Parker, 1978, see review by Meeker, 1990). The recent recommendations of the North American Spine Society's Ad Hoc Committee on Diagnostic and Therapeutic Procedures has rated chiropractic adjustment as an established procedure for mechanical low back pain (NASS, 1991).

Some studies have demonstrated the utility of thoracic manipulation in relieving pain associated with angina pectoris (Rogers, 1976, Rinzler, 1948, see review by Mootz, 1992). However, it was not clear whether patients had true angina or suffered from a referred costo-thoracic syndrome that mimicked the pain of angina. There are published case studies suggesting successful management of enuresis with spinal adjustment. However, a recent study, which confirmed some positive response rate, did not find a success rate that matched other behavioral medicine regimens (Leboeuf, 1991).

Another comparative study evaluated chiropractic dynamic thrust adjustment with typical medical management of asthma patients (Bronfort, 1989). This study, which employed a crossover design, showed that patients in both treatment groups obtained a beneficial initial response. However, long-

term success rates were better in the medically managed group, even after crossover into the alternative treatment group.

There is evidence that adjustment stimulates certain metabolic activity within some types of white blood cells (Brennen, 1990). There is also preliminary evidence suggesting a relationship between adjustment and serum beta-endorphin levels and other circulating pituitary hormones (Vernon, 1989). A randomized controlled study on a small number of patients with elevated blood pressure demonstrated a significant reduction in posttreatment blood pressure for subjects adjusted in the thoracic spine employing an Activator adjusting instrument (Yates, 1988).

There is a paucity of information in the literature comparing one manual approach to another. Even in the area of low-back pain, where there are now over thirty trials, only a few authors have clearly defined the specific manipulative intervention employed. Usually it is unclear whether adjustment, manipulation, mobilization or a combination of these has been used. Hence it is beyond the scope of this chapter, and capabilities of the contributors, to consider individual conditions and interventions and exact appropriateness. Rather, procedures are presented on a basis of generic categorizations, with discussion regarding utility for specific conditions only where this is possible and appropriate.

The exact number of named chiropractic techniques is thought to be about 200. However, there is a great deal of overlap, and a number of techniques involve only minor modifications of others. Additionally, many named techniques have both analytical and therapeutic components. Only the treatment portions of technique procedures are presented here. Analysis and other diagnostic considerations are discussed in other chapters (see History and Physical Examination, Diagnostic Imaging, Clinical Laboratory, Clinical Impression, Frequency of Care, and Outcomes Assessment).

Exercise has been the subject of a number of clinical trials and was recently the subject of meta-analysis which showed most exercise regimens to be far less consistent in beneficial effects than studies on manipulation (Koes, et al., 1991; Anderson, 1992). However, many exercise and education protocols are in widespread use and considered standard approaches within the medical community (White and Anderson, 1991, Mayer and Gatchell, 1987). Physiotherapeutic modalities are relatively standardized (Schaefer, 1984, Stonebrink, 1990) and are generally used as ancillary procedures in chiropractic practice.

Manipulation under anesthesia or sedation (MUA) has been traditionally performed by allopathic and osteopathic practitioners. With inclusion in hospitals in recent years, some chiropractic practitioners are now trained to perform these procedures in the hospital setting. There is one randomized controlled trial (Siehl, 1971) and at least six clinical reports (Francis, 1989; Krumhansl, 1986; Morey, 1976; Morey, 1973; Rumney, 1968; Siehl, 1963) in the literature describing the results of MUA and suggesting it can be an effective procedure upon carefully selected patients. These patients usually have specific neuromusculoskeletal disorders and fail to respond to conservative treatments, including manipulation, in the hospital or office setting. Force required during MUA is usually less than during adjustment or manipulation without anesthesia. Both high-velocity and low-velocity maneuvers are used. There is, however, less patient feedback and control.

V. ASSESSMENT CRITERIA

Note: The Kaminski algorithm (1987) was proposed for the purpose of allowing technique developers and colleges to determine the current state of development of chiropractic procedures. Kaminski's categories have been revised and an expanded scale is used here to allow for greater consensus and expert input.

Procedure Ratings (System I)

Established: Accepted as appropriate by the practicing chiropractic community for the given indication in the specified patient population.

Promising: Given current knowledge, this appears to be appropriate for the given indication in the specified patient population. As more evidence and experience accumulates, this interim rating will change. This connotes provisional acceptance, but permits a greater role for the current level of clinical use.

Equivocal: Current knowledge exists to support a given indication in a specified patient population, though its value can neither be confirmed nor denied. As more evidence and experience accumulates this interim rating will change. Expert opinion recognizes a need for caution in general application.

Investigational: Evidence is insufficient to determine appropriateness. Further study is warranted. Use for a given indication in a specified patient population should be confined to research protocols. As more evidence and experience accumulates this interim rating will change.

Doubtful: Given current knowledge, this appears to be inappropriate for the given indication in the specified patient population. As more evidence and experience accumulates this interim rating will change.

Inappropriate: Regarded by the practicing chiropractic community as unacceptable for the given indication in a specified patient population.

Quality of Evidence:

The following categories of evidence are used to support the ratings.

Class I:

Evidence provided by one or more well-designed controlled clinical trials; or well-designed experimental studies that address reliability, validity, positive predictive value, discriminability, sensitivity, and specificity.

Class II:

Evidence provided by one or more well-designed uncontrolled, observational clinical studies, such as case-control, cohort studies, etc.; or clinically relevant basic science studies that address reliability, validity, positive predictive value, discriminability, sensitivity, and specificity; and published in refereed journals.

Class III:

Evidence provided by expert legal opinion, descriptive studies or case reports.

Suggested Strength of Recommendations Ratings

Type A. Strong positive recommendation. Based on Class I evidence or overwhelming Class II evidence when circumstances preclude randomized clinical trials.

Type B. Positive recommendation based on Class II evidence.

Type C. Positive recommendation based on strong consensus of Class III evidence.

Type D. Negative recommendation based on inconclusive or conflicting Class II evidence.

Type E. Negative recommendation based on evidence of ineffectiveness or lack of efficacy based on Class I or Class II evidence.

Safety and Effectiveness

Safety: a judgment of the acceptability of risk in a specified situation, e.g., for a given health problem, by a provider with specified training (at a specific stage of the disorder, etc.).

Effectiveness: producing a desired effect under conditions of actual use.

VI. RECOMMENDATIONS

A. Manual, Articular Manipulative and Adjustive Procedures

1. Specific Contact Thrust Procedures

a. High Velocity Thrust: High-velocity thrust procedures (also referred to as osseous adjusting procedures) are probably the most commonly recognized, most widely taught, and most widely used of the adjustive and manipulative techniques within the chiropractic profession.

7.1.1 Rating: Established for the care of patients with mechanical low-back problems.
Evidence: Class I, II, III
Consensus Level: 1

7.1.2 Rating: Established for the care of patients with many other neuromusculoskeletal problems.
Evidence: Class II, III
Consensus Level: 1

7.1.3 Rating: Equivocal for other purposes.
Evidence: Class II, III
Consensus Level: 1

Comments: These procedures must be considered in light of their intended application, types of patients and conditions independently managed, and the nature of the thrust.

b. High Velocity Thrust with Recoil: There is little evidence in the literature specifically evaluating the effectiveness of thrust with recoil as compared to non-recoil thrust. Although distinct in application due to the recoil, typical joint cavitation and movement occurs with this procedure as it does with dynamic thrust without recoil. It is reasonable to assume that similar physiologic responses occur with both forms of thrust. Although comparative trials are needed, this modification is not controversial and it is reasonable to assume that studies evaluating thrust with or without recoil would have similar outcomes.

7.1.4 Rating: Promising to established for the care of patients with neuromusculoskeletal problems.
Evidence: Class II, III
Consensus Level: 1

7.1.5 Rating: Equivocal for other purposes.
Evidence: Class II, III
Consensus Level: 1

Comments: These procedures must be considered in light of their intended application, types of patients and conditions independently managed, and the nature of the thrust.

c. Low-Velocity Thrust: Low-velocity thrust may or may not result in joint gapping, depending on degree of pre-stress and amplitude. In the absence of specific comparative studies on low-velocity thrust, it is reasonable that any low-velocity thrust that results in joint gap is likely to have effects similar to high velocity thrusts from a mechanical point of view. For low-velocity thrust that does not cause cavitation, the literature on mobilization is thought to be representative if substantial range of motion to joints and soft tissues is induced. Reflex and global (widespread) ef-

fects of such procedures have not been well studied and are addressed in the section on reflex procedures.

7.1.6 Rating: Equivocal to promising for the care of patients with neuromusculoskeletal problems.
Evidence: Class II, III
Consensus Level: 1

7.1.7 Rating: Investigational to equivocal for the care of patients with some organic conditions.
Evidence: Class II, III
Consensus Level: 1

Comments: These procedures must be considered in light of their intended application, types of patients and conditions independently managed, and the nature of the thrust.

2. Non-Specific Contact Thrust Procedures

Mobilization: Mobilization (passive movement through the physiologic joint range) does not exceed the passive end range and therefore involves no cavitation of the joint and hence is distinct from manipulation. The purpose of mobilization is to increase range of motion within a restricted joint. Much of the clinical outcome literature on mobilization is blended with the manipulation literature.

7.2.1 Rating: Established
Evidence: Class I, II, III
Consensus Level: 1

3. Manual Force, Mechanically Assisted Procedures

a. Drop Tables and Terminal Point Adjustive Thrust: This procedure is a dynamic thrust with or without recoil that is in widespread use within the profession. The thrust involves positioning and pre-stress of joints in similar and modified fashion to other dynamic thrust procedures but involves small translational movement of a section of the adjusting table beneath the patient and the segment to which the thrust is applied.

7.3.1 Rating: Promising to established for the care of patients with neuromusculoskeletal problems.
Evidence: Class III
Consensus Level: 1

7.3.2 Rating: Investigational to equivocal for other purposes.
Evidence: Class III, with probable applicability of Class II studies involving high velocity thrust without mechanical assistance.
Consensus Level: 3

Comments: These procedures must be considered in light of their intended application, types of patients and conditions independently managed, and the nature of the thrust.

b. Flexion-Distraction Tables: These devices allow for manually assisted mechanical distraction to be applied primarily to the lumbar and thoracic spine along with other ranges of motion. This approach of flexion-distraction is a standard, widely taught procedure. There is a great deal of supportable and reasonable mechanical and physiologic rationale in the literature for the appropriate use of these procedures for the care of patients with neuromusculoskeletal problems.

7.3.3 Rating: Established
Evidence: Class II, III
Consensus Level: 2

c. Pelvic Blocks: These paired wedges are used primarily for positioning the lumbosacral and sacroiliac joints to produce a sustained stretch. This procedure is in fairly common use, and there is reasonable rationale and expert opinion on its utility in certain situations.

7.3.4 Rating: Promising for the care of patients with neuromusculoskeletal problems.
Evidence: Class III
Consensus Level: 1

4. Mechanical Force, Manually Assisted Procedures

a. Fixed Stylus, Compression Wave Instruments: These devices are typically used in the upper cervical spine. A non-moving stylus is positioned against a pre-stressed motion segment. A moving piston strikes the stylus producing a compression wave along the stylus. It is speculated that a force is transmitted to the adjacent tissue and transmitted to the osseous and articular structures. With minimal tissue deformation and no amplitude change, the pliability and elasticity of the intermediate soft tissue is likely to absorb and disperse some or all of the force transmitted.

7.4.1 Rating: Equivocal
Evidence: Class III
Consensus Level: 1

Comments: Rationale for procedure is poorly substantiated and good efficacy studies are lacking. There are no direct safety concerns with proper application. These sorts of instruments suffer from the same limitations as low-force thrusts and will require significant investigation over time. Although use is not widespread, such instruments and protocols are taught in the curriculum of a few institutions and are not known to be restricted by regulatory agencies. There is clinical opinion and some case study information suggesting utility.

b. Moving Stylus Instruments: Spring loaded and piston activated adjusting instruments can be adjusted by amplitude, position and/or acceleration. One instrument known as an "Activator" has an adjustable amplitude with a spring loaded cocking mechanism that permits an adjustable range of reproducible accelerations. This instrument has been tested in animal models using pressure transducers and accelerometers and has demonstrated small but reproducible oscillation of bony vertebrae. Other devices employing similar

mechanisms (such as the Pettibon instrument) may have similar effects.

These instruments when applied by and for rationales similar to dynamic thrust are likely to produce effects similar to some low-amplitude manual thrusting or mobilization procedures. They are also likely to stimulate cutaneous nerve endings and produce reflex effects. However, more investigation is required regarding rationales for application for several of these instruments.

7.4.2 Rating: Promising to established.
Evidence: Class I, II, III
Consensus Level: 1

B. Manual, Nonarticular Manipulative and Adjustive Procedures

1. Manual Reflex and Muscle Relaxation Procedures

a. Muscle Energy Techniques: A variety of procedures fall under this classification including post-facilitation stretch, post-isometric relaxation, and reciprocal inhibition, among others. In addition, there are several chiropractic techniques that use procedures mechanically and physiologically similar to these as part of their therapeutic armamentarium. The rationale for such procedures is based on the concept of reciprocal innervation and inhibition between agonist and antagonist muscles. Treatment is directed at finding such sites and having the patient do movements and muscle contractions, typically against some kind of active resistance in order to cause a relaxation of a hypertonic muscle. These techniques are commonly in use and are the subject of much investigation.

7.5.1 Rating: Promising
Evidence: Class II, III
Consensus Level: 1

b. Neurologic Reflex Techniques: These are a variety of techniques that attempt to stimulate proprioceptive and other sensory nerve endings by application of light touch or sustained pressure on various soft tissue or bony structures.

7.5.2 Rating: Equivocal for muscle relaxation.
Evidence: Class III
Consensus Level: 1

7.5.3 Rating: Investigational for other purposes.
Evidence: Class III
Consensus Level: 1

Comments: There is evidence that demonstrates that mechanical stimulation may influence muscle relaxation, sudomotor activity, vasoconstriction/dilation, gastric secretions. Some practitioners use varieties of passive spring tension "plunger" devices for this purpose. Persuasive clinical studies only exist for somatic conditions. Procedures that result in only slight temporary soft tissue deformation or none at all (such as brief or sustained touch-like pressure to the skin) are not presently represented in the literature, and no well-articulated or substantiated physiologic rationales exist for effectiveness. These procedures would benefit from detailed investigation.

c. Myofascial Ischemic Compression Procedures: Ischemic compression involves placing a sustained compressive force on a tight or contracted muscle. This is thought to relax the muscle and thereby reduce stress to any joints to which the muscle is attached. The chiropractic profession has employed myofascial ischemic compression procedures and other soft tissue procedures as part of a care regimen for a long time (e.g., Receptor-tonus Technique, myofascial trigger point therapy).

7.5.4 Rating: Established for muscle relaxation.
Evidence: Class II, III
Consensus Level: 1

d. Miscellaneous Soft Tissue Techniques: There are many different kinds of muscle work in widespread use. They involve applying manual pressure in order to relieve muscle spasm. Some common techniques of muscle work include: massage (superficial, effleurage, petrissage, percussion), pressure point work (acupressure and shiatsu), and deep tissue techniques (Rolfing). There is little controversy regarding the clinical utility of such procedures for relaxation and uncomplicated musculoskeletal dysfunction. However, comparative clinical investigations are sparse. Light massage has occasionally been used as a placebo control in manipulation studies.

7.5.5 Rating: Established
Evidence: Class II, III
Consensus Level: 1

2. Miscellaneous Procedures

a. Neural Retraining Techniques: A variety of procedures aimed at developing neuromuscular coordination exist within the chiropractic profession. Such procedures constitute portions of some popular techniques. Primarily, these approaches involve repeated active movements under a variety of mechanical conditions in order to "pattern" the motor system for particular activities. There is rationale and support in the exercise physiology, kinesiology, and neurologic rehabilitation literature for many of these practices. There is overlap with other reflex procedures including muscle energy techniques. In terms of training for developing coordination and conditioning there is little controversy, due to the plausibility of rationale,

but a minimum of outcome investigations. Examples of these approaches include Janda, Feldenkrais, Alexander, cross crawl, etc.

7.6.1 Rating: Equivocal to promising in some conditioning and neuromuscular coordination contexts.
Evidence: Class II, III
Consensus Level: 1

7.6.2 Rating: Investigational for other purposes.
Evidence: Class II, III
Consensus Level: 1

Comment: There are proponents of other neural "organization" or "reeducation" procedures that claim a variety of clinical applications including the treatment of visceral, psychologic, and genetic conditions. There are poorly described rationales that may offer a starting point for model development, but no truly scholarly efforts are available to date. There is little or no literature available which documents effectiveness and such protocols are rarely taught as core material at accredited institutions. At best these procedures should be considered investigational, and, depending on the plausibility of certain applications, may be considered inappropriate to doubtful.

b. Conceptual Mind-Body Approaches: These approaches are based on the idea that mental thought (by the clinician) can influence physiological function of the patient. However, there is no information that suggests that a given doctor can directly influence a patient's physiology or disease process in specific situations. Although interesting, application to chiropractic care is speculative.

7.6.3 Rating: Inappropriate
Evidence: Class III
Consensus Level: 1

Comment: There is widespread acceptance of the importance of the doctor-patient relationship in the healing process. There is also burgeoning popular support for the mind-body relationship in the healing process. Facilitating this process in all types of therapeutic encounters is likely to be of benefit for patients' mental and social states. However, there is no justification for the substitution of metaphysical modalities for standard mechanical and chiropractic interventions. These issues are important fields in and of themselves (psychology, psychoneuroimmunology). It should be noted that one well-designed prospective, randomized, controlled trial of intercessory prayer on 393 hospitalized cardiac patients did demonstrate beneficial therapeutic effects (Byrd, 1988).

c. Surrogate Approaches: All chiropractic treatment approaches that utilize another person or a device as a mediator for receiving treatment on behalf of the patient have no defensible rationale or documentation of effectiveness and are therefore unacceptable in chiropractic practice.

7.6.4 Rating: Inappropriate
Evidence: Class III
Consensus Level: 1

C. Nonmanual Procedures

1. Exercise and Rehabilitation

a. Mobility and Stretching Exercise: Active mobility maintenance and stretching by the patient are traditionally encouraged in chiropractic practice. Training, counseling and advice in stretching and mobility exercises are common, and various descriptions of chiropractic programs exist in the literature. Trials on exercise in chiropractic settings have not been published, but there is function and performance information available in exercise physiology and sports medicine literature.

7.7.1 Rating: Promising to established.
Evidence: Class I, II, III
Consensus Level: 1

b. Strengthening, Conditioning and Rehabilitation: Active conditioning exercise is thought to be helpful for both healing and prevention of many mechanical back and neck problems. Conditioning and spinal stabilization programs are becoming more common for chiropractic management of low-back conditions. In addition, numerous programs are in place that involve job simulation and work hardening protocols that are directed at chiropractic management and conditioning for specific tasks.

7.7.2 Rating: Promising to established.
Evidence: Class I, II, III
Consensus Level: 1

c. Passive Stretch: Passive stretch is gentle sustained muscle lengthening applied by the practitioner or therapist. Its use is common within the chiropractic profession. There are a number of variations of application including several modalities to distract the patient from potential discomfort such as 1. cryotherapy (ice, coolant sprays, etc.) and 2. analgesic balms. These distractors are usually applied just before or simultaneous with the passive stretch and are for the purpose of distracting the patient from the possible discomfort of sustained stretch on the muscles and tissues. Practitioners, especially within the field of sports chiropractic, teach and use these procedures frequently.

7.7.3 Rating: Established
Evidence: Class I, II, III
Consensus Level: 1

2. Educational Programs

a. Back School/Spinal Care Courses: Knowledge about how to take care of one's health problems and how to modify behavior or lifestyle is likely to be beneficial for most patients. Back school programs and patient education have traditionally been an integral part of chiropractic case management. It is supportable when used as an appropriate teaching aid.

7.8.1 Rating: Promising to established.
Evidence: Class I, II, III
Consensus Level: 1

b. Wellness Care/Disease Prevention/Health Promotion: A relatively new area of interest in chiropractic as a distinct service, prevention has long been a primary consideration of the chiropractic profession's approach to health care. Typical disease prevention programs, smoking cessation, weight reduction efforts and the like fit well within chiropractic practice scopes. Organizations such as the American Chiropractic Association, International Chiropractors' Association and the Chiropractic Forum of the American Public Health Association have adopted policies or expressed support for such programs and practitioners with a particular expertise and interest in this area are increasing in number.

7.8.2 Rating: Promising to established.
Evidence: Class II, III
Consensus Level: 1

c. Nutritional Counselling: Nutritional training is included in the chiropractic curriculum. As a general issue concerning scope of practice, there is little disagreement regarding the capability or qualifications of practitioners to counsel patients concerning nutritional matters.

7.8.3 Rating: Established
Evidence: Class I, II, III
Consensus Level: 1

Comment: Specific nutritional therapy is an extensive field that requires a great deal of delineation. This should be addressed in the future.

d. Biofeedback: Some practitioners have begun to use biofeedback training as a means of teaching patients to control stress and other conditions. Its utility has been fairly well documented and its clinical application in chiropractic case management may be beneficial.

7.8.4 Rating: Promising to established.
Evidence: Class II, III
Consensus Level: 1

3. Electrical Modalities

Electrical modalities (e.g., muscle stimulating, electrochemical, electro-acupuncture) have long been a part of chiropractic education and they are specifically included in scope of practice regulations in most jurisdictions. Standard electrical modalities are often used as ancillary to chiropractic manual procedures, and although there has been historical and political controversy regarding the clinical utility of all physiotherapeutic modalities in chiropractic practice, their inclusion in chiropractic scope of practice is not a significant area of debate. Protocols are well delineated. Muscle stimulation, galvanic current, microcurrent, iontophoresis, and TENS among others are representative modalities within this grouping. There is good evidence that many of these procedures produce therapeutic changes in muscle tone. There is some conflicting evidence for the effectiveness of electroanalgesia. Iontophoresis of some compounds may be regulated specifically in some jurisdictions.

7.9.1 Rating: Promising to established.
Evidence: Class I, II, III
Consensus Level: 1

4. Thermal Modalities

These include cryotherapy, infrared, hydrotherapy, hydrocollator, diathermy and others. These are standard within the chiropractic scope of practice in most jurisdictions. Protocols are documented and standardized. Cooling modalities are well established in the control of inflammation whereas heating modalities tend to promote palliation and general relaxation.

7.10.1 Rating: Established
Evidence: Class I, II, III
Consensus Level: 1

5. Ultraviolet

Ultraviolet radiation is a conservative procedure used in the treatment of superficial cutaneous and mucosal conditions. It is typically included as a physiotherapeutic modality in most chiropractic jurisdictions.

7.11.1 Rating: Established
Evidence: Class II, III
Consensus Level: 1

6. Ultrasound and Phonophoresis

Ultrasound is thought to be beneficial in increasing metabolic activity through deep heating and micromassage. Standard ultrasound and phonophoresis are typically included as standard ancillary procedures in chiropractic care. However, limitations may exist regarding phonophoresis of regulated compounds. Protocols are documented and standardized but may vary between jurisdictions.

7.12.1 Rating: Established
Evidence: Class I, II, III
Consensus Level: 1

7. Bracing, Casting, and Supports

Supports, braces, casting, orthotics and the like are often useful components of chiropractic care. Practitioners are

trained for the application of many such appliances. However, more specialized training is required for scoliosis appliance prescription and other complex procedures.

7.13.1 Rating: Promising to established.
Evidence: Class II, III
Consensus Level: 2

8. Traction

Mechanical traction is frequently employed to stretch muscles, joints, and intervertebral discs. Its use is typically included in chiropractic education and is considered as a viable mechanical modality.

7.14.1 Rating: Promising to established.
Evidence: Class I, II, III
Consensus Level: 1

D. Special Interest Areas

1. Manipulation Under Sedation/Anesthesia (MUS/MUA)

Manipulation under sedation has been included in medical and osteopathic practice for some time. Chiropractic practitioners, because of their expertise in manual methods, have begun participating in the application of these procedures in the hospital setting in conjunction with anesthesiologists. These programs are subject to strict protocols as well as state and federal regulations.

7.15.1 Rating: Equivocal
Evidence: Class II, III
Consensus Level: 1

Comment: Although MUS/MUA is considered potentially useful, chiropractic involvement in such programs is a new area of special interest that requires further exploration.

2. Acupuncture

Acupuncture is a healing art that has been utilized for over 5,000 years. It is taught at some chiropractic colleges and is utilized by some practitioners. Its primary clinical use is for pain control.

7.16.1 Rating: Promising
Evidence: Class I, II, III
Consensus Level: 1

Comment: This is a complex field that warrants special training. A thorough discussion is beyond the scope of this document. Use may be regulated in some jurisdictions.

3. Homeopathic Remedies

Homeopathic remedies are thought to be of therapeutic value in some circumstances. Many homeopathic preparations are in use by some practitioners. Typically used for the relief of immediate symptoms and pain, homeopathic preparations are usually non-toxic to the patient and protocols for their usage are standardized and documented.

7.17.1 Rating: Equivocal
Evidence: Class II, III
Consensus Level: 1

Comment: This is a complex field that warrants special training. A thorough discussion is beyond the scope of this document. Use may be regulated in some jurisdictions.

VII. COMMENTS, SUMMARY OR CONCLUSIONS

Chiropractic modes of care encompass a wide variety of approaches. As chiropractic addresses health care from a perspective involving the role that body structure plays in overall physiologic function, many procedures emphasize manual care procedures such as adjusting, manipulation, soft tissue work, and physiotherapeutic modalities. However, the profession has traditionally maintained a strong interest in wellness care and disease prevention, as well as lifestyle and ergonomic issues. Therefore education, conditioning, nutrition, counseling and other approaches are often used by many practitioners. Although some specialty certification programs exist within the profession, these are not yet fully standardized.

The literature on the effectiveness of manual interventions has shown great promise for manipulation and to a lesser degree mobilization for care of various mechanical problems, especially certain low-back and neck conditions. There is an absence of good comparative studies to help clarify differences between technique approaches. The recommendations in this section are based on reasoning from biologic models, clinical experience, and expert opinion derived from both Delphi and Nominal Group consensus methodology.

It should be emphasized that chiropractic practitioners are typically well trained in a variety of standard assessment procedures, as well as specialized neuromusculoskeletal evaluation protocols. There has traditionally been an emphasis in chiropractic practice on lifestyle, wellness, prevention, and other natural approaches to health care.

Many practitioners have training and experience in a variety of alternative procedures such as acupuncture or homeopathy. It is beyond the scope of this chapter to cover these and other procedures (e.g., psychosocial, lifestyle and nutrition) to the level of detail they deserve. It is recommended that future guidelines on modes of chiropractic care give the detail for these procedures that is found for manual procedures in this chapter.

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IX. MINORITY OPINIONS

None

8

Frequency and Duration of Care

Chapter Outline

I. OVERVIEW

Guidelines concerning the treatment plan should be tempered with a balance of scientific information and systematic observation derived from clinical experience.[1] Further, in order to be practical, they must be periodically upgraded to reflect advances in the ever-changing knowledge database. Their purpose is to assist the clinician in decision making based on the expectation of outcome for the uncomplicated case. They are NOT designed as a prescriptive or cookbook procedure for determining the absolute frequency and duration of treatment/care for any specific case.

The review and recommendations made in this section have been drawn from clinical experience and clinical/scientific data on the response of patients receiving chiropractic health care services. No attempt has been made to select for individual conditions by region of complaint or by diagnosis. Most data reported in the clinical literature does not make these kinds of distinctions.

The majority of quantitative information available addresses the management of low-back and leg pain complaints. This is not surprising since these conditions currently account for most of the complaints seen by all health care providers who work with musculoskeletal disorders. The references to low-back disorders in this section are used only as examples. There is no intent to imply that these conditions constitute the totality of chiropractic expertise or practice. Rather, since these recommendations were born from experience and from data on multivariate clinical circumstances, they may be extrapolated with appropriate case-specific modifications to most of the common complaints for which chiropractic care is sought.

Virtually all chiropractic providers who submit claims for payment from third party payers receive disbursements based on contractual language. Commonly this requires that "treatment/care" be documented as having "therapeutic necessity." For that reason this chapter will refer to provider services under the rubric of "treatment/care" as a pragmatic representation of the business actually conducted by the chiropractic profession on a daily basis. There is no intent to engage in or to settle any philosophical debate on appropriate language.

Reducing Variations in Practice

The endurance of robust treatment variations in common practice [1] results from an absence of tested theory. Treatment diversity, or uncertainty, exists because of the differences among practitioners in their clinical evaluation of patients (diagnosis), or in their belief in the value of a procedure for meeting their patient's needs (therapy).[3] Some scattered efforts have been made to categorize treatment outcomes by condition (Connecticut,[4] Georgia,[5] Oregon,[6] Minnesota,[7] Ohio,[8] Washington.[9]) Each has struggled with competing priorities and with quality of evidence. This review is based upon a formal consideration of the available database and seeks to draw appropriate conclusions seasoned by the cumulative years of practical experience of the panel members.

Clinical expectation regarding treatment outcome must be based upon more than personal opinion. The approach to the development of guidelines for chiropractic quality assurance and standards of practice pertaining to the frequency and duration of treatment focuses on the uncomplicated case and logically includes the following considerations:

1. The natural history of common spinal disorders
2. The characteristics and stages of tissue repair processes
3. Reasonable treatment/care outcome classified into short and long range goals

Classifications of Patients

The care of common spinal complaints does not fit well into any diagnostic classification system because of a dual uncertainty surrounding the diagnosis and the efficacy of treatment.[10] Theoretically, complaints can be formulated into structural, neurophysiologic, and biomechanical diagnostic subsets.[11] Yet, these categorizations are not always helpful in setting realistic short and long term treatment/care goals. For example, a disc herniation may be discovered fortuitously in an asymptomatic patient and not require care. On the other hand, in an anatomically small spinal canal it may become quite disabling and defy conservative management.

Clinical descriptors such as those proposed by the Quebec Task Force[12] are useful in helping predict the course of the condition. More concrete treatment/care protocols, then, may be based on the clinical impressions rather than on knowledge of the lesion mechanics or treatment efficacy.[12, 14, 15]

Principles of Case Management

The primary missions of health care delivery are to provide sufficient care to restore health, maintain it, and prevent the recurrence of injury and illness. To meet these objectives, the practitioner uses a myriad of procedures and skills that collectively can be grouped into three categories—passive intervention, active intervention, and patient education. The practical boundaries on what will constitute necessary and sufficient treatment/care are situational. However, guidelines framing expectations of treatment outcome can be drawn from the literature and adapted by practical experience on a case-by-case basis.

The first principle of case management is that early return to activity is associated with reduced disability and symptoms.[16, 17, 18] A second principle is based upon the experience gained from monitoring the response of patients having no treatment,[19, 20] and those with treatment. The lesson learned is that there is a natural history of recovery for uncomplicated

cases[21] that can serve as a time frame from which to evaluate and shape a successful treatment plan. A third principle is that chronicity should be prevented wherever possible. Patients who are at risk for becoming chronic show characteristic patterns involving their illness and life situation.[22] Warning signs include:

1. Somatic complaints that remain static longer than 2-3 weeks
2. Anxiety or depression
3. Functional or emotional disability
4. Family turmoil
5. Drug dependence: recreational, non-prescription or prescription

A fourth guiding principle is that repeated use of acute care measures alone generally fosters chronicity, physician dependence and over-utilization.[23] Finally, therapeutic motivation, goals and fiscal responsibility are different for elective care than for therapeutically necessary care.

II. DEFINITIONS

Active Rest: The resting of a tissue or body part only to the point of restriction of deforming and pathological forces during the healing period, while at the same time allowing normal physiological stresses. Also called relative rest.

Adequate Trial of Treatment/Care: A course of two weeks each of two different types of manual procedures (four weeks total), after which, in the absence of documented improvement, manual procedures are no longer indicated.

Chronicity: Stages of progress of a disorder that are related both to severity and duration: acute, subacute, chronic, and recurrent.

Complicated Case: A case where the patient, because of one or more identifiable factors, exhibits regression or retarded recovery in comparison with expectations from the natural history.

Elective Care: Treatment/care requested by the patient designed to promote optimum function to alleviate subjective symptomatology in cases having reached maximum therapeutic benefit.

Manual Procedures: For purposes of this chapter this term includes adjustive or manipulative procedures, and other manual techniques.

MaximumTherapeutic Benefit (Maximum Medical or Chiropractic Improvement): Return to pre-injury/illness status or failure to improve beyond a certain level of symptomatology or disability, whatever the treatment/care approach.

Natural History: The anticipated clinical course of recovery for uncomplicated disorders either without treatment/care, or with conservative treatment/care.

Preventative/Maintenance Care: Care given to reduce the incidence or prevalence of illness, impairment, and risk factors, and to promote optimal function.

Stages of Treatment/Care: (sequential or concurrent)

1. Acute Intervention: Initial therapeutic intervention to assist and promote anatomical rest, reduce muscle spasm and inflammatory reaction, and alleviate pain.
2. Remobilization: Continuing intervention to increase the pain-free ranges of motion and to minimize de-conditioning.
3. Rehabilitation: Efforts to restore strength and endurance in the pain-free range, and increase physical work capacity. Rehabilitation is treatment/care applied for more chronic or complex problems in patients with impaired capabilities. It may be used sequentially or concomitantly with other care depending on the specific characteristics of a problem.
4. Life Style Modification: Adaptations of life style necessary to modify social and recreational activity, diminish work environment risk factors, and adapt to psychological elements affecting, or altered by, the disorder.

Supportive Care: Treatment/care for patients having reached maximum therapeutic benefit, in whom periodic trials of therapeutic withdrawal fail to sustain previous therapeutic gains that would otherwise progressively deteriorate. Supportive care follows appropriate application of active and passive care including lifestyle modifications. It is appropriate when rehabilitative and/or functional restorative and alternative care options, including home-based self-care and lifestyle modifications, have been considered and attempted. Supportive care may be inappropriate when it interferes with other appropriate primary care, or when the risk of supportive care outweighs its benefits, i.e. physician dependence, somatization, illness behavior, or secondary gain.

Therapeutic Necessity: Exists in the presence of an impairment (illness/injury) evidenced by recognized signs and symptoms, and likely to respond favorably to the treatment/care planned.

Treatment/Care Dynamics-Manual Procedures:

1. Threshold: The minimum rate and magnitude of joint load needed to bring about a change.
2. Dosage: The frequency of care necessary and sufficient to maintain effects while healing occurs.
3. Duration: The minimum treatment/care interval to obtain a stable response.
4. Combination: The potentiation or competition of response by simultaneous treatment/care applications.

Treatment/Care Goals: Written short term and long range expectations of patient response to the treatment plan.

Treatment/Care Type:

1. Passive Care: Application of treatment/care modalities by the care-giver to a patient, who "passively" receives care.
2. Active Care: Modes of treatment/care requiring "active" involvement, participation, and responsibility on the part of the patient.

Treatment Plan: A written description of intended therapeutic actions divided according to relevant treatment/care goals and prognosis.

Uncomplicated Case: A case where the patient exhibits progressive recovery from an illness or injury at a rate greater than, or equal to, the expectation from the natural history.

III. LIST OF SUBTOPICS

A. Short and Long Range Treatment Planning
B. Treatment/Care Frequency
C. Patient Cooperation
D. Failure to Meet Treatment/Care/Objectives
E. Uncomplicated Cases
F. Complicated Cases
G. Elective Care

IV. LITERATURE REVIEW

Natural History

Earlier schools of thought in chiropractic placed less emphasis on diagnosis and more on the response to therapeutic trial—a descriptive analysis. When combined into groups as is done in the DRG or Quebec schemes of classification, patterns emerge in the course of treated and untreated conditions.[24,25,26,27,28] These observations provide a natural history that can serve as a reference point for treatment/care expectations. The most meaningful outcome measures available are the rate of return to work, continued use of health care services, and recurrence of back-related injuries.[29]

Regardless of how a patient is categorized diagnostically, clinical decision-making can be rationally organized for most back pain sufferers. The natural history of back pain and other conditions for uncomplicated episodes gives a defensible basis from which a measurable plan of action can be made.

Clearly, the duration and intensity of in-office treatment/care for an uncomplicated case should not extend beyond the time frame observed in reports of the natural untreated course. As a set of minimal standards, attention to how the patient is progressing in comparison with the natural history helps to set an upper limit on the time during which a case should be followed without modification of the treatment plan. Figure 8-1 (page 128) shows the progress believed to characterize most back pain patients who require intervention.

Each episode of the condition can be perceived in the context of its own time course and described as acute, subacute, chronic, or recurrent. Some controversy exists about definitions for each category. They appear to be loosely based upon the duration of absence from work or upon an assessment of relative clinical improvement.

Episode Time-Course

Table I lists the aggressive, intermediate, and conservative time limits for each category. Recurrent episodes of back pain are not listed separately, since they are treated similarly to acute cases. Differences in the cutoffs chosen in each study reflect the relative values each group places upon intervention to avert chronicity. There is universal agreement that of those whose symptoms persist for more than 3 to 4 months, more than half will still be disabled at the end of a year.[30]

Table 1 Staging the Episode: Time-Course

Quebec Study (1987)	*Frymoyer (1988)*	*Mayer & Gatchel (1988)*
Acute 0-7 days	0-6 weeks	0-8 weeks
Subacute 7 days-7 weeks	6-12 weeks	8-16 weeks
Chronic 7 weeks +	> 12 weeks	> 16 weeks

Standards in patient management require close attention to three elements of the treatment plan. They are: 1) criteria for selecting treatment/care procedures; 2) close monitoring of the therapeutic response in comparison with the expected outcome of natural history; and 3) flexibility of the treatment/care protocol when less favorable or unexpected responses are encountered.

As with any other form of therapy, it is likely that manual procedures follow dynamic principles. That is, treatment/care response will depend upon threshold effect, dosage, duration of administration, and additive effects from combination with other agents.[31]

Scientific study of the relative efficacy and mechanism for different procedures and combined efforts has only begun recently.[32] For example, the mechanical response of a motion segment may be influenced by many modifiers. Local muscle tone and the patterning of recruitment during voluntary movement affect the distribution of stresses that are transmitted through the spinal tissues. The passive mechanical properties of disc, ligaments, and muscle may be altered by inflammatory or degenerative processes. Pathologic barriers imposed by intra-articular adhesions or meniscoid entrapments may be present and are thought by some to be potential mechanisms for disrupting normal mechanics. Finally, the occupational hazards of prolonged static postures or high peak spinal loads

can inhibit responses. For example, the body's healing processes must proceed and inflammation subside before the effects of prolonged antalgic loading of the spine can be mitigated.

Treatment Plans

The treatment plan for therapeutically necessary care can be divided into four phases (Table II), each having distinct objectives that allow for passive and active benefits. When the patient exhibits acute distress, efforts to reduce soft tissue and joint stresses are applied to diminish inflammation and swelling. A short term of reduced mobility to limit the joint loading effects of gravity may be warranted. Passive forms of treatment/care, including manual and palliative procedures, may be used with deference to the type of mechanical lesion present. When pain and discomfort have abated, the area can be remobilized with low speed and minimal load exercises directed to improve flexibility without incurring mechanical stress. As the range of pain free motion is improved, a gradual increase in exertion can be introduced. Lastly, when a maximal range of motion is achieved, rehabilitation for strength and endurance can begin.

Table II Stages of Treatment/Care: Goals and Objectives

Passive Care
1. Acute Intervention (including manual procedures)
   A. To promote anatomical rest
   B. To diminish muscular spasm
   C. To reduce inflammation
   D. To alleviate pain

Active Care
1. Remobilization
   A. To increase the range of pain free motion
   B. To minimize deconditioning
2. Rehabilitation
   A. To restore strength and endurance
   B. To increase physical work capacity
3. Life Style Adaptations
   A. To modify social and recreational activity
   B. To diminish work environment risk factors
   C. To adapt psychological factors affecting or altered by the spinal disorder.

It is beneficial to proceed to the rehabilitation phase (if warranted) as rapidly as possible, and to minimize dependency upon passive forms of treatment/care. Studies have shown a clear relationship between prolonged restricted activity and the risk of failure in returning to pre-injury status. Often a complete resolution of pain is not possible until patients begin to focus on increasing the number and kind of activities in which they participate. Return to work usually can be commenced at 80-90% level of pre-injury status.[32] Even then, some residual pain can be expected, although usually it will be offset by the benefits of increased productive functioning.

Predictions from the Case History

Most back pain studies have found that the duration of symptoms is a predictor of response to treatment/care with manual procedures. The duration of symptoms is inversely related to the likelihood of positive clinical response. Bronfort[34] reported that patients with a shorter duration of symptoms were more likely to respond to manipulation (85% cured within six months for patients with less than seven days of initial pain, only 35% with more than 28 days of initial pain.) Similar results are shown by Maitland,[35] Glover,[36] Evans,[37] and Potter.[38]

Singer et al.[39] describe a relationship between three descriptive factors in the episode history noted at the time of patient consultation, and the duration of conservative care. Pain intensity and duration prior to the consultation, and the number of prior episodes were observed to affect the time necessary to return the patient to preinjury activity and recovery at least to a point of mild pain. In general, more severe pain at treatment/care onset was associated with longer treatment/care times. In like manner, patients suffering with pain longer than eight days before commencing therapy took a mean of 21 days to recover. With less duration of pain, only 13 days were required. Similarly, patients with up to three prior episodes required 12 days, while more than eight episodes extended recovery to 27 days.

Passive Care

The scientific literature is not helpful in deciding when manual treatment/care should be stopped, either with respect to improvement or worsening of symptoms. Controlled trials or case series have been reported with ranges between 1 and 19 sessions of manipulation lasting anywhere from a single day to two months. Triano[40] has suggested an algorithm of decision-review points triggered by the individual patient's response in contrast to the natural history. Hansen[41] recommends a second opinion if there is no objective or subjective sign of improvement (or worsening of the condition) in two weeks, or treatment of three times per week that exceeds four weeks. The 1990 RAND Consensus Panel unanimously agreed to a definition of adequate therapeutic trial for spinal manipulation. They recommended a trial course of two weeks each using alternative manipulative procedures before considering treatment/care to have failed. Without evidence of improvement over this time frame, spinal manipulation is no longer indicated.

Several observational or retrospective studies have compiled information on the number of treatments that have been given to patients. Varying experimental methodologies were used. Reporting on case records of 3,943 patients from multiple private offices, Phillips and Butler[42] found a mean of 12.5 treatments (SD, 13.1). Separately, Phillips[41] reported a mean of 9.0 treatments in 871 cases. Patients fit all categories

from acute, subacute to chronic. Symptoms had been present for less than 30 days in 57%, for 60 to 180 days in 11% and for longer than 180 days in 22%. The mean length of case management was 11.4 days. Twenty-four percent were attended for a week or less while 56% received care for up to 30 days. One hundred and three patients[44] with lumbosacral pain were treated with up to four sessions of manipulation. They were followed for one to three years. Recurrence of symptoms appeared in only 11.7% during that time. In another study examining workers' compensation case data, Jarvis et al.[45] calculated a mean of 12.9 treatments over an average of 54.5 days.

Manipulative services on patients with work-related back disorders in Florida averaged 29 office-based procedures per patient.[46] In another office based prospective observation of 100 consecutive low back pain cases, Cox et al.[47] found a 50% pain reduction within a mean of 10 treatment sessions over 16 days. Maximum relief was gained at 41 days and after 16 treatment sessions.

Nyiendo and Haldeman[48] reported a range for the number of patient visits across all complaints as 1-81, with a mean of 4.4. In a prospective study controlled for volunteer bias, Triano et al. reported a range of 1-22 sessions.[49] Moreover, the results of this study appear more representative of private-practice experience than other published profiles. Several conclusions from this study are helpful in judging the frequency and duration of care for symptomatic episodes:

1. Patients with chronic disorders may require more treatment/care to resolve symptomatic episodes than do other categories of complaint.
2. Lordotic areas of the spine, on average, required twice the care of complaints involving the thoracic and transitional regions.
3. Most cases studied resolved well within six weeks of intervention consistent with the expectations from natural history (Figure 8-1, Page 128).
4. Patients for whom care is necessary beyond six weeks may require up to 11 (mean = 3.8) additional sessions before reaching resolution.

Statistics describing clinical experience with manipulation fit well within guidelines based upon natural history outcomes. More aggressive in-office intervention early during treatment/care may ultimately result in reducing the amount of disabling injury and the necessity to engage in more extensive inpatient procedures. These conclusions closely resemble determinations derived from functional rehabilitation and from the recommendations of the Ontario study for an earlier aggressive treatment approach.

It is possible that the presence of pathologic or anomalous structures may impede clinical progression.[50] Re-injury and exacerbation from unexpected events also may alter treatment/care goals. Likewise, biomechanical and psychosocial stress may be important deterrents to recovery. Bronfort[51] showed that the presence of psychological overlay (defined by the hysteria and hypochondriasis scores on the MMPI), and the presence of ergonomic influences was associated with poorer response to chiropractic manipulation. Circumstances such as these require the artful practice of patient management. The ability of the attending clinician to identify the primary problem is a major factor in minimizing the time of patient suffering.[52] A decision algorithm simplifies the sorting out process in these cases (Figure 8-2, Page 129). Its value lies in helping clarify and discriminate practitioner and patient responsibilities in working toward case resolution. The overriding concern is a focus upon the patient's rate of improvement in comparison with that predicted by the natural history.

The patient who experiences sufficient severity or duration of back discomfort may wish to seek consultation. From that time forward, treatment/care is divided into the four stages of intent described above. Case management includes decisions about timing in the implementation of each stage. Some small variation can be expected from case to case as this derives from circumstances in the patient's habits, life style, or occupation, and accidental encounter. These circumstances should be sought whenever the progress of treatment/care approximates or intersects the estimated time line of Figure 8-1. A systematic interview with the patient, sometimes including members of the family, will often reveal influences competing with treatment/care objectives. After correcting these factors, trial therapy should be reimplemented.

If extenuating circumstances are not evident, or if a renewal of trial therapy fails to bring about an adequate rate of improvement, it is wise to reconsider the initial diagnosis. Special testing or imaging may be warranted depending upon the practitioner's level of suspicion and the results of monitoring the renewed treatment plan. Whether or not the diagnostic impression is upheld, a change in the therapeutic plan needs to be instituted. Failure to achieve a satisfactory response after working through the scenario laid out in the algorithm should result in an assessment for maximum therapeutic improvement or referral for a second opinion. Patients who progress into a state of chronicity can be identified and aggressively rehabilitated at an earlier stage.

Active Care

While only 4 percent of back pain patients fail to return to pre-injury status after six months, these patients are responsible for most back related health care costs. The preponderance of evidence from studies of medication treatment, manipulation, back school, and physical therapy shows that when any of these conservative treatments cease,[53] the natural course of on-going disability reasserts itself for these cases. Clearly, new treatment/care options are needed to improve upon these long range clinical outcome statistics.

The chiropractic profession has responded to this need in managing cases at risk for becoming chronic. Advanced understanding for the progression of acute pain to chronic,[54] deconditioning syndromes,[55] illness behavior,[56] and the risk of

physician dependence has resulted in more providers actively specializing in preventive and rehabilitative practice.[37] Their primary purpose is to provide a vehicle for successful transition of patient care from relying upon passive treatment/care intervention to active patient participation. The factors that enter into consideration of appropriateness include:

1. Duration of the painful episode
2. The number of previous episodes
3. Response to acute intervention
4. Anticipated future physical activity
5. Patient motivation
6. Training of the practitioner and staff

Once therapeutic necessity has been determined, success of the rehabilitation plan will be determined primarily by the latter three elements.

Some anti-inflammatory approaches might be applicable at this phase, i.e., relative rest or active rest.[60] Other forms of passive treatment/care, including manual and palliative procedures, are used with deference to the type of mechanical lesion present, and are discussed under the section above on passive care. Pain-free isometric contraction signals the appropriate timing for expanding the range of motion. Once pain and discomfort are controlled, the area is remobilized with low speed, minimal load exercises directed to improve flexibility without being mechanically stressful. As range of pain-free motion is improved, a gradual increase in exertion can be introduced. Finally, rehabilitation for strength and endurance can begin.

Should the patient fail to progress through the stages proportional to the natural history, a search for complication, somatization, non-compliance, or reinjury should be made. After correcting these factors, trial therapy should be implemented again. Cases persisting without substantial improvement and that have no underlying complications warrant consideration for rehabilitation.

Patients at risk for becoming chronic generally present common warning signs.[39] They include: 1) stationary symptoms of somatic pain for two or three weeks; 2) functional impairment; 3) chemical dependency used recreationally or for pain control; and 4) emotional distress that may include family disruption. The presence of such indicators should signal the practitioner to move quickly away from passive care as the primary emphasis.

Reaching the rehabilitation phase as rapidly as possible and minimizing dependence upon passive forms of treatment/care usually lead to the optimal result. Prolonged limited activity is related to risk of failure in returning to preinjury status. Often complete resolution of pain is not possible until the patient begins to focus on increasing the number and kind of activities in which they participate. Even then, some residual pain can be expected, but it may be offset by the benefits of increasingly productive function. While optimization of physical performance may be desirable, continuation of care past the treatment/care goal is considered elective care.

Treatment/Care Protocols

There are nearly as many preferences in exercise programs available as there are health care providers using them. What is more important, however, is the recognition that care should not focus selectively on the injured areas alone but should involve associated areas that support the injury. Program design should have balanced components based on the needs of the patient. Elements that should be addressed include:

1. The dissuasion of pain related behavior
2. Education on body biomechanics
3. Supervised training for flexibility with stability, strength, coordination, and endurance

For patients already demonstrating signs of deconditioning or chronicity, this will require more than handing out a simple list of exercises to be performed at home.

Pain Behavior

Pain behavior and illness conviction are best managed with a conceptual shift in thinking about pain. The care giver must switch focus from injury and attention to the patient's level of discomfort to what the patient is able to do.[60] An understanding that movement is safe and helpful, even if not completely comfortable, needs to be emphasized. Where psychosocial factors predominate in the assessment, referral for counseling should be made. However, lesser psychosocial effects arise from ongoing pain itself. Focus upon rehabilitation as a means to improve the quality of life and to reduce suffering can result in a significant reduction on secondary somatization.

Patient Education

Educational instructions are to be given to promote safe habits. Job and biomechanical analyses help steer topics toward specific activities and conditions in which the person is likely to find himself or herself. However, a general comprehension of function and stressors should be attempted using terms familiar to the patient. Topics including the classical bending, lifting, pushing and pulling, entry and exit from vehicles, sitting, yard work, recreation, personal care, and sexual activity all should be included.[61,62] Emphasis should be placed on personalizing the activities commonly experienced by the patient.

Exercise Training

Flexibility and Stability: The long term goal of rehabilitation is to restore the patient to preinjury function and reduce the chances of recurrent episodes. Repetitive microtrauma superimposed on previous injury can lead to advanced degenera-

tion.[63] Spinal stabilization is designed to teach trunk muscle recruitment as an effort to control and reduce flexion and torsional stresses on the joint segments. Through the use of voluntary muscles, pain-free regional postures can be maintained while the patient carries out normal daily activities. The necessary posture and combination of muscle actions determined experimentally are specific for each case. Once the comfortable position is found, the patient is assisted while rehearsing progressively more complex tasks, keeping the body part in its neutral, pain-free position.

Strength and Endurance: Early on, during recovery, isometric exercises and stretching within the pain-free range of motion may be used to limit the effects of deconditioning.[64] Once the case has successfully passed the remobilization phase, progressively increasing loads throughout the full range of motion are initiated. These may be accomplished through use of free weights, weight stack machines, or the same computerized isokinetic or isoinertial machines that aid in assessment of function.

The usual exercise training plan begins with direct supervision, three to five times per week, of assigned exercise tasks intermixed with rest periods. Many progressive-resistance protocols are available. These are summarized by Christensen[65] and Saal and Saal.[66] The combination of multiple sets of repetitions with increasing or decreasing increments of weight results in benefits for both strength and endurance. The maximum exertion is increased weekly over a course of four to six weeks for the typical case. Computerized instruments may be used in analogous fashion. They offer immediate feedback and may help maintain user interest, but their use is not essential to a good clinical outcome.

Persons who fail to comply with the treatment/care schedule or who are insincere in their efforts should be discontinued and discharged from care. The remaining patients are reassessed near the completion of the treatment plan to determine the outcome.

V. ASSESSMENT CRITERIA

Procedure Ratings (System I)

Established: Accepted as appropriate by the practicing chiropractic community for the given indication in the specified patient population.

Promising: Given current knowledge, this technology appears to be appropriate for the given indication in the specified patient population. As more evidence and experience accumulate this interim rating will change. This connotes provisional acceptance, but permits a greater role for the current level of clinical use.

Equivocal: Current knowledge exists to support a given indication in a specified patient population, though value can neither be confirmed nor denied. As more evidence and experience accumulates this interim rating will change. Expert opinion recognizes a need for caution in general application.

Investigational: Evidence is insufficient to determine appropriateness. Further study is warranted. Use for a given indication in a specified patient population should be confined largely to research protocols. As more evidence and experience accumulates, this interim rating will change.

Doubtful: Given current knowledge, this appears to be inappropriate for the given indication in the specified patient population. As more evidence and experience accumulate this interim rating will change.

Inappropriate: Regarded by the practicing chiropractic community as unacceptable for the given indication in the specified patient population.

Quality Of Evidence

The following categories of evidence are used to support the ratings.

Class I:
Evidence provided by one or more well-designed controlled clinical trials; or well-designed experimental studies that address reliability, validity, positive predictive value, discriminability, sensitivity, and specificity.

Class II:
Evidence provided by one or more well-designed, uncontrolled, observational clinical studies such as case control, cohort studies, etc.; or clinically relevant basic science studies that address reliability, validity, positive predictive value, discriminability, sensitivity, and specificity; and published in refereed journals.

Class III:
Evidence provided by expert opinion, descriptive studies or case reports.

Suggested Strengths of Recommendation Ratings

Type A. Strong positive recommendation based on Class I evidence, or overwhelming Class II evidence when circumstances preclude randomized clinical trials.

Type B. Positive recommendation based on Class II evidence.

Type C. Positive recommendation based on strong consensus of Class III evidence.

Type D. Negative recommendation based on inconclusive or conflicting Class II evidence.

Type E. Negative recommendation based on evidence of ineffectiveness or lack of efficacy based on Class I or Class II evidence.

Safety and Effectiveness

Safety: a judgment of the acceptability of risk, in a specified situation, e.g., for a given health problem, by a provider with specified training (at a specific stage of the disorder etc.).

Effectiveness: producing a desired effect under conditions of actual use.

VI. RECOMMENDATIONS

Note: Statistical descriptors of treatment frequency, such as mean/median/mode, should NOT be used as a standard to judge care administered to an INDIVIDUAL patient. The particular factors of each case will govern the course of recovery and need to be a part of the considerations in assessing clinical progress.

A. Short and Long Range Treatment Planning:

At the outset of treatment/care, a written estimated time frame for reaching intermediate functional milestones (short term goals, e.g., the ability to move the affected part, exert force, walk, etc.) and treatment/care outcomes (long term goals, e.g., return to work, renew sports, full activity, etc.) should be made. The length of time to reach these objectives can be affected by specific historical factors.

NOTE: These factors, when combined (two or more), do not necessarily imply combined delay in recovery, but must be evaluated on a case-by-case basis.

1. Preconsultation Duration of Symptoms. Pain less than eight days: No anticipated delay in recovery. Pain more than eight days: Recovery may take 1.5 times longer.
2. Typical Severity of Symptoms. Mild pain: No anticipated delay in recovery. Severe pain: Recovery may take up to two times longer.
3. Number of Previous Episodes. 0-3: No anticipated delay in recovery. 4-7: Recovery may take up to two times longer.
4. Injury Superimposed on Preexisting Condition(s). Skeletal anomaly: May increase recovery time by 1.5-2 times. Structural pathology: May increase recovery time by 1.5-2 times.

8.1.1 Rating: These recommendations are safe and have limited effectiveness in predicting recovery rate. They have a rating of promising based on Class II and III evidence.
Consensus Level: 1
Strength of Recommendation: Type B

B. Treatment/Care Frequency:

Specific recommendations related to acute, subacute and chronic presentations are given below. In general, more aggressive in-office intervention (three to five sessions per week for one to two weeks) may be necessary early. Progressively declining frequency is expected to discharge of the patient, or conversion to elective care.

8.2.1 Rating: The general approach to frequency is safe and effective provided it is carried out within the guidelines of natural history. The rating is established and is supported by Class II and III evidence.
Consensus Level: 1
Strength of Recommendation: Type B

C. Patient Cooperation:

The nature of the patient's disorder and the purpose and strategy of the treatment plan should be adequately explained to the patient. Patients who prove to be insincere or non-compliant to treatment/care recommendations should be discharged from care, with referral when appropriate.

8.3.1 Rating: This recommendation is safe and effective. The rating of promising is given when used in an effort to avoid physician dependence and overuse of services based on Class II and III evidence.
Consensus Level: 1
Strength of Recommendation: Type B

D. Failure to Meet Treatment/Care Objectives :

1. Acute Disorders: After a maximum of two trial therapy series of manual procedures lasting up to two weeks each (four weeks total) without significant documented improvement, manual procedures may no longer be appropriate and alternative care should be considered.

2. Unresponsive Acute, Subacute, or Chronic Disorders: Repeated use of passive treatment/care normally designed to manage acute conditions should be avoided as it tends to promote physician dependence and chronicity.

3. Systematic interview of the patient and immediate family should be carried out in search for complicating or extenuating factors responsible for prolonged recovery.

4. Specific treatment/care goals should be written to address each issue.

5. Continued failure should result in patient discharge as inappropriate for chiropractic care, or having achieved maximum therapeutic benefit.

8.4.1 Rating: Safe and effective procedures that are established and supported by Class I, II, and III evidence.
Consensus Level: 1
Strength of Recommendation: Type A

E. Uncomplicated Cases: (acute episode)

Observing the consistency of practice experience defined by the studies listed in the review of literature for passive care, *only* acute episodes can truly be considered uncomplicated. Acute episode (first occurrence, recurrent, or exacerbation of a chronic condition).

1. Symptom Response: Significant improvement within 10-14 days; three to five treatments per week.
2. Activities-of-Daily-Living (ADL): The promotion of rest, elevation, active rest, and remobilization, as needed, are expected to improve ADL followed by a favorable response in symptoms.
3. Return to Pre-episode Status: six to eight weeks; up to three treatments per week.
4. Supportive Care: Inappropriate.

8.5.1 Rating: These recommendations are safe and effective in meeting the desired objectives. It has an established rating based upon the relationship to natural history. It is supported by Class I, II, and III evidence.
Consensus Level: 1
Strength of Recommendation: Type A.

F. Complicated Cases:

Implementation of up to two independent treatment plans relying on repeated use of passive care is generally acceptable in the management of cases undergoing prolonged recovery.

1. Signs of Chronicity: All episodes of symptoms that remain unchanged for two to three weeks should be evaluated for risk factors of pending chronicity.

Patients at risk for becoming chronic should have treatment plans altered to de-emphasize passive care and refocus on active care approaches.

8.6.1 Rating: Criteria for chronicity are established, safe and effective with Class I, II, and III evidence.
Consensus Level: 1
Strength of Recommendation: Type A

2. Subacute Episode:
   a. Symptom Response: Symptoms have been prolonged beyond six weeks, and passive care in this phase is as necessary, not generally to exceed two treatments per week, to avoid promoting chronicity or physician dependence.
   b. Activities of Daily Living (ADL): Management emphasis shifts to active care, dissuasion of pain behavior, patient education, flexibility and stabilization exercises. Rehabilitation may be appropriate.
   c. Return to Pre-episode Status: 6-16 weeks.
   d. Supportive Care: Inappropriate.

8.6.2 Rating: These recommendations are safe and effective in reaching the desired objective. They have a promising rating based upon the relationship to natural history and are supported by Class II and III evidence.
Consensus Level: 1
Strength of Recommendation: Type B

3. Chronic Episode
   a. Symptom Response: Symptoms have been prolonged beyond 16 weeks, and passive care is for acute exacerbation only.
   b. Activities of Daily Living (ADL): Supervised rehabilitation and life style changes are appropriate.
   c. Return to Preinjury Status: May not return. Maximum therapeutic benefit and declaration should be considered.
   d. Supportive Care: Supportive care using passive therapy may be necessary if repeated efforts to withdraw treatment/care result in significant deterioration of clinical status.

8.6.3 Rating: These chronic episode recommendations are safe and effective in reaching the desired objectives of sustaining the optimal health status under the circumstances. The rating is promising. Chronic disorder treatment/care is supported by Class II and III evidence.
Consensus Level: 1
Strength of Recommendation: Type B.

G. Elective Care:

Under specific circumstances for individual cases, elective care may be safe and effective. Elective care must be designed to avoid physician dependence and chronicity. Therapeutic necessity is absent by definition.

8.7.1 Rating: Unrated
Consensus Level: 1

VII. COMMENTS, SUMMARY, OR CONCLUSION

There are many unknown features that obscure our understanding of the nature of most musculoskeletal disorders. Manipulative/adjustive procedures are an important option in the initial management. While efforts continue to be made to understand more completely the pathoanatomical and functional

features, a systematic method for adopting outcome expectations is available, and even perplexing cases can be managed within a time frame that avoids or reduces the risk of chronicity or the development of physician dependence. Treatment/care established upon documented therapeutic need can be more rationally based when elements of natural history and modifying factors from the patient's lifestyle and environment are considered.

VIII. REFERENCES

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IX. MINORITY OPINIONS

None.

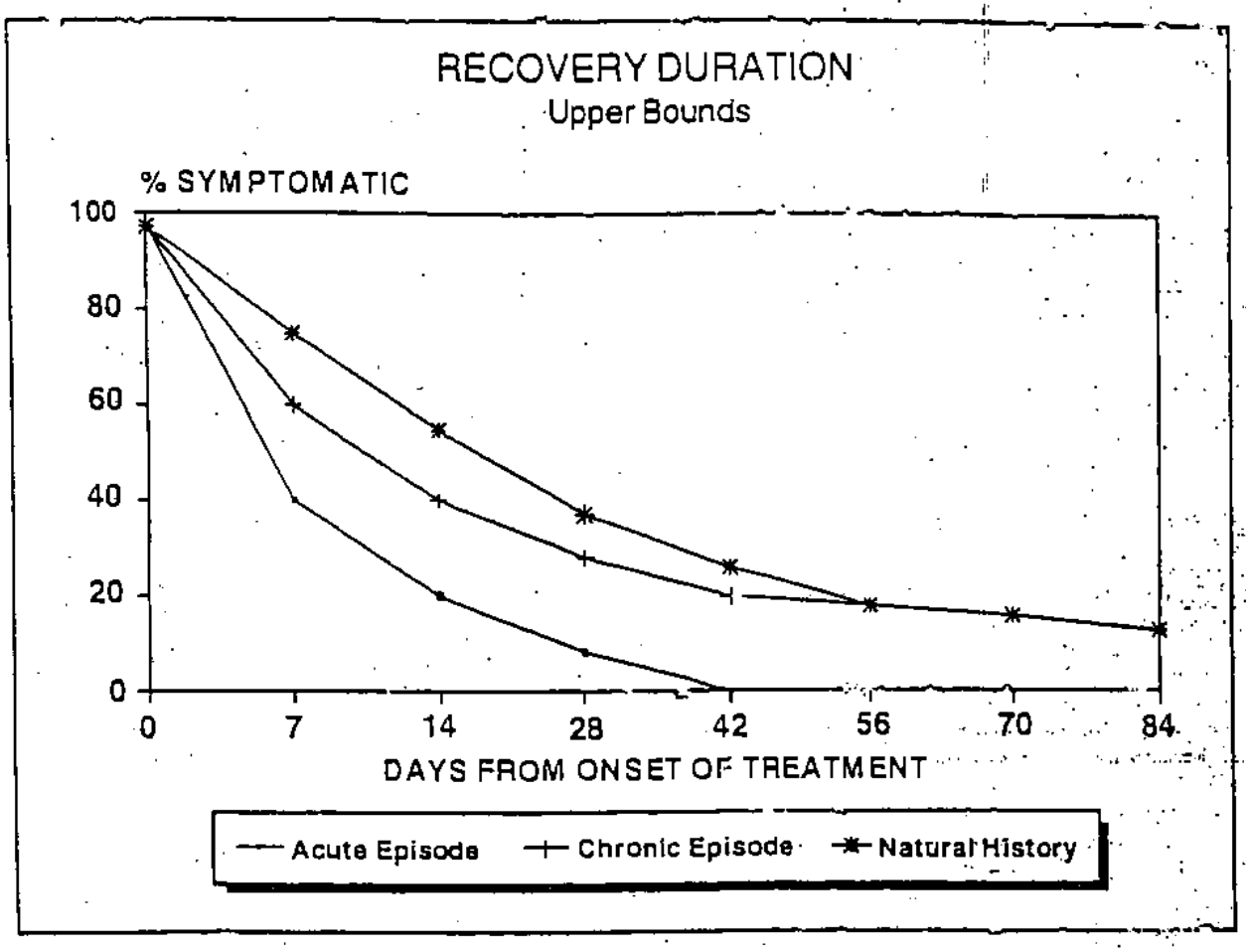

Figure 8-1 Patient's progression in comparison with the natural history (From Triano, 1991).

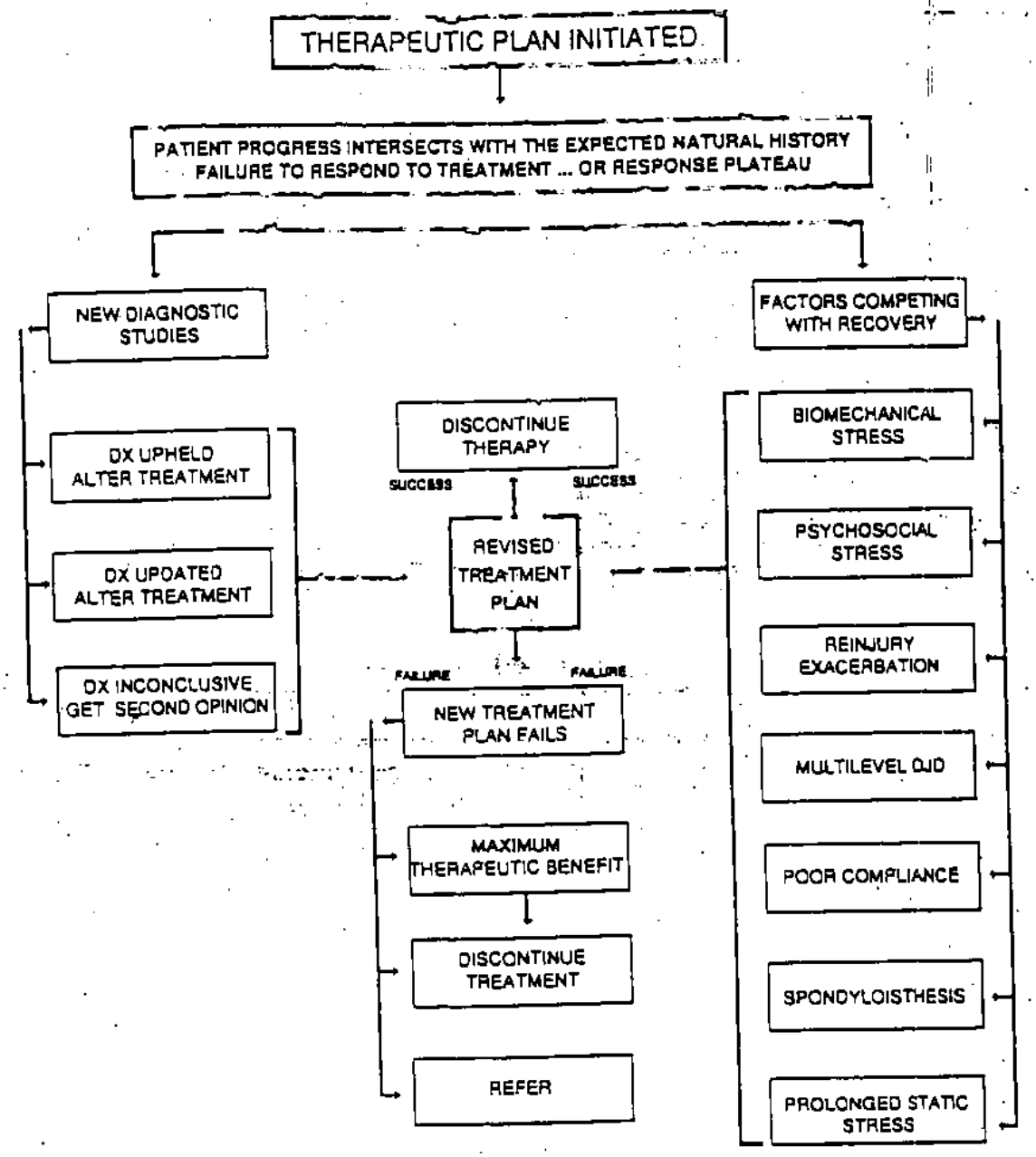

Figure 8-2

9

Reassessment

Chapter Outline

I. OVERVIEW

Reassessment refers to patient evaluations performed after the initiation of patient care. Reassessment is essential for monitoring the patient's progress and is also termed "outcomes assessment." Clinical research addresses the development and application of reassessment instruments and procedures. Appropriate application of these to clinical practice is of great importance.

The primary reason for reassessment is to evaluate the patient's clinical state. From this and a knowledge of prior condition, rate of progress and specific interventions utilized to manage the patient's condition, more informed decisions can be made regarding the appropriateness of care, efficiency of care rendered, need for continued care, and the need to modify care. A number of questions have been raised with regard to reassessment such as: Why should patients be reassessed, what specifically should be reassessed, when should reassessment be performed, and how should reassessment be conducted? In considering these topics, it is important to keep in mind the distinctive qualities of chiropractic as a manual healing art.

For the purposes of this paper, three temporal patterns of reassessment are identified: interactive, periodic, and follow-up. Since the practice of chiropractic inherently involves continual reassessment by virtue of the "hands-on" nature of the therapies, an ongoing evaluation is required with each visit. This is done in order to arrive at an ongoing clinical impression and determine the immediate need for chiropractic intervention. This is referred to here as "interactive" reassessment. Periodic reassessment is utilized in situations where changes are likely to be seen over a more extended period of weeks or months. The dynamic nature of the recuperative process requires that periodic reassessment be performed to track the patient's progress and determine the need for continued care or the need to modify the management program. Follow-up reassessment is performed at the end of the management program or when the patient has attained maximal clinical improvement. Such an assessment is often performed to ascertain the degree of residual deficit, such as disability ratings, or the degree of recovery.

II. DEFINITIONS

Assessment: An examination performed with the intent of arriving at a qualitative or quantitative description of a patient's condition. The term suggests any evaluation procedure performed for the purpose of obtaining information regarding the patient's state or condition.

Evaluation: Synonymous with assessment.

Initial Patient Evaluation: Represents the assessment procedures that are performed on a patient upon initial contact and are used to arrive at a clinical impression and a plan for patient management. (Also: preliminary assessment, preliminary evaluation, clinical workup, preliminary workup.) Initial evaluation may include a series of diagnostic or evaluative sessions separated by days or weeks when the express purpose of these sessions is to evaluate the patient's state prior to the initiation of care (i.e., obtain a baseline).

Diagnosis: A specific decision regarding the nature of the patient's complaints.

Nominative: Pertaining to decisions based mainly on subjective or "soft" information (e.g., palpation, most ROM, reflex challenges, etc.).

Substantive: Pertaining to decisions based on mainly objective or "hard" information (such as x-ray, MRI, precise ROM).

Baseline: The temporal course of a patient's condition prior to the initiation of care, determined by a series of clinical evaluations performed during separate diagnostic sessions over a period of time.

Reassessment: Evaluation for the purpose of following the progress of a patient under clinical management. The term does not include multiple assessment sessions employed for baseline evaluation and carries the express connotation of assessment performed after the initiation of patient care.

Progress: Any change in the patient's condition. It does not necessarily mean improvement.

Interactive Reassessment: Evaluation of a patient by procedures utilized on each visit to assess the immediate need for manual intervention.

Periodic Reassessment: Evaluation of a patient at intervals of weeks or months, for the purpose of assessing the need for continued care, modified care, cessation of care or referral.

Follow-up Reassessment: Evaluation of a patient at the end of a course of therapy or management program for the purpose of assessing the status of the patient at maximal clinical improvement.

Vertebral Subluxation Complex (VSC): An aberration of normal spinal biomechanics, usually involving a restriction or loss of normal movement of a motion segment, and associated aberrations in the tissues which support articular motion (e.g., nerve, muscle, connective and vascular).

Subluxation Syndrome: The clinical signs and symptoms thought to relate to pathophysiology or dysfunction of spinal motion segments or to peripheral joints that may be amenable to manipulative/adjustive procedures.

III. LIST OF SUBTOPICS

A. Reassessments—General Principles
B. Interactive Reassessment
C. Periodic Assessment

IV. LITERATURE REVIEW

Texts with chapters on diagnosis do not specifically deal with the issue of reassessment and are content to describe the procedures from a largely mechanical perspective. Therefore the frequency of reassessment is left implicitly to the judgment of the treating practitioner. Currently, justification for any particular pattern of reassessment must be culled from the clinical research literature and expert opinion. A representative selection of the literature is referenced at the end of this chapter.

In clinical practice there is typically a single assessment in the initial patient evaluation, but it is not uncommon for several consecutive assessments to be conducted to create a baseline for the patient's progress. The approach taken may depend upon the patient's condition. For example, a patient with severe, acute pain due to an apparent lumbar disc herniation will have little tolerance for multiple session evaluations to establish a baseline for management. By contrast, the establishment of a baseline for juvenile scoliosis patients typically requires evaluations over a period of several months.

Patients are reassessed for a number of reasons. Primary among them is the ongoing need for the practitioner to determine the necessity and appropriateness of further care. Reassessment gives the practitioner an opportunity to assess the effectiveness or success of the chosen treatment plan by providing a monitor of patient progress, either improvement or deterioration. It is important to determine whether improvement is occurring at an appropriate rate. If not, appropriate changes in the treatment plan can be made, including possible referral.

A reassessment is often performed to satisfy the requirements of third-party payers. Their concerns are often the justification of continued care, determination of patient progress, and determination of disability rating.

As a general rule, reassessment will focus on those areas in which positive findings were obtained during the initial clinical evaluation. Exceptions to this occur when additional signs or symptoms develop during the course of treatment which mandate re-evaluation of previously negative tests or the use of procedures not previously employed. When the natural history of a condition is known, reassessment can provide valuable insight into the effectiveness of the treatment program in altering its course.

It is unreasonable to adopt the approach that every known test is performed on the initial examination and subsequently repeated with each reassessment. Good clinical judgment combined with careful observation will direct the practitioner to those areas and procedures which will provide the most valuable information. The clinical tests used during reassessment will depend on the nature of the condition being evaluated.

"Interactive assessment" includes procedures which direct treatment for that patient visit. These typically include procedures which provide indications for manipulation/adjustment, such as palpation and other spinal motion assessment.

Periodic reassessment includes: 1) repetition of actions or clinical procedures which upon prior examination provided information about the chief complaint and which led to the clinical impression. Examples include range of motion, tenderness and positive pain provocation signs; 2) repetition of tests wherein abnormalities were detected on initial examination (e.g., deep tendon reflexes); 3) new procedures not previously performed but indicated by the patient's clinical condition; 4) special studies (e.g., C.T. scan) which may impact the course of therapy when there has been failure to improve or deterioration in the patient's condition.

Spinal radiography is used widely as a reassessment tool but definitive studies on level of appropriateness are lacking. There is also little scientific evidence to validate many of the commonly used procedures and tests in neuromuscular diagnosis. There is even less documentation of validity and reliability with respect to procedures specific to the manual arts. Existing criteria and practice appear to have evolved empirically from clinical experience and convention. However, such procedures are widely used. As in all health care, if we depend entirely upon scientific method to determine the inclusion or exclusion of evaluation procedures, we would be left with a paucity of procedures with which to arrive at a working clinical impression.

The way in which reassessments are made needs considerable clarification. Interactive procedures should be simple and allow for assessment in an ongoing practice. Analog pain scales provide a tool for regular pain assessment, whereas pain questionnaires are more cumbersome and difficult to administer on an ongoing basis. Periodic evaluations may have more formal structure and detail. They may include more extensive questionnaires regarding pain, patient satisfaction and activities of daily living, functional disability assessment, and more extensive physical examination procedures. The evaluative procedures selected will depend upon the nature and role of reassessment.

Frequency of periodic reassessment is determined by several factors such as the severity or urgency of the condition or the likelihood of progression and degeneration. Scoliosis is an excellent example of a condition in which the frequency of reassessment varies with the severity and location of the condition, the age of the patient and history of prior progression. Truly life-threatening conditions requiring continuous monitoring, or even daily monitoring, are rarely found in chiropractic practice, and if they are the patient should be referred to an appropriate facility. Severe acute conditions should be assessed frequently. A patient's need for reassessment may also change during the course of care, depending upon progress. If the patient's condition demonstrates marked improvement, then reassessment should become less frequent. Conversely, if the patient deteriorates, reassessment should be performed as soon as possible to determine an appropriate course of action.

The practitioner's role in integrating information from diverse sources and prescribing or administering treatment can be assisted by reassessment information contributed by a vari-

ety of individuals. Some aspects of reassessment may involve appropriately trained and qualified employees of the attending practitioner. Others may require the assistance of specialized facilities, such as advanced imaging centers. The chiropractic practitioner assumes the role of team captain, coordinating the efforts of a health care team in the evaluation, diagnosis and management of the patient.

V. ASSESSMENT CRITERIA

Procedure Ratings (System II)

Necessary: Strong positive recommendation, based on Class I evidence, or overwhelming Class II evidence when circumstances reflect compromise of patient safety.

Recommended: Positive recommendation, based on consensus of Class II and/or strong Class III evidence.

Discretionary: Positive recommendation, based on strong consensus of Class III evidence.

Unnecessary: Negative recommendation, based on inconclusive or conflicting Class II, III evidence.

Quality of Evidence:

The following categories of evidence are used to support the ratings.

Class I:

A. Evidence of clinical utility from controlled studies published in refereed journals.

B. Binding or strongly persuasive legal authority such as legislated or case law.

Class II:

A. Evidence of clinical utility from the significant results of uncontrolled studies in refereed journals.

B. Evidence provided by recommendations from published expert legal opinion or persuasive case law.

Class III:

A. Evidence of clinical utility provided by opinions of experts, anecdote and/or by convention.

B. Expert legal opinion.

VI. RECOMMENDATIONS

A. Reassessments - General Principles

Reassessments are an integral component of case management and should be made following an appropriate period of care.

9.1.1 **Rating:** Necessary
Evidence: Class II, III
Consensus Level: 1

The necessity for and the content of reassessments are determined by the patient's response. Patients responding as expected might be reassessed later and with fewer tests; those not responding or responding more slowly should be re-evaluated sooner and possibly more thoroughly. A knowledge of the natural history of the condition greatly facilitates decisions concerning the timing of reassessment.

9.2.1 **Rating:** Necessary
Evidence: Class II, III
Consensus Level: 1

Appropriate reassessment shall be made as soon as possible if the patient demonstrates a marked worsening of clinical status.

9.3.1 **Rating:** Necessary
Evidence: Class III
Consensus Level: 1

Appropriate reassessment shall be made if the patient begins to manifest clinical signs or symptoms in areas not previously evaluated.

9.4.1 **Rating:** Necessary
Evidence: Class II, III
Consensus Level: 1

Reassessment should be performed by persons appropriately trained and qualified in the specific procedures.

9.5.1 **Rating:** Necessary
Evidence: Class II, III
Consensus Level: 1

Reassessment should be performed, as closely as possible, in the same manner as the initial assessment.

9.6.1 **Rating:** Recommended
Evidence: Class I, II, III
Consensus Level: 1

Reassessments performed solely to satisfy third party interests should be performed with due regard for all the recommendations presented in this chapter.

9.7.1 **Rating:** Recommended
Evidence: Class III
Consensus Level: 1

Interactive reassessment should be performed during each patient encounter for the purpose of confirming or modifying a clinical impression.

B. Interactive Reassessment

9.8.1 **Rating:** Necessary
Evidence: Class III
Consensus Level: 1

C. Periodic Reassessment

Periodic reassessment should be performed only after it would be reasonably expected that some measurable change in the patient's clinical condition would have occurred.

9.9.1 Rating: Necessary
Evidence: Class III
Consensus Level: 1

Periodic reassessment should be made in all areas in which there were prior positive clinical findings.

9.10.1 Rating: Necessary
Evidence: Class III
Consensus Level: 1

VII. COMMENTS, SUMMARY OR CONCLUSION

None.

VIII. REFERENCES

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IX. MINORITY OPINIONS

None.

10

Outcome Assessment

"If we are told that the serum cholesterol is 230 mg per 100 Ml, that the chest x-ray shows cardiac enlargement, and that the electrocardiogram has Q waves, we would not know whether the treated object was a dog or a person. If we were told that capacity at work was restored, that the medicine tasted good and was easy to take, and that the family was happy about the results, we would recognize a human set of responses."

(Feinstein, 1972)

Chapter Outline

I. OVERVIEW

Donabedian (1982) discussed health care quality in terms of structure (organization), process (procedures) and outcomes (benefits and harms). He defined outcomes to mean a change in a patient's current or future health status that can be attributed to antecedent health care. By using a broad operational definition of health, such things as improvement in social and psychological function can be added to the more traditional measures of physical and physiological function. Coile (1990) writes that while the history of quality care in the U.S. may have focused on the first two concepts, the current trend is swinging to assessment of outcomes as a way to hold health care practitioners accountable for their work. Ellwood (1988) agrees that outcomes are integral to definitions of quality health care.

Chiropractic clinicians and researchers have also recognized and stressed the importance of emphasizing outcome assessments (McLachlan, 1991; Hansen, 1991; Adams, 1991; Jose, 1991). This trend is consistent with chiropractic practice because the chiropractic profession has always philosophically emphasized health in its broader definitions and championed the positive potential of human beings in their environment.

The broad perspective on health outcomes leads to contemplation of a very large number of assessment or measurement procedures ranging from the social to the physical sciences. Discussion of all possible outcome assessments is beyond the scope of this chapter. The emphasis will be on outcomes related to conditions of the neuromusculoskeletal system because they represent the largest proportion of chiropractic patient complaints. General health assessment measures are very important and will also be discussed. In general, a parsimonious view of outcomes is taken, still with the idea that the needs of the patient, the practitioner and society are all important in assuring the overall quality of chiropractic care.

Outcome assessments vary considerably depending on the scope of clinical phenomena one might want to measure and the target patient population. General health outcome assessments, which have received considerable attention in recent years, attempt to measure a number of attributes deemed important to the overall concept of health. Health outcomes are important to patients, whereas physicians traditionally use more specific outcomes such as laboratory test results to assess the effects of care.

At first glance, it would seem that the results of diagnostic tests and the diagnosis itself would make ideal outcome measures. But this point of view is too narrow, emphasizing mostly physiological mechanisms more important to the practitioner's decision-making process than to the broader needs of patients and society.

There is a distinction between procedures used for diagnosis and those used for assessing the outcome of care. The purpose of a diagnosis is to label the pathological entity so that the doctor can formulate an appropriate treatment plan. Different diagnoses usually imply different treatments. In contrast, the purpose of an outcome assessment is to measure a change in patient status as a result of treatment. The same outcome assessment may be used to measure the effect of different treatments for any number of diagnoses (for example, a general health questionnaire). Also, a diagnosis may not change even though the health status of the patient may improve under care. On the other hand, if the goal of treatment is to eliminate the diagnosed disorder (i.e., "cure" the patient), then the appropriate diagnostic and outcome procedures may be one and the same.

The discussion and recommendations in the chapters on imaging, instrumentation, clinical laboratory, clinical impression, and reassessment also have a bearing on the general topic of outcome assessment. Because those chapters deal in some detail with diagnostic procedures potentially useful as outcome procedures, and with other case management considerations, some procedures may be only briefly mentioned here.

Appropriate standardized outcome assessments are useful in normal clinical practice for they can:

- Consistently evaluate the effect of care over time
- Help indicate the point of maximum therapeutic improvement
- Uncover problems related to care such as noncompliance
- Document improvement to the patient, doctor, and third parties
- Suggest modifications of the goals of treatment if necessary
- Quantify the clinical experience of the doctor
- Justify the type, dose, and duration of care
- Help provide a data-base for clinical research
- Assist in establishing standards of treatment for specific conditions.

This chapter will recommend methods of assessing outcomes of chiropractic care based upon defined criteria, scientific evidence, and expert opinion that are valid, reliable, clinically useful in chiropractic practice, and able to be interpreted by those interested in the role of chiropractic health care in society.

II. DEFINITIONS

Outcome Assessment: This term refers to a procedure or method of measuring a change in patient status over time, primarily to evaluate the effect of treatment.

Chiropractic Care: This term refers to the behaviors, methods, procedures, etc., that chiropractic practitioners employ in the case-management of patients.

Instrument: This refers to a specific tool or measuring device. It includes questionnaires filled out by patients.

General Health Assessments: These are usually questionnaires completed by patients and scored for a number of attributes deemed important to the overall concept of health.

Disease (Condition Specific) Assessments: These outcome procedures can run the gamut from physiological tests to questionnaires. They are designed to elicit information about the specific signs and symptoms and other clinical characteristics of diseases or conditions. Condition specific assessments are usually more limited in scope than general health assessments.

Meta-analysis: This refers to a type of study that statistically pools the data from many relevant single studies in order to make summary conclusions about a topic.

Spinal Manipulative Therapy (SMT): This term refers to the range of manual care delivered in chiropractic practice. It includes adjustive, manipulative and mobilization procedures.

Subluxation Syndrome: This term is defined here to mean the clinical signs and symptoms that relate to pathophysiology or dysfunction of spinal and pelvic motion segments or to peripheral joints that may be amenable to manipulative/adjustive procedures.

Definitions of Concepts for Outcome Measures

In order to make suitable recommendations with respect to outcome measurements, a number of concepts must be considered (Deyo, 1991; Bombardier, 1987).

Validity/accuracy: This concept refers to the truth. It is the answer to the question: Does this outcome procedure/instrument actually measure what it is supposed to measure? In order to evaluate validity, the outcome procedure must correlate highly with a "gold standard" of comparison. In the absence of a "gold standard," other forms of validity testing can be applied. Systematic error causes a procedure to be less than 100% valid or accurate. Scientific experimentation is very suitable for determining the validity of a procedure.

Responsiveness: This term refers to the ability of an outcome assessment to detect clinically important changes over time. Sometimes this is referred to as the sensitivity of an outcome assessment to treatment. Responsiveness is a particularly important attribute of an outcome assessment because subtle beneficial clinical effects of care should be able to be detected. Scientific experimentation, especially randomized controlled clinical trials, provide the best evidence for the responsiveness of an outcome assessment.

Reliability/precision: While distinctions of definitions between these words do exist, the general meaning here reflects the ability of an outcome procedure to consistently give the same value upon repeated measurements of the same phenomenon (e.g., patient). Random error causes a procedure to be less than 100% reliable or precise. Scientific experimentation is very suitable for determining the reliability of a procedure. Related terms are intra-observer (-examiner-rater) reliability and inter-observer (-examiner-rater) reliability. These refer respectively to the degree that one observer agrees with his own repeated measurements; and the degree that two or more observers agree with each others' measurements of the same phenomenon. Reliability must be established in order to ensure that variation in an outcome assessment over time reflects a true change rather than measurement error.

Applicability/clinical relevance: This term refers to the relevance of an outcome procedure, in other words, how it may impact upon case-management decisions. It answers the question: Is this outcome important to measure in clinical practice? Relevance also varies with health condition. Different types of patients require different types of outcome assessments. Scientific experimentation is important in determining this characteristic.

Practicality: This refers to the feasibility issues related to an outcome procedure in clinical practice. Such things as cost, time efficiency, training requirements, patient acceptance, etc., must play a role in this determination. Scientific experimentation plays a significant role here, as well as clinicians' resources and inclinations, which may vary.

Safety: Safety refers to the degree of health risk an outcome procedure may present; especially to patients, but also to doctors and their staff.

Ratings: Two separate rating scales will be employed depending upon the nature of the recommendation.

III. LIST OF SUBTOPICS

A. Functional Outcome Assessments

B. Patient Perception Outcome Assessments
- Pain
- Satisfaction

C. General Health Outcome Assessments

D. Physiological Outcomes
- Range of Motion (regional)
- Thermography
- Muscle Function
- Postural Evaluations

E. Subluxation Syndrome
- Vertebral Position Assessed Radiographically
- Abnormal Segmental Motion/Lack of Joint End-play
- Abnormal Segmental Motion Assessed Radiography
- Soft Tissue Compliance and Tenderness
- Asymmetric or Hypertonic Muscle Contraction

F. Principles of Application

IV. LITERATURE REVIEW

The outcomes of health care may be characterized as falling into one of the following categories: death, disease, disability, discomfort, dissatisfaction, and destitution (Lohr, 1988). A more positive taxonomy would simply use the opposites of these words, e.g., survival rates, lack of disease, ability, comfort, satisfaction, and thrift. While easily understood in general, operational definitions and assessment procedures for outcomes of care that match the attributes mentioned above are more difficult to obtain.

For this review, a citation search was derived from original research, review papers and books from the chiropractic, medical and scientific literature. The topic and its research base is large. A great deal of material was referenced from Interstudy, an organization devoted to the scientific development of outcome assessments. Personal experience and opinions of those conducting clinical trials in the chiropractic community were also considered.

The literature on outcome assessments can be divided into studies that have concentrated on the development of procedures, those that have tested procedures for validity and reliability, and those that have used the procedures in assessing the effects of treatment in randomized clinical trials. The latter studies provide the best information on responsiveness.

The literature review will be divided into five major subtopics, reflecting the nature of the outcome assessment procedures under discussion: 1) functional outcome assessments; 2) patient perception outcome assessments; 3) general health outcome assessments; 4) physiological outcome assessments; and 5) the subluxation syndrome as an outcome assessment.

Disease-specific physiological measurements related to treatment outcomes number in the hundreds if not thousands, so only a small number of most relevant procedures deemed important to chiropractic practice are described here. Others are described in other chapters. The subluxation syndrome as an outcome assessment has elements of function, perception and physiology, but requires special consideration because of its importance to chiropractic clinical theory and practice.

It is difficult to conceptually separate some of the physiological outcomes from those related more specifically to the subluxation syndrome. Some readers may therefore disagree with the committee's categorization and feel that some procedures under physiological outcomes should be relegated to the subluxation syndrome category. The argument exists because there are different opinions about just how comprehensive the definition of the subluxation syndrome should be in terms of encompassing different types of spinal and locomotor pathophysiology or dysfunction.

Economic outcomes (assessing the costs and cost-effectiveness of care) are becoming increasingly important. Indeed, some have argued that cost accountability is more important to third-party payers than health outcomes. Practitioners certainly are not immune to such forces and they must pay attention to the economic effects of their care. The discussion of cost outcomes will not, however, be covered in this chapter. A good discussion of economic outcome issues related to chiropractic can be found in Nyiendo (1990).

Functional Outcome Assessments

Assessing a patient's function is a logical way to assess the behavioral effects of a disease and the outcome of care. Usually, patient functioning is verbally discussed between the patient and practitioner, but new questionnaire techniques may make such information more objective. For this chapter, functional outcome assessments refer to questionnaires designed to measure a patient's limitations in performing the usual human tasks of living. Functional questionnaires seek to quantify symptoms, function and behavior directly, rather than to infer them from less relevant physiological tests.

There are a large number of functional scales described in the scientific literature. Most of them have been developed to assess the behavioral effects of diseases of the neuromusculoskeletal system and to assess the effects of treatment for those diseases. Deyo (1990) presented an excellent review and summary of many functional assessments used in back pain research. Of particular note are the *Pain Disability Index* (Tait, 1987), the *Million Disability Questionnaire* (Million, 1982), the *Oswestry Disability Questionnaire* (Fairbank, 1980), *The Roland Morris Disability Questionnaire* (Roland, 1983), the *Waddell Disability Index* (Waddell, 1982), and the *Dallas Pain Questionnaire* (Lawlis, 1989). A modification of the *Oswestry Questionnaire* to make it useful for neck function was recently published by Vernon (1991).

A very detailed discussion of the validity, reliability, responsiveness, relevance, feasibility, and safety of the many functional scales is beyond the scope of this chapter. For further information the book *Measuring Health: A Guide to Rating Scales and Questionnaires* (McDowell and Newell, 1987) is very useful. In general, while there may be some gaps in the research base for many individual functional questionnaires, the usefulness of these types of instruments is apparent.

In terms of responsiveness, which is the ability of an instrument to document changes in health status, it is instructive to examine the clinical trials with respect to manipulative/adjustive treatment methods. This is not to suggest, however, that chiropractic care is synonymous with spinal manipulative therapy. Chiropractic care encompasses a wide range of conservative therapeutics.

There are at least 28 randomized clinical trials of spinal manipulative therapy (SMT) for painful complaints in the scientific literature (Shekelle, 1991; Haldeman, 1991; Ottenbacher, 1985; Anderson, 1992). In one meta-analysis (Anderson, 1992), the authors categorized the outcome assessments in 23 randomized trials into eight categories: patient re-

port of pain, overall clinical improvement assessed by the patient, overall clinical improvement assessed by the practitioner, range of trunk flexion, range of trunk extension, straight leg raising, work activities, and activities of daily living.

In general, the outcomes showing the greatest improvement with treatment by spinal manipulation were the functional measures (activities of daily living) and patients' report of pain. Outcome assessments in the form of ranges of trunk motion did not indicate as much improvement on the average, although improvement was certainly demonstrated in a proportion of studies. Clinical trials using the straight leg raising test as an indicator of improvement demonstrated mixed results, which is not surprising given the very mixed nature of the patients' complaints.

Most clinical trial investigators created their own functional scales and so did not use standardized outcome assessments of known validity and reliability. Berquist-Ullman (1977) used patients' reports of pain and dysfunction. Rasmussen (1979) used a measure of pain, spinal mobility, function and "fitness for work." Coxhead et al. (1981) reported measures of patient report of pain and return to work. Ongley et al. (1987) reported disability scores, and visual analog scales. MacDonald et al. (1990) used a disability scale and a linear analog pain scale. Nevertheless, most trials demonstrated a responsiveness to treatment.

Hadler et al. (1987) used the standard Roland Morris Disability scale while Meade et al. (1990) used the *Oswestry Disability Questionnaire*. Hsieh (1991) concluded that the *Roland Morris Questionnaire* and the *Oswestry Questionnaire* gave consistent but slightly different results in a chiropractic clinical trial.

Clinicians contemplating the use of functional instruments should be aware of differences between them and be able to choose the most appropriate assessment for their specific situation.

Patient Perceptions Outcome Assessments

Patient perceptions of pain and satisfaction have not traditionally been considered very important as outcomes in any quantitative fashion. This is probably because it was felt that patient perceptions were too subjective and variable to be of much use. This is despite the fact that clinical impressions of the value of treatments are most likely based on favorable comments by patients to their practitioners. Currently, however, health services researchers have discovered that patient perceptions, measured with appropriate procedures, may be an excellent way to measure many aspects of the quality of care (Donabedian, 1980; Cherkin, 1990).

Pain: Pain is a perception and most chiropractic patients have pain of the neuromusculoskeletal system. Low-back and neck pain probably represent about two thirds of all chiropractic patient concerns (Nyiendo, 1989).

In the acute stage, pain is a symptom indicating that tissue damage has occurred. In the chronic state, pain may persist in the absence of detectable tissue trauma and become a disease in its own right. It makes sense for practitioners to attempt to measure pain as a way of evaluating the success of their care (Sandoz, 1985).

There is a great deal of research in the scientific literature on pain measurement (McDowell, 1987; Melzack, 1983; Vernon, 1990). Indeed, many orthopedic and neurologic examination procedures rely upon patients' report of pain provocation. To discuss the entire range of potential assessment methods is again beyond the scope of this chapter, but details may be found in the references noted above and in other chapters.

Pain has a number of dimensions including severity (intensity), duration, and frequency. The dimension that is most commonly assessed is severity (Jensen, 1986). Methods run the gamut from single questions to complex surveys. In most cases, the patients report their own perception of pain.

Visual Analog Scales (VAS) consist of a 10 cm line anchored by two pain descriptors at either end of the line. Patients are asked to mark on the line a point that represents their perceived pain intensity. The properties of VAS have been extensively studied (Huskisson, 1982).

Numerical Rating Scales ask the patient to choose a number between 0-100 that represents their pain intensity. Another pain scale uses 11 ranked levels numbered 0-11 graphically depicted in boxes.

The so-called "Behavioral Rating Scale" has six levels, each with a description such as for the third level, "pain present, cannot be ignored, but does not interfere with everyday activities." Verbal rating scales use single word descriptors in three, four, five or more ranks.

One commonly used scale from the *McGill/Melzack Pain Questionnaire* called the Present Pain Intensity scale uses the words, "none, mild, discomforting, horrible, and excruciating."

An interesting comparison among the scales mentioned above indicated there were few differences between them, except that the "Visual Analog Scale" and the "Numerical Rating Scale" were more practical (Jensen, 1986).

Pain diaries can be useful to measure other dimensions of pain. Patients are instructed to daily indicate on a form the intensity, duration and frequency of their pain complaints. Parker (1978) used a patient report headache diary of severity, duration and frequency, and a disability score calculated from it. Pain diaries may also be very useful for single-case time-series research designs (Keating, 1985).

A famous pain measurement instrument is the *McGill Melzack Pain Questionnaire* (Melzack, 1975). It has been used in back pain treatment research and to describe chiropractic patients (Nyiendo, 1990). The *McGill Questionnaire* consists of twenty categories of words that describe qualities of pain. Patients indicate which words apply in their case. At least six different pain variables can be calculated from the instrument. While relatively well-studied in terms of validity and reliability (McDowell, 1987), it may present

some practical difficulties in clinical practice because it should be administered by an interviewer.

Most, if not all, clinical trials of SMT have utilized some way of measuring pain. For example, Coyer and Curwen (1955) used an outcome of "well" defined by lack of signs and symptoms of low-back pain presumably judged by the practitioner in consultation with the patient. Edwards (1969) assessed treatment on a five point scale of signs and symptoms judged by the doctor. Glover et al. (1974) used a scale of pain relief from 0 - 100%. Doran and Newell (1975) used a patient-reported six level pain relief scale. Koes et al. (1991) reported a randomized clinical trial for back and neck pain using severity of complaints and "global perceived effect," a subjective assessment of overall improvement. Lopes et al. (1991) in another clinical trial for cervical pain assessed pain and range of motion comparing a single manipulation to a mobilization. Both favorably affected range of motion, but pain measures favored manipulation.

Patient Satisfaction: Patient satisfaction is an important perception having not only to do with the actual effectiveness of treatment, but also the setting and the process of receiving care (Donabedian, 1980). Patient satisfaction may be an important marker of quality of care (Cleary, 1988), and it is increasingly evident that patient satisfaction is a consumer marketing target for managed care organizations.

Patient satisfaction outcomes have been studied by Ware and others (Ware, 1978; Lochman, 1983). Clearly, there are a number of dimensions that can be measured. They include: interpersonal manner, technical quality, efficacy/outcomes, accessibility/convenience, finances, continuity, physical environment, and availability. The *Patient Satisfaction Questionnaire* measures all eight dimensions (Ware, 1983). Ware also developed four questions that measure general satisfaction with care. According to Cherkin (1990), the *Visit-Specific Satisfaction Questionnaire* (Ware, 1988) is probably very appropriate for chiropractic outcomes.

Deyo (1986) developed a patient satisfaction scale specifically for patients with low-back pain. Recently, Cherkin (in press) developed and validated a back pain patient questionnaire that addressed three key dimensions of satisfaction: caring, information, and effectiveness.

One of the valuable aspects of assessing patient satisfaction is its global nature. For the great majority of ambulatory patients, certain dimensions of satisfaction may be assessed regardless of the nature of the health complaint or the diagnosis. Works by Sawyer (1991), Cherkin (1989), and Kane (1974) have suggested high levels of satisfaction with chiropractic care.

General Health Outcome Assessments

Assessment of general health status is philosophically congruent with the chiropractic viewpoint; that is, an emphasis on health as opposed to disease. General health has been notoriously difficult to define in operational terms, but progress in recent years has led to the development of a number of useful instruments that are increasingly being used as assessments of the outcome of health care (Nelson, 1989; Bronfort, 1991). A full detailed discussion of health status measurement is beyond the present scope, but an excellent review of the difficult conceptual issues and examples of various scales may be found in the book edited by Spilker entitled, *Quality of Life Assessments in Clinical Trials* (1990), and in other references (Kirschner, 1987).

The *Sickness Impact Profile* (SIP) (Bergner, 1981) is an extensively studied patient survey of a number of behavioral and psychosocial dimensions thought to reflect general health status: sleep and rest, eating, work, home management, recreation and pastimes, ambulation, mobility, body care and movement, social interaction, alertness behavior, emotional behavior, and communication. It has been used in back pain research (Deyo, 1986) as well as in other areas.

Another measure of general health was developed during the *Medical Outcomes Study* (Stewart, 1988) and has now been modified by *Interstudy* (1990). The SF36 questionnaire measures three major health attributes (functional status, well-being, and overall evaluation of health) and eight health concepts which yield eight indices: physical functioning, social functioning, role limitations due to physical problems, role limitations due to emotional problems, mental health, energy/fatigue, pain, and general health perception (*Interstudy*, 1990). The SF36 appears to be a useful way to standardize assessments across many types of clinical settings and for a variety of types of patients. The SF36 has been and is being used in several chiropractic outcome studies (Nyiendo, 1991; Kassak, 1991; Jose, 1991).

Another useful general health measure is the set of COOP Charts (Nelson, 1987). These utilize simple representative pictures as choices to answers that yield nine indices of general health. Three focus on specific dimensions of function, two are related to symptoms or feelings, three are concerned with perceptions, and one is a health covariate. They appear to be very practical, easy to administer and score and correlate well with other less practical measures.

Physiological Outcome Assessments

Range of Motion (regional): A standard examination of spinal and other joint physiology includes the measurement of the range of motion (ROM) that can be obtained by the patient. ROM is used to assess disability and impairment because of the assumed relationship to spinal function (AMA, 1988). Lack of motion is also considered a treatable dysfunction that can be addressed by a variety of manual and rehabilitative procedures. Commonly, these are SMT and exercise therapy.

In this section, regional trunk and neck mobility along with peripheral joint mobility will be considered. Segmental spinal

joint mobility is addressed in the section on subluxation syndrome.

Devices and methods of measuring ROM range from the simple to the sublime. Standard joint goniometers are common, but now there are more sophisticated tools, many with electronic data recording capabilities. Mobility can be assessed with the patient actively involved, or as the passive object being mobilized. One or all planes of motion may be assessed.

The reliability of a number of common methods of measuring trunk mobility of the lumbar spine was reviewed by Liebenson (1989). He concluded that the modified Schober technique, inclinometers, flexible rulers, and spondylometers had received the most scientific support. The fingertip-to-floor method was not considered valid because of errors introduced by hip motion, hamstring flexibility and arm length. Zachman (1989) compared a simple goniometer and the "rangiometer" and assessed examiner reliability for cervical ROMs. The "rangiometer" was considered moderately reliable. Nansel (1989) concluded that taking the mean of five repeated measures of cervical lateral flexion with an inclinometer was also a reliable method.

The responsiveness of kinematic measurements of the range of regional spine motion (neck or trunk mobility) has been repeatedly demonstrated in clinical trials of manipulative therapy (Anderson, in press; Ottenbacher, 1985), and under laboratory conditions. Nansel et al. (1989) measured cervical lateral bending asymmetries with a simple goniometer and found they could be reduced by lower cervical adjustments. In additional study, rotational asymmetries in the transverse plane were reduced by upper cervical adjustments (Nansel, 1991).

Evans (1978) reported outcomes of spinal flexion, while Sims-Williams (1978,1979) used spinal mobility (goniometer), and straight leg raising. Zylbergold (1981) made use of assessments of spinal mobility, and Nwuga (1982) used measures of spinal mobility and straight leg raising. Farrell (1982) used a functional rating questionnaire and lumbar motions as outcomes. Godfrey et al. (1984) utilized spinal mobility, while Gibson (1985) measured spinal flexion.

Arkuszewski (1986) used six signs and symptoms on a three point scale: posture, gait, pain, active spinal mobility, manual examination of spine, and a neurological evaluation. Waagen (1986) used a global index of spinal mobility created by summing the results of all planes of motion. Mathews (1987) also measured spinal mobility. Hoehler (1981) used measures of spinal mobility, straight leg raising, activities of daily living, and patient report of effectiveness.

While most studies of SMT have concentrated on lumbar spinal mobility, a number of trials assessed motion in the cervical spine. Brodin (1982) measured neck pain and cervical mobility as outcomes. Nordemar (1981) and Mealy (1986) used neck pain and cervical mobility. Howe (1983) assessed measures of cervical mobility and improvement in pain and stiffness. Lopes (1991) also assessed range of motion and pain immediately after manipulation.

Training and practice are required to conduct a valid and reliable assessment of ROM. Clinicians should be aware of the range of errors inherent in a chosen method. Also, such issues as patient positioning, patient motivation and proper interpretation of the instrument must be addressed. The cost of measuring devices can range from $15.00 to many thousands of dollars depending on the sophistication. Done skillfully, measuring ROM is generally safe.

Thermography: Thermography is the recording of heat from the body. There are many devices including sophisticated computer-assisted infrared imaging procedures, liquid crystal sheets, and a variety of hand-held instruments (many traditional to chiropractic practice). Infrared and liquid crystal technologies capture entire body regions, such as the trunk and lower extremities, yielding images similar to other imaging modalities. Thermography is not an anatomical test; however, it is thought to be primarily a physiological test of the vascularization of the skin. Hand-held instruments only measure very small areas of skin at a time. It has been established that, within limits, skin temperature is symmetrical. Asymmetry of heat emission determined by comparing one side of the body to the other is considered to be abnormal (Meeker, 1986).

Thermography is a controversial topic with some organizations endorsing it (Vlasuk, 1992), and others with substantially more conservative conclusions (American Academy of Neurology, 1990). As a diagnostic procedure, thermography may have use in certain disorders of the neuromusculoskeletal system (Plaugher, 1991; Meeker, 1986). It appears to be diagnostically sensitive to some disorders, but the major criticism is that diagnostic specificity is lacking to the extent that it cannot replace other types of examination procedures. The research database on thermography has been severely criticized in one meta-analysis of the procedure for lumbar spine disorders (Hoffman, 1991), and its overall utility in clinical practice has also been questioned (Awerbuch, 1991).

There are a few limited studies of the reliability of some thermographic devices in chiropractic settings (Meeker, 1986; Plaugher, 1991; DeBoer, 1985; Keating, 1990). Nonexistent to moderate agreement above chance was generally demonstrated (depending on the instrument and the anatomy tested), but the authors were uniformly cautious about stating the technique was reliable enough for clinical purposes.

There are no randomized clinical trials using thermography as an outcome assessment, so responsiveness to treatment has not been determined. There are some published reports of thermographic changes while under conservative care (Sucher, 1990; Kelso, 1982; Diebert, 1972; Brand, 1982) but these have been uncontrolled, non-blinded, small sample observational efforts at best. Clearly, additional research is needed in this area.

Thermographic equipment can be inexpensive for the hand-held devices to many thousands of dollars for complete infrared systems. Standardized examination protocols are being established (e.g., Vlasuk, 1992) for infrared and liquid crystal

procedures. Generally these are detailed and require technical expertise. Certification programs have been established to train doctors to interpret thermograms. A legally acceptable examination done by protocol may take up to an hour. Fees charged to patients and third parties may be substantial.

There is very little published standardization for the less expensive hand-held devices, which may be included in patient examinations with little inconvenience of time or cost.

Muscle Function: The evaluation of muscle function encompasses a number of parameters: strength, work and power, and endurance (Sapega, 1990). Several modes of muscle contraction can be tested separately. These are termed isotonic, isokinetic, and isometric. The distinctions center upon the nature of the applied load or by the velocity and direction of change in the length of the muscle. Concentric contractions indicate a shortening of the muscle whereas eccentric contractions occur as the muscle is lengthening. Various sophisticated machines can now measure various combinations of these muscle function parameters in the extremities and the spine.

Quite a number of factors can affect the validity and reliability of muscle function testing. These include but are not limited to: stabilization and positioning of the body, velocity of test movements, gravitational influences, familiarity with testing procedures, inertial forces, calibration, time of day, and patient motivation (Sapega, 1990).

Most manual muscle testing procedures which are commonly used in the chiropractic profession combine elements of isometric testing with eccentric dynamic variable resistance. Manual methods are qualitative. It has been shown that examiners interpret muscular strength or weakness more on the basis of total effort they exert while overcoming a patient's resistance than on either the peak or average force (Sapega, 1990). This lessens the validity of manual tests as true tests of muscular strength (Nicholas, 1978). In one study, patients with as much as a 50% decrease in strength were rated as normal by manual methods (Watkins, 1984). Trained examiners found it difficult to detect differences of less than 25% between paired limbs (Beasley, 1956).

The reliability of manual muscle testing was assessed with a dynamometer in a chiropractic setting (Hsieh, 1990). The authors concluded that the "patient initiated" method yielded satisfactory scores for tests of the iliopsoas, the clavicular portion of the pectoral is major, and the external rotators of the hip. Dynamometers have also shown fair to good reliability in other studies (Sapega, 1990). There are no clinical reliability studies of manual muscle testing as used in some chiropractic techniques where a dichotomous decision ("strong" vs. "weak") is required. There are no clinical trials of a retrospective or prospective nature demonstrating the responsiveness of manual muscle testing to chiropractic care.

Instrumented measures of muscle function are further described in the chapter on instrumentation. Each method has advantages and disadvantages, but most have demonstrated adequate reliability when strict protocols are followed, and the ability to demonstrate changes in patients undergoing exercise or musculoskeletal rehabilitation.

Manual muscle tests are practical and generally safe. The instrumented methods can be inexpensive in the case of hand-held dynamometers to many thousands of dollars for the more sophisticated computerized measurement systems. If risks are minimized by following proper testing protocols the instrumented methods are also safe.

Posture: Postural measures are defined here to include measurements of humans of generally topographical nature. Anatomical relations include apparent limb length inequality, the shape of the spine (degree of lordosis, scoliosis, kyphosis), etc.

Apparent leg length inequality (specifically, lower limb length inequality) is often used as an indication for chiropractic care. There are many assessment methods; some are discussed in the chapter on instrumentation. The topic has been extensively reviewed by Mannello (1991). A range of clinical reliability has been established for some methods. The relationship of lower limb length to the chiropractic subluxation syndrome, however, has not been experimentally determined. There are no clinical trials using lower limb length measurements as outcome assessments, so responsiveness to care has not been established.

Two studies indicate that manipulations/adjustments may increase cervical lordosis (measured radiographically) (Leach, 1983; Owens, 1990). The clinical relevance of such changes, however, remains controversial.

Subluxation Syndrome

Historical chiropractic theory holds that manipulable lesions (subluxation syndrome) may be a cause or concomitant of some disease processes, especially dysfunctions of the locomotor system. Therefore, chiropractic care (primarily spinal adjustments and other manual procedures directed at joints) has had as one of its primary goals the reduction of clinical findings thought to be associated with such lesions.

The chiropractic subluxation syndrome (as opposed to simple joint misalignment) is described by most authorities (Haldeman, 1991; Schafer, 1989) as consisting of clinical signs and symptoms at a specific dysfunctional joint, which when manipulated or adjusted tend to diminish. Chiropractic practitioners use the concept of subluxation syndrome as a point of departure for clinical decision-making, most often to locate the site and decide on the nature of a manipulative/adjustive treatment procedure. Many practitioners have been taught that the subluxation syndrome is an adequate way to assess treatment, but this view is under increasing critical scientific scrutiny (Triano, 1990). One way to discuss the potential of using the subluxation syndrome as an outcome assessment of care is to describe some of its components.

Vertebral Position: Traditional chiropractic theory suggested that misalignment of vertebrae is a primary sign of a subluxation syndrome. The model for this deduction was probably based on notions of normal spinal geometry and symmetry, and images obtained from plane radiographs (Mootz, 1989). Palpation of bony processes could also lead to clinical conclusions of misalignment.

On plain radiographs, misalignments may be measured in many different ways; for example, by observing facet joint or vertebral body interfaces. Images can be obtained in a spinal neutral position while standing, sitting, or lying down. Radiographs have also been obtained with patients bent to the end-range in a plane of motion, for example as in lumbar lateral bending "stress" films. Many methods of "listing" or describing vertebral misalignments are common in chiropractic practice. Some methods are mostly qualitative (e.g., Gonstead) while some are quantitative (e.g., Grostic).

According to Haldeman (1991), most practitioners use the measurements of positional relationships of the spine to make a decision about the direction and nature of a manipulative/adjustive thrust, rather than to diagnose the site of the manipulable lesion.

To be a valid outcome measure, misalignments should theoretically reduce with therapy. A number of retrospective studies (Aldis and Hill [1982], Grostic and DeBoer [1982], Anderson [1980]) suggest that changes in apparent misalignments in the upper cervical spine do occur in patients under manipulative/adjustive care. In the lumbar spine, a similar observational study suggests that mild retrolisthesis may be reduced (Plaugher, 1990). (However, all other radiographic parameters in that study did not show changes.) A clinical trial (Roberts, 1978) also did not detect radiographic changes in low-back pain patients under manipulation. In one controlled experiment, Hosek (1984) found that upper cervical changes in the adjusted group were no different than those found in the non-adjusted control group.

There are very few experimentally controlled studies indicating that manipulations/adjustments are the reason for changes in misalignments seen over time. As Owens (1991) points out, errors in measurements due to patient re-positioning in front of a radiographic apparatus, radiographic distortion, examiner reliability, as well as normal biological variability may be equally responsible for changes in misalignments as treatment. Additional experimental studies are required.

Reports by Owens (1991) and others (Bronfort, 1984) suggest that margins of error in the radiographic measurement of angular relationships between vertebrae are on the order of one to two degrees depending on the method and portion of the spine under observation. But the central question still remains. That is, what is the clinical significance of misalignments, and do they really reduce as a consequence of manipulative/adjustive care? What is the correlation between the reduction of a misalignment and improved health for the patient? These questions beg for additional research.

One study (Keating, 1990) found no reliability of palpation for misalignment of vertebrae. There are no clinical trial outcome studies using palpation of bony landmarks as indicators of misalignment.

Abnormal Spinal Segmental Motion/Lack of Joint End-play: Abnormal vertebral motion is a logical outcome assessment since adjustive and manipulative methods by definition introduce forces into the body in an attempt to make tissues move. Abnormal motion may be most commonly assessed by radiographs or by palpation. Radiographs taken at end-ranges of motion are actually static images indirectly used to ascertain if an expected range of motion in a joint occurred. Videofluoroscopy is a relatively new imaging technique that can record spinal motion in real-time on video. (Imaging procedures are discussed extensively in another chapter).

Palpation of spinal tissues is a traditional diagnostic procedure for determining the site of a manipulable lesion and many palpatory techniques have been described (Schafer, 1989). The two most commonly defined palpatory parameters for abnormal vertebral motion are range-of-motion, or more precisely the inability of a joint to demonstrate an expected amount of motion in a specific plane; and the presence (or absence) of passive joint "play." Joint "play" or "end-feel" has been defined as the manual perception of a certain elasticity or compliance when the joint has been passively stretched to its limit. Lack of joint "play" is considered an indication for adjustment or manipulation. Logically, the return of normal range and quality of movement in a joint could be a good outcome measure of manipulation. Most practitioners are convinced of the clinical value of palpation.

Several qualitative reviews have summarized the scientific literature on spinal palpation in chiropractic (Panzer, 1991; Haas, 1991). Acceptable clinical reliability has been difficult to demonstrate although rates of agreement are greater than chance. Most studies have suffered from methodological flaws, however. Validity studies have been problematic due to the lack of acceptable "gold standards," but at least one small and restricted study (Jull, 1988) indicated 100% correlation between a palpating therapist's determination of the side and level of cervical joint pathology and a determination made independently by diagnostic joint and nerve block procedures.

Jull (1987) also published motion palpation norms for 200 healthy subjects of various ages on a five point rating scale. Age was correlated with segmental hypomobility. Intra-examiner and inter-examiner reliability was assessed and indicated Pearson's correlation coefficients ranging from 0.81 to 0.98.

Haas and Nyiendo (1990, 1991) have questioned the validity and reliability of lateral lumbar bending radiographs for patients with low-back pain. There does not seem to be a greater prevalence of "abnormal" findings in persons with a history of back pain compared to those without back pain. There are only a few studies using specific vertebral motion or joint "play" as an outcome measure. One study of SI joint palpation over time as patients received adjustments suggested

that as patients recovered, abnormal palpatory signs diminished (Herzog, 1990). Arkuszewski (1986) in a cohort study indicated that spinal palpatory signs also diminished to a greater extent in patients receiving manipulation compared to other treatments.

Soft-Tissue Compliance and Tenderness: Compliance refers to the attribute of flexibility or "hardness" when the soft tissues are pressed with a palpating finger or with a pressure scale. Usually in chiropractic practice, tissue compliance is assessed manually and is therefore qualitative. Compliance can also be assessed quantitatively with a pressure gauge instrument designed to measure the distance a plunger sinks into the skin at a given weight (Fisher, 1987, 1990). It is assumed that muscle tone is the primary physiology being measured, but other events, such as edema, may also play a role in compliance.

Waldorf (1991) concluded that prone segmental bilateral paraspinal tissue compliance measures (averaged together for a single segmental score) had a test/retest variation of less than 10% after two weeks in normal healthy pain-free subjects. Lawson's (1991) results also suggested good clinical reliability. Another study (Nansel, in press) using compliance as an outcome measure of cervical adjustments, demonstrated statistically significant changes in the lumbar paraspinal area. Fischer (1987) documented increases in tissue compliance in a small sample of patients undergoing physical therapy.

Tenderness refers to the sensation of pain expressed by a subject when pressure is applied to the body. Tenderness actually refers to a supposed hypersensitivity to pressure, although what this means quantitatively is rarely defined. A more precise definition is pressure pain tolerance. Tolerance can be further subdivided into threshold (the point where an initial sensation of discomfort is felt) or maximum (the point at which the patient cannot stand additional pressure stimulation). Tenderness threshold is one of the major palpatory signs used by practitioners for diagnostic and treatment assessment purposes. Most of the time clinical assessments are qualitative, but quantitative measurements of tenderness can be made with an algometer. An algometer (pressure pain meter) measures the degree of pressure a patient can endure before a pain sensation is elicited. The amount of pressure is then recorded.

Some tenderness norms have been published (Simms, 1988; Fischer, 1987), but these were with small relatively unrepresentative population samples. Clinical reliability of tenderness measures has been supported with studies by Reeves (1986) and Ohrbach (1989), who used algometers, and Keating (1990), who tested digital palpation.

Vernon (1990) measured pressure pain tolerance with an algometer in cervical paraspinal soft tissues before and after cervical adjustments in a small group of patients. Compared to a control group receiving mobilization, the adjusted group demonstrated a dramatic increase in pressure tolerance. This suggests that quantitative measurements of tenderness are responsive to manual treatments. Fischer (1988) documented decreases in tenderness with physical therapy. In addition, Jaeger (1986) indicated decreases in sensitivity in myofascial trigger points with passive stretch therapy.

Tissue compliance and pressure pain tolerance assessments, whether measured by palpation or with suitable instruments, can be incorporated into physical examination procedures with relative ease. The assessments are safe and inexpensive and appear to be responsive to conditions and treatments commonly seen in chiropractic practice. The quantitative methods are more suitable for documenting outcomes of care.

Asymmetric or Hypertonic Muscle Contraction: Although visual observations of postural antalgia and palpation of noncompliant soft tissue suggest muscle hypertonicity, these are merely explanations for what is actually seen or felt. Actual measurements of muscle activity can be obtained with electromyographic (EMG) methods. Needle methods are invasive and generally are beyond the scope of primary care chiropractic (although there are exceptions). Surface methods, which use electrodes on the skin, are within the scope and have become somewhat popular in chiropractic practice.

There is no question that surface EMG does measure some aspects of muscle activity, but it is not very muscle specific. Surface EMG tends to pick up signals from all muscular activity below the electrode. There is also a great deal of controversy about the clinical relevance, reliability, and responsiveness of various surface EMG examination methods (Nouwen, 1984; Triano, 1991).

A number of studies have discussed the relationship between trunk EMG and back pain (Dolce, 1985). Investigators have come to conflicting conclusions; some suggest that EMG can discriminate between subjects with and without back pain, others have not been able to demonstrate discriminatory ability (Cram, 1986; Nouwen, 1984). The data are confusing because many different parameters of EMG have been studied in poorly described clinical and control populations with noncomparable research designs and with flaws in experimental design and statistical analyses.

There are no high quality controlled studies that have indicated that spinal segmentally specific measures of surface EMG activity are related to segmental pathophysiology of the spine (subluxation syndrome). In addition, at least two studies in chiropractic settings did not support the hypothesis that findings of asymmetric paraspinal EMG can differentiate between subjects with and without a history of back pain (Meeker, 1991; Leach, 1991). Certain other measurements, such as the lack of "flexion relaxation response" and thoracolumbar ratios may have clinical value (Triano, 1987; Leach, 1991).

The few reliability studies that exist have demonstrated adequate within-session results but poor between-session (over time) consistency (Ahern, 1986; Matheson, 1988). One study claiming clinical reliability with hand-held "scanning" sensors had a median Pearson's R of only 0.64 for assessments one hour apart (Cram, 1990). Biederman (1984) has been very

critical of the reliability of EMG assessments and has identified a number of important sources of error.

Responsiveness has been assessed in studies with biofeedback therapy (Nouwen, 1984) and spinal manipulation (Shambaugh, 1987; Ellestad, 1988). These studies have been criticized and none have concluded that spinal segmentally specific changes have occurred as a result of treatment. Overall EMG activity did apparently decline.

Equipment varies from relatively simple hand-held devices to computer driven recording systems that yield a multitude of data. Training is necessary to conduct a valid examination, which can be time-consuming to do properly. There is very little standardization of examination procedures at this time. Surface EMG measurements are generally safe.

Reflex Testing: A number of chiropractic approaches use putative reflexes to test for the existence of a subluxation syndrome. Some of the more well-known are termed "isolation" tests (Activator Methods, 1985), the "arm fossa" test (De Jarnette, 1984), vertebral "challenge" (Walther, 1988), and "therapy localization" (Walther, 1988). Generally, these tests rely upon digital stimulation of spinal or paraspinal tissues to cause a change in apparent leg position or muscle function to indicate a positive finding.

Youngquist (1989) reported Kappa co-efficients over 0.50 for interexaminer agreement on the presence of a cervical subluxation complex with the "isolation test" taught by Activator Methods. The study design has been criticized, however, and there are no clinical trials using the "isolation test" as an outcome assessment.

LeBouef (1990) reported that the positive results of the arm-fossa test were statistically different between lumbar symptomatic and non-lumbar symptomatic patients. Still, the percentage of false-negative test results was 40%. In additional study LeBouef (1992) concluded that 18 assessment procedures including the arm-fossa test were unlikely to be reproducible enough to constitute useful clinical procedures. There are no studies of the use of the arm-fossa test as an outcome assessment of chiropractic care.

There are no peer-reviewed studies of validity, reliability, or responsiveness to care of the "challenge" or the "therapy localization" procedure.

These tests, while appearing empirically useful to some practitioners also lack a theoretical base that could explain their modes of action. Their use is hotly debated by chiropractic clinicians.

V. ASSESSMENT CRITERIA

Procedure Ratings (System I)

Established: Accepted as appropriate by the practicing chiropractic community for the given indication in the specified patient population.

Promising: Given current knowledge, this technology appears to be appropriate for the given indication in the specified patient population. As more evidence and experience accumulate, this interim rating will change. This connotes provisional acceptance, but permits a greater role for the current level of clinical use.

Equivocal: Current knowledge exists to support a given indication in a specified patient population, though value can neither be confirmed nor denied. As more evidence and experience accumulate, this interim rating will change. Expert opinion recognizes a need for caution in general application.

Investigational: Evidence is insufficient to determine appropriateness. Further study is warranted. Use for a given indication in a specified patient population should be confined to research protocols. As more evidence and experience accumulate this rating will change.

Doubtful: Given current knowledge, this appears to be inappropriate for the given indication in the specified patient population. As more evidence and experience accumulate, this interim rating will change.

Inappropriate: Regarded by the practicing chiropractic community as unacceptable for the given indication in the specified patient population.

Quality of Evidence:

The following categories of evidence are used to support the ratings.

Class I:

Evidence provided by one or more well-designed controlled clinical trials; or well-designed experimental studies that address reliability, validity, positive predictive value, discriminability, sensitivity, and specificity.

Class II:

Evidence provided by one or more well-designed uncontrolled, observational clinical studies, such as case-control, cohort studies, etc. or clinically relevant basic science studies that address reliability, validity, positive predictive value, discriminability, sensitivity, and specificity; and published in refereed journals.

Class III:

Evidence provided by expert opinion, descriptive studies or case-reports.

Procedure Ratings (System II)

Necessary: Strong positive recommendation based on Class I evidence, or overwhelming Class II evidence when circumstances reflect compromise of patient safety.

Recommended: Positive recommendation based on consensus of Class II and/or strong Class III evidence.

Discretionary: Positive recommendation based on strong consensus of Class III evidence.

Unnecessary: Negative recommendation based on inconclusive or conflicting Class II, III evidence.

Quality of Evidence

The following categories of evidence are used to support the ratings.

Class I:

A. Evidence of clinical utility from controlled studies published in refereed journals.

B. Binding or strongly persuasive legal authority such as legislation or case law.

Class II:

A. Evidence of clinical utility from the significant results of uncontrolled studies in refereed journals.

B. Evidence provided by recommendations from published expert legal opinion or persuasive case law.

Class III:

A. Evidence of clinical utility provided by opinions of experts, anecdote and/or by convention.

B. Expert legal opinion.

VI. RECOMMENDATIONS

NOTE: The recommendations on the following procedures or methods refer specifically to their use as outcome assessments and not necessarily to their use for other clinical purposes such as for diagnosis, prognosis, or for designing treatment plans.

A. Functional Outcome Assessments (By Questionnaire)

As a category, functional outcome assessments of everyday tasks are very suitable for evaluating treatment of dysfunctions of the neuromusculoskeletal system. Many questionnaires could be used; choice should depend upon the validity, reliability, responsiveness, and practicality demonstrated in the scientific literature.

10.1 Rating: Established for assessing patients with neuromusculoskeletal disorders.
Evidence: Class I, II, III
Consensus Level: 1

B. Patient Perception Outcome Assessments

Pain: Pain measurement is generally a relevant, valid, reliable, responsive, and safe outcome assessment. Practicality may vary depending on the specific procedure used.

10.2.1 Rating: Established
Evidence: Class I, II, III
Consensus Level: 1

Patient Satisfaction Measures: Patient satisfaction measures are an important marker of quality and are useful in clinical practice. Satisfaction is best assessed using standard questionnaires measuring a number of dimensions. Scales may be found in the scientific literature. Although additional research as satisfaction relates to chiropractic practice is required, validity, reliability, responsiveness, relevance, safety and practicality are scientifically supported.

10.2.2 Rating: Established
Evidence: Class I, II, III
Consensus Level: 1

C. General Health Outcome Assessments

As a category of outcomes, general health is possible and desirable to assess. Depending on the particular scale chosen, validity, reliability, and responsiveness have been demonstrated. The measures are safe; some are more practical than others. General health assessments should be used along with condition specific assessments.

10.3.1 Rating: Established
Evidence: Class I, II, III
Consensus Level: 1

D. Physiological Outcomes

Range of Motion: Depending upon the method applied, assessment of range of motion is a valid, reliable, responsive, safe outcome assessment. Depending on the level of automation, practical considerations may vary.

10.4.1 Rating: Established
Evidence: Class I, II, III
Consensus Level: 1

Thermography: Thermographic exams of the trunk and extremities with infrared or liquid crystal may be valid for certain diagnoses of the neuromusculoskeletal system. The validity of the numerous single and dual probe type hand-held instruments is less clear. The few reliability studies that exist are not particularly encouraging. There is very little scientific data to support the responsiveness of thermographic measurements to changes in health status. The procedures are generally safe, but the practicality of thermography depends upon the equip-

ment and the examination procedures used. Thermograms should be interpreted by those trained in the procedure.

10.4.2 Rating: Investigational to equivocal as an outcome assessment for patients with neuromusculoskeletal conditions.
Evidence: Class II, III (For minority opinion, see Section IX, 10.7.1)
Consensus Level: 3

Muscle Function: There are many methods of assessing the parameters of muscle function. Manual methods have not been explored adequately enough to assure validity, reliability, relevance and responsiveness to care. Manual methods, however, are practical and generally safe and tend to be popular. Studies with automated methods (e.g., Cybex, etc.) have suggested a greater level of confidence, but require expert training, and are time-consuming.

10.4.3 Rating: Established for instrumented methods to measure muscle function.
Evidence: Class I, II, III
Consensus Level: 1

10.4.4 Rating: Equivocal for manual methods to measure muscle function.
Evidence: Class II, III
Consensus Level: 1

Postural Evaluations: Certain postural parameters may be responsive to treatment, but validity, reliability and relevance issues still need to be addressed scientifically. Depending on the method, postural observations are probably practical and safe.

10.4.5 Rating: Promising
Evidence: Class II, III
Consensus Level: 1

E. Subluxation Syndrome

The subluxation syndrome provides decision-making information for application of chiropractic treatment methods, primarily adjustments and manipulations. Regarding outcome assessments, the various components must be considered separately. These are discussed below.

Vertebral Position Assessed Radiographically: The clinical relevance of small changes in vertebral position is scientifically controversial. Responsiveness of vertebral position to manipulative/adjustive treatment care has been established in some cases. Observational studies have not ruled it out. Many practitioners accept measurement of vertebral position as routine and customary. The risk/benefit ratio of using radiographs for measuring vertebral position as an outcome assessment should be carefully considered.

10.5.1 Rating: Equivocal
Evidence: Class II, III
Consensus Level: 1

Abnormal Segmental Motion/Lack of Joint End-play Assessed by Palpation: There are a few validity studies of joint palpation although the existing literature on reliability is disappointing. There are studies suggesting that palpatory signs diminish with treatment, but the degree of responsiveness has been difficult to quantify. In skilled hands, palpation is safe.

10.5.2 Rating: Equivocal to Promising (as an outcome assessment for patients with neuromusculoskeletal conditions)
Evidence: Class II, III
Consensus Level: 1

Abnormal Segmental Motion Assessed Radiographically: There are few validity studies, reliability has been questioned, and the relevance is controversial. While responsiveness of segmental motion to treatment has not been confirmed experimentally, observational studies have not ruled it out. The risk/benefit ratio of radiographs to assess this outcome must be seriously considered.

10.5.3 Rating: Investigational (as an outcome assessment for patients with neuromusculoskeletal conditions).
Evidence: Class II, III
Consensus Level: 1

Soft-Tissue Compliance and Tenderness: Clinical studies indicate a relationship between tenderness and painful neuromusculoskeletal conditions. Clinical reliability has been established. Compliance and tenderness appear to be responsive to treatment. Algometers, tissue compliance meters, and palpatory methods appear to be practical and safe.

10.5.4 Rating: Promising (as an outcome measure for patients with neuromusculoskeletal conditions).
Evidence: Class I, II, III
Consensus Level: 1

Asymmetric or Hypertonic Muscle Contraction: There is no question that surface EMG procedures measure some aspects of muscle activity. However, clinical relevance and reliability have been more difficult to demonstrate scientifically. The responsiveness of EMG measurements to treatment has not been confirmed experimentally to any great degree. Surface methods are safe.

10.5.5 Rating: Equivocal for fixed electrodes as an outcome assessment for patients with neuromusculoskeletal conditions.
Evidence: Class I, II, III
Consensus Level: 1

10.5.6 Rating: Investigational to Equivocal for scanning EMG as an outcome assessment for neuromusculoskeletal conditions
Evidence: Class II, III (For minority opinion see Section IX, 10.7.2)
Consensus Level: 3

F. Principles of Application

The subluxation syndrome should be used as an outcome assessment only when the actual parameters being measured have been explicitly identified.

10.6.1 Rating: Recommended
Evidence: Class II, III
Consensus Level: 1

Outcome assessments should only be performed and interpreted by appropriately trained and qualified individuals.

10.6.2 Rating: Necessary
Evidence: Class II, III
Consensus Level: 1

When outcome assessments are used, consideration must be made for their established test properties, for patient compliance, and for the nature of the condition(s) being assessed.

10.6.3 Rating: Necessary
Evidence: Class II, III
Consensus Level: 1

Patient outcomes should be assessed at appropriate intervals during case management depending upon the nature of the condition and the patient's progress.

10.6.4 Rating: Necessary
Evidence: Class II, III
Consensus Level: 1

Generic functional and health status outcome measurements are essential for comparing outcomes across different patient populations and treatment interventions, while disease or condition-specific measures assess the special concerns of patients with certain diagnoses. Outcome information is very valuable to doctors of chiropractic, and to the chiropractic profession. Therefore, whenever feasible, a general health outcome of chiropractic care should be assessed by a standardized, commonly accepted method; and whenever feasible, a condition specific outcome of chiropractic care should be assessed by a standardized, commonly accepted method.

10.6.5 Rating: Recommended
Evidence: Class II, III
Consensus Level: 1

VII. COMMENTS, SUMMARY OR CONCLUSION

None.

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IX. MINORITY OPINIONS

Thermography: Thermographic exams of the trunk and extremities with infrared or liquid crystal may be valid for certain diagnoses of the neuromusculoskeletal system. The validity of the numerous single and dual probe type hand-held instruments is less clear. The few reliability studies that exist are not particularly encouraging. There is very little scientific data to support the responsiveness of thermographic measurements to changes in health status. The procedures are generally safe, but the practicality of thermography depends upon the equipment and the examination procedures used. Thermograms should be interpreted by those trained in the procedure. (For majority recommendation see 10.4.2.)

10.7.1 Rating: Equivocal as an outcome assessment for patients with neuromusculoskeletal conditions

Asymmetric or Hypertonic Muscle Contraction: There is no question that surface EMG procedures measure some aspects of muscle activity. The responsiveness of EMG measurements to treatment has not been confirmed experimentally to any great degree. Surface methods are safe. (For majority recommendation see 10.5.6.)

10.7.2 Rating: Equivocal
Evidence: Class I, II, III

11

Collaborative Care

Chapter Outline

I. OVERVIEW

All patients of all primary health care providers have the right to expect health care services at the highest level of quality. The preservation of patient trust and confidence depends on this. When the needs of the patient demand the inclusion of other providers[1] or institutions in the program of care, extra caution and extra effort are required to ensure that no gaps in service or conflicts will be allowed to jeopardize the quality of care. The chiropractic practitioner should be aware of programs of cooperation and/or collaboration which can assist the patient.

Relationships between health care professionals can only become more complex, and possibly more contentious as we presently enter an era of great change and instability in health care. Concepts such as "managed care," "preferred provider" and "gatekeeper physician" are becoming the new currency of health care policy. As efforts to control health care costs center more and more on the managed care theory of cost and utilization containment, a credible protocol for interaction becomes an urgent necessity.

To ensure that all requirements for patient care can truly be addressed, this new model must consider cooperative relationships in all settings, including institutional settings such as the hospital; nursing home, and hospice, and among all health care professionals. The model to be devised must be comprehensive, clear to all parties involved, and flexible and dynamic enough to adapt to the daily realities of practice.

Finally, as competition for the health care dollar intensifies, it is particularly important that the chiropractic profession take steps to ensure that relationships with other providers are not tainted by economic self-interest or professional rivalry. Likewise, we must carefully safeguard the rights of chiropractic patients and ensure that other providers are conscious of the need to conduct patient care in a totally objective and professional manner. When professions interact in the delivery of health care services, economic and social factors as well as professional territorialism should never be allowed to override the fundamental obligation to the patient. There is no place for such distractions in the delivery of quality health care.

II. DEFINITIONS

Case Management: the process of evaluating patient needs or indicated care so as to provide service at the optimum level. All providers make case management decisions for each patient using a variety of variables and indicators. This concept takes on additional meaning in managed health care plans, where a professional "gatekeeper" or "key physician" is designated by the patient or by the plan, and has responsibility to determine what care should be provided for a given episode. In such managed health care plans it is the role of the managing "gatekeeper" to provide or authorize only such care as is truly needed. This care is from the most appropriate provider having regard to considerations of quality control and cost-containment.

Clinically Necessary: services or supplies which are determined to be:

(1) appropriate and necessary for the symptoms, diagnosis/clinical impression or care/treatment of the patient condition, and,

(2) provided for the diagnosis/clinical impression or direct care and treatment of the health care condition, and,

(3) according to standards of good primary health care practice within the organized professional community, and,

(4) not primarily for the convenience of the patient, or one or more of the patient's providers, and,

(5) the most appropriate supply or level of service. For hospital stays, this means that acute care as an inpatient is necessary due to the kind of services the patient is receiving or the severity of the patient's condition, and that safe and adequate care cannot be received as an outpatient or in a less intensified clinical setting.

Collaborative Care: the reciprocal interprofessional interaction of two or more health care providers in the management of the patient's current health status.

Emergency: onset of a medical/health condition manifesting itself by acute symptoms of sufficient severity that the absence of immediate attention could reasonably result in:

1. permanently placing the patient's health in jeopardy;
2. causing other serious health consequences;
3. causing serious impairment to bodily functions; or
4. causing serious and permanent dysfunction of any bodily organ or part.

Gatekeeper: Health care professional designated to exercise responsibility for, and control of, the utilization of health care services. (The concept of "gatekeeper physician" is the cornerstone of HMO/prepaid plan efforts to deliver care at the optimum level, thus avoiding both underutilization and overutilization.)

MHCO (Managed Health Care Organization): An organized system for providing health care in a geographic area, accepting the responsibility to provide or otherwise assure the delivery of an agreed upon set of services to a voluntarily enrolled group of persons (e.g., HMO, PPO, etc.).

Overutilization: The provision of more than an appropriate or adequate amount of care in a given case. (See "underutilization".)

Patient Satisfaction: Degree of confidence and gratification accompanying the delivery of health care services. Patient satisfaction relates strongly to perceptions on the part of the patient that his/her wishes are being carried out, that quality

care is being delivered, and that patient sensitivities are being respected. These perceptions are based on subjective patient feelings, and may or may not deal with issues of technical appropriateness of care or outcomes.

Doctor Visit: a visit to the doctor of medicine, chiropractic, osteopathy or other physician for the purpose of examination, diagnosis, treatment/care, or advice.

Primary Care Doctor:

(1) any health care provider capable of providing first level contact and intake into the health delivery system (portal-of-entry provider).

(2) any health care provider licensed to receive patient contact in the absence of physician referral.

Quality of Care: the degree to which care is provided in an appropriate manner, within an appropriate time frame.

Referral: the direction of a patient to another health care professional or institution for evaluation, consultation or care. Referrals may be made or received for purposes of consultation; concurrent care, post-chiropractic care, the administration of diagnostic procedures, the evaluation of diagnostic findings, emergency care or because a clear determination has been made on the part of the practitioner that a patient condition is outside his/her scope of professional experience.

Underutilization: the provision of less than an appropriate or adequate amount of care in a given case.

Utility: significant benefit to both the patient and clinician resulting from a reduction in uncertainty pertaining to the case.

III. LIST OF SUBTOPICS

Reasonable Patient Expectations in the Cooperative and Collaborative Care Setting

A. The Patient and the Primary Care Provider
B. Freedom of Choice and Informed Consent
C. Professional Knowledge and Understanding
D. Referrals
E. Exchange of Information and Records between Providers
F. Professional Interaction in the Hospital or Other Institutional Setting.
G. Economic Considerations

IV. LITERATURE REVIEW

Collaboration can be defined as the reciprocal interprofessional interaction of two or more health care providers. Collaborative care involves this interaction in the management of the patient's current health status. Collaborative care, therefore, includes care in a private practitioner's office, where interaction exists on a daily basis between the practitioner and his/her assistants, as well as care within a complex institutional setting such as a medical specialty ward in a hospital[2] and care within a managed care setting. Various specialty fields exist within chiropractic and are available as a resource.[3]

Hospitals and other institutional inpatient settings represent to some degree a new frontier for chiropractic. Chiropractic has an enormous contribution to make in this context. As well, hospitals are of great social, political and economic importance in North America. It is here that the largest publicly-supported concentration of leading-edge diagnostic equipment is to be found. Hospitals are also the scene of the vast majority of clinical information gathering and research.[4,5]

Collaborative care is neither new nor unique to this generation of providers,[1,6,7] though cooperative relationships between the medical and chiropractic professions have been less frequent in the past. The federal court judgment in 1987 in Wilk et al. vs. AMA et al.,[8] which effectively eliminated formal barriers previously established to the collaboration of the chiropractic and medical professions, has been a key factor in increasing cooperation. However, as greater emphasis is now being placed on the concept of nominating one primary care doctor as a "gatekeeper"[9] whose function is to ensure appropriate care yet contain specialist and other costs,[10] new effort is required to understand the appropriate role of different health disciplines. This is a difficult task for a number of reasons.

Firstly, from an organizational viewpoint, much of modern medicine is based on a "problem-oriented model" rather than one based either on the management of chronic, incurable illness or disease prevention. The problem-oriented model is less conducive to an interdisciplinary team approach than a "goal-oriented model" where the patient's achievement of highest possible level of health is the goal of all concerned.[11]

Secondly, as a number of authors have observed, coordination of health services has become a major characteristic of primary care.[12] As a result, an information system which fosters effective communication between health care professionals is essential.[13, 14] This is a particularly pertinent issue for chiropractic practice, where terms unique to the profession have been perpetuated in an effort to maintain an identity and philosophy.[15] As noted by Anderson, however, terms that are precise and accurate should be used because in interprofessional relationships, communication may well be frustrated by simple language barriers alone. If the principal goal is to aid the patient in the most appropriate and cost-effective manner, language preferences must be secondary to effective communication in the collaborative care setting.

Thirdly, overlap in knowledge and skills between the providers in any given case can result in confusion of roles. Which professional is to assume responsibility for which facets of individual care?[16] Role disagreement has been cited as an important factor in several arenas, from nurse practitioner/doctor in the Western world[17] to physicians/lay providers in

the health care team in third world countries.[10] It has been shown that there are significant differences both in time under care and the choice of diagnostic and therapeutic techniques provided to a patient depending upon the professional specialty of the provider.[19]

Clarity of roles is vital. This clarity is dependent to some extent on the probability of a successful treatment outcome and to some extent upon the provider chosen. This should be understood when clinical policies and guidelines are made on decision-making in patient management.[20] Dixon[21] has noted that while policies can be helpful in simplifying complex clinical dilemmas, they have at times been adopted without evidence of benefit and that research studies using appropriate clinical methodology should be encouraged in order to prevent useless or even dangerous algorithms of treatment.

The development of wise patient care guidelines, incorporating the many approaches available in health care today, should provide for the most effective balance of resources for the patient's needs. Determining the role of each profession in the various algorithms for patient management should reflect the varying and unique needs of each individual patient. Developing such algorithms, which are currently not in place nationwide, may reasonably be expected to have a significant impact on health outcomes in general, as well as on the difficult interprofessional issue of cost-containment. To that end, for example, Wennenberg[22] has stated that patients' understanding of their treatment options is anticipated to be a major contributing factor in their treatment selection. He noted that health care allocation by patient preference is likely to be cost-effective because patients prefer and select less invasive, less expensive treatments. It is in the best interest, therefore, of all concerned that the health care system have all its professional resources, and ready information on them, available to all patients.

Initially, as the chiropractic profession explores the arena of collaborative care more fully, documents generated by practitioners engaging in this work and setting out interprofessional referral protocols can serve as guidelines.[23,24,25] As part of the health care system at large, however, the chiropractic profession must now begin to focus more of its resources in researching and developing clinical standards relevant to collaborative care. As noted earlier, such efforts are needed to meet the many and varied needs of all patients.[26]

V. ASSESSMENT CRITERIA

Procedure Ratings (System II):

Necessary: Strong positive recommendation, based on Class I evidence, or overwhelming Class II evidence, when circumstances reflect compromise of patient safety.

Recommended: Positive recommendation, based on consensus of Class II and/or strong Class III evidence, expert opinion.

Discretionary: Positive recommendation, based on consensus of Class III evidence.

Unnecessary: Negative recommendation, based on inconclusive or conflicting Class II, Class III evidence.

Quality of Evidence

The following categories of evidence are used to support the ratings.

Class I:

A. Evidence of clinical utility from controlled studies published in refereed journals.
B. Binding or strongly persuasive legal authority such as legislative or case law.

Class II:

A. Evidence of clinical utility from the significant results of uncontrolled studies published in refereed journals.
B. Evidence provided by recommendations from published expert legal opinion or persuasive case law.

Class III:

A. Evidence of clinical utility provided by opinions of experts, anecdote and/or by convention.
B. Expert legal opinion.

VI. RECOMMENDATIONS

A. The Patient and the Primary Care Provider

1. Patients are entitled to a clear explanation of why the participation of other health professionals has been determined to be necessary.

11.1.1 Rating: Necessary
Evidence: Class II, III
Consensus Level: 1

B. Freedom of Choice and Informed Consent

1. All health care professionals should recognize and respect the right of the patient to select his/her own method of health care and the setting in which that care is delivered, as well as the right of the patient to change providers at will.

11.2.1 Rating: Necessary
Evidence: Class III
Consensus Level: 1

2. Primary health care providers should supply sufficient information to enable the patient to make an informed decision regarding choices in treatment/care and of providers.

11.2.2 Rating: Necessary
Evidence: Class III
Consensus Level: 1

C. Professional Knowledge and Understanding

1. Chiropractic practitioners should be familiar with medical procedures and terminology as needed, so as to effectively understand and relate medical care delivered to or recommended to a patient.

11.3.1 Rating: Recommended
Evidence: Class II, III
Consensus Level: 1

2. Chiropractic practitioners should make every reasonable effort to be familiar with alternative health care providers whose care may have implications for the care of their patients, and should strive to communicate such information, as appropriate, to the patient.

11.3.2 Rating: Recommended
Evidence: Class III
Consensus Level: 1

D. Referrals

1. Primary health care providers should consult or refer if the needs of the patient so indicate.

11.4.1 Rating: Necessary
Evidence: Class I, II, III
Consensus Level: 1

2. Chiropractic practitioners should accept referrals from other health care providers.

11.4.2 Rating: Recommended
Evidence: Class III
Consensus Level: 1

E. Exchange of Information and Records between Providers

1. Chiropractic practitioners referring a patient to a peer or another professional should take all necessary steps to provide information from the case history and diagnostic findings to the practitioner receiving the referral in an effort to minimize unnecessary testing or repetition of diagnostic procedures.

11.5.1 Rating: Recommended
Evidence: Class III
Consensus Level: 1

2. Postreferral communication between referring and receiving practitioners should be complete and adequately detailed. Appropriate records of clinical findings or recommendations should be exchanged.

11.5.2 Rating: Recommended
Evidence: Class III
Consensus Level: 1

3. Questions about care decisions made or recommended by another provider should be addressed directly to that provider in a constructive manner. Relying on the patient to be an effective messenger of critical information is inappropriate.

11.5.3 Rating: Recommended
Evidence: Class III
Consensus Level: 1

4. Response to requests for records should occur in a timely fashion. Likewise, records requested by the practitioner that are another practitioner's property should be returned in a timely fashion.

11.5.4 Rating: Recommended
Evidence: Class III
Consensus Level: 1

F. Professional Interaction in the Hospital or Other Institutional Setting

1. In a collaborative or cooperative care setting, every effort should be made to develop and present to the patient a consensus among all participating practitioners on the recommended course of care.

11.6.1 Rating: Recommended
Evidence: Class III
Consensus Level: 1

2. Practitioners should seek access to other health care facilities and institutions as necessary to meet the needs of their patients. This may include authority to admit or co-admit the patient into the appropriate clinical setting or hospital.

11.6.2 Rating: Recommended
Evidence: Class III
Consensus Level: 1

3. In the process of concurrent care, each professional party should be aware of the care decisions made by other participants, and fully coordinate activities and information for the patient's benefit.

11.6.3 Rating: Recommended
Evidence: Class III
Consensus Level: 1

4. The resolution of disputes between members of different professions on the course of care for a given patient should be based on: a) the best professional judgment of the practitioners involved; b) the objective evaluation of appropriate clinical

options and intervention alternatives; and c) responsible family involvement where appropriate.

Informed consent on the part of the patient continues to be necessary.

11.6.4 Rating: Recommended
Evidence: Class III
Consensus Level: 1

5. To facilitate patient access to the widest possible range of health care resources and options, practitioners are encouraged to seek participation in managed health care organizations (e.g., HMOs, PPOs, etc.).

11.6.5 Rating: Recommended
Evidence: Class III
Consensus Level: 1

G. Economic Considerations

1. No referral should be sought or made on the basis of economic considerations and no financial relationship should exist between parties in a referral process. No fee, rebate or commission should be paid to any referring provider for the referral.

11.7.1 Rating: Necessary
Evidence: Class III
Consensus Level: 1

2. Primary providers should cooperate to secure proper insurance payment for all clinically-indicated health care services.

11.7.2 Rating: Recommended
Evidence: Class III
Consensus Level: 1

VII. COMMENTS, SUMMARY, OR CONCLUSION

Professional behavior should be governed by the principles of the art and science of chiropractic, and a strict set of ethical canons which go beyond the legal obligations of licensure. Ethical requirements are as compelling and imperative to the delivery of quality care as any clinical indications.

Interaction between professions in a hospital or other institutional setting will be governed by the laws and regulations of the jurisdiction within which the facility operates and the rules and bylaws of the hospital or facility. Recognition of the degree to which professional roles are specified by such regulations should eliminate much of the confusion and concern surrounding the participation of chiropractic practitioners in the hospital setting.

In situations where patients need or request diagnostic outpatient services or inpatient care, the practitioner should provide a full and accurate explanation of his/her professional access to such facilities. It is important that degrees of institutional access be understood by all parties in a collaborative care situation. Under no circumstances should any chiropractic practitioner overlook or minimize the need to employ outside services because he/she does not have access, referral or staff privileges at a specific facility. It is incumbent upon the practitioner to find a means to meet patient needs on a timely basis, all such considerations notwithstanding.

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IX. MINORITY OPINIONS

None.

12

Contraindications and Complications

Chapter Outline

I. OVERVIEW

Most forms of treatment carry some risk of harm to the patient. While chiropractic procedures are considered comparatively safe, special caution is warranted with certain conditions. These include, for example, vertebral artery syndrome, herniated disc, and bone weakening processes.

Prevention of complications from treatment is facilitated when good professional judgment is exercised and quality care is provided. Elements common to all primary care practitioners include sufficient history taking and record keeping, thorough examination, timely re-evaluation procedures throughout the course of case management, good communication with the patient and appropriate response in the event that an unexpected incident does occur. With serious manipulative accidents, it is of critical importance that the intervention or procedure associated with the onset of the complication not be repeated.

Some of the complications reported in the literature could have been prevented. The development of acceptable preventative strategies to minimize future risk should be directed by methods of consensus, illuminated by continuous evaluation of research, protocol experience, and risk management and peer review programs. The expected goal of establishing guidelines for standards of practice is to assist practitioners to set and abide by standards which improve all aspects of patient care.

The scope of manipulative incidents and reactions may range from short-term pain and stiffness to cerebrovascular accidents arising from a dissecting aneurysm. This review of complications of and contraindications to high-velocity thrust procedures outlines various clinical conditions requiring treatment modification. Other manual procedures (e.g., soft tissue and low force technique procedures) are not addressed in this chapter. Guidelines for sound clinical management and prevention are recommended.

II. DEFINITIONS

Complication: The unexpected aggravation of an existing disorder or the onset of an unexpected new disorder as a result of treatment.

Classification of Complications.

a) **Adverse Effect:** Any detrimental result of an action or treatment.

b) **Reaction:** A slight or benign adverse effect of short duration usually lasting no more than a few days.

c) **Accident or Incident:** An unexpected event occurring by chance, unknown causes, carelessness, negligence, or a combination thereof, resulting in serious or permanent impairment, injury, or fatality. The onset of signs and symptoms may be immediate or a day or two following the treatment.

d) **Indirect Complication:** Delay of diagnosis and appropriate treatment as a consequence of using a procedure or treatment that, in retrospect, has proven to be of no benefit for the condition.

Contraindication—Absolute: Any circumstance which renders a form of treatment or clinical intervention inappropriate because it places the patient at undue risk.

Contraindication—Relative: Any circumstance which may place the patient at undue risk unless treatment approach is modified.

Effectiveness: Effectiveness refers to the potential any given procedure or group of procedures has to produce a desired effect under actual conditions of use.

Iatrogenesis: Disorders or complications caused by health care providers.

Instability: An unstable joint condition resulting in damage or symptoms under the influence of physiologic loading.

Joint Dysfunction (Manipulable lesion, subluxation, functional spinal lesion): Decreased or aberrant joint mobility for which manipulation is indicated. In this context the term excludes states of hypermobility or instability.

Management: A plan of action for treatment of the patient in accordance with diagnosis, progress, and expectations of outcome.

Manual Therapy: Broadly described as a skilled manual method of movement of the soft tissues and articulations. May include all manual procedures, such as massage, muscle energy and strain-counterstrain techniques, trigger point therapy, joint mobilization, manipulation, and articular adjustment.

a) **Stretching:** Techniques that attempt selectively to apply tensile forces along the length of specific ligaments or muscles. Loads used are quasistatic and are thought to bring about increased flexibility of the appropriate joint through passive means. Relaxation of muscle spasm and creep deformity of the elastic elements in connective tissues are commonly assumed mechanisms of action.

b) **Mobilization:** Passive movement within the physiologic joint space, administered by a clinician for the purpose of increasing overall range of joint motion.

c) **Soft Tissue Procedures:** A variety of manual techniques for soft tissue. As muscles and noncontractile structures lose function and elasticity, they have an effect on joint function. Most soft tissues are richly innervated with a variety of proprioceptive mechanisms, and often chiropractic application of soft tissue procedures will follow a traditional chiropractic rationale of attempting to improve a clinically identifiable aberrant neurologic reflex or pain pattern. Such work may be used in conjunction with other adjustive or manipulative approaches. Some practitioners use a

variety of soft tissue procedures for nonarticular purposes as well (e.g., abdominal pressure points may be stimulated in a constipated patient).

d) High-Velocity Thrusting: Techniques involving movement of the selected joint to its end range of voluntary motion, followed by the application of an impulse loading. These methods are among the most common in chiropractic practice and are often referred to as "manipulation" or "adjustment" to differentiate them from less dynamic procedures.

Motion Segment: The smallest functional unit, made up of two adjacent articulating surfaces and contiguous and intervening soft tissues.

Negligence: Breach of the legal duty of care placed on all practitioners to exercise reasonable care and skill in the circumstances.

Risk Management: A systematic preventative strategy to minimize patient harm and practitioner liability through education and the development of guidelines for practice.

Safety: Safety refers to a judgment of the acceptability of any risk in a specified situation during the application of a specific procedure or group of procedures provided by an individual with specified and appropriate training.

Specialist: A health care provider who has obtained a professionally accepted or recognized level of additional training and competence with respect to specific procedures or disorders.

III. LIST OF SUBTOPICS

Conditions selected have come from a review of the scientific and medicolegal literature as well as insurance claim information.

A. Articular Derangements

1. Arthritides
   i) Acute arthropathies
   ii) Subacute and chronic ankylosing spondylitis
   iii) Degenerative joint disease
   iv) Spondylolysis and spondylolisthesis
2. Dislocation, fractures, instability
3. Os odontoideum
4. Articular hypermobility
5. Postsurgical joint
6. Acute joint injury
7. Scoliosis

B. Bone Weakening and Destructive Disorders

1. Juvenile osteochrondroses
2. Osteoporosis, osteomalacia
3. Bone tumors
4. Malignancy
5. Infection of bone and joint

C. Circulatory and Cardiovascular Disorders

1. Vertebrobasilar, etc.
2. Aneurysm
3. Bleeding disorders

D. Neurological Disorders

1. Myelopathy, cauda equina syndrome

IV. LITERATURE REVIEW

Over the past two decades there has been a rapid growth of literature on manipulation-induced accidents or injuries. (Dvorak 1991; Patjin, 1991; Schmitt, 1991; Terrett, 1990, 1987; Grieve, 1986; Gotlib and Thiel, 1985; Schmidely and Koch, 1984; Gutmann, 1983; Dvorak and Orelli, 1982; Ladermann, 1981; Gatterman, 1981; Jaskoviak, 1980; Kleynhans, 1980; Livingston, 1971). There can be little doubt that the elevated level of reporting arises from a general increase in awareness of complications by all professionals interested in spinal manipulative therapy. Because some alleged "consequences" are consistent with the natural history of a condition, anecdotal or polemic reports must be distinguished from those that provide objective evidence of true manipulation-induced injuries. Some case reports of injury have proven to be unfounded upon further unbiased inquiry.

Complications that do occur in a chiropractic office setting may be attributed to the following (Shekelle et al. 1991):

- misdiagnosis
- presence of coagulation dyscrasias
- cervical manipulation
- presence of a herniated nucleus pulposus
- improper technique application

The relative harm caused by therapeutic procedures used by chiropractic practitioners may be appreciated by reviewing claims of malpractice. The National Chiropractic Mutual Insurance Company listed the six most common claims in 1990 as:

- disc problems - 29%
- failure to diagnose - 13%
- fracture - 9%
- soft tissue - 7%
- cerebrovascular accidents - 6%
- aggravation of prior condition - 4%

A review of claims made in Canada from 1978 to 1985 revealed that cervical injuries represented 34% of the frequency and 50% of the total cost of claims. The second most reported claim was lumbar injury accounting for a frequency of 19% and cost of 26% of all claims made. Common reasons for malpractice claims against practitioners were inappropriate treatment and poor patient communication. Aside from the treatment of functional disorders of the spine and extremities, other co-existing and unrecognized conditions are a significant factor in some accident claims. (Canadian Chiropractic Protective Association — CCPA Claims Review, to 1985).

A more recent CCPA Claim Review, for the period January 1986 to December 1990, revealed the following:

Lumbar spine injury	36 (23% of claims)
Rib Fracture	29 (19%)
Neck Injury	24 (16%)
Soft tissue/non-spinal injury	26 (13%)
CVA	12 (8%)
Other *	24 (16%)

(* fee dispute, patient perception of general injury, failure to diagnose, improper treatment, practitioner concern over lawsuit)

With respect to the frequency of complications, Ladermann (1980) identified 135 case reports of serious complications over a 30 year period from 1950-1980, a time period during which tens of millions of manipulations were administered by a variety of practitioners. Kleynhans (1980), analyzing some of these case studies, outlined a number of likely practitioner-related causes of adverse reactions and suggested three main factors: lack of knowledge or diagnostic error; lack of technique skill; and lack of rational clinical attitude in case management. These causes could well account for a number of iatrogenic injuries reported in the literature, e.g., pathological fractures (Austin, 1985; Holta, 1942), ruptured abdominal aneurysms (Komberge, 1988), electrotherapy burns and injuries, etc.

Jaskoviak (1981) and Terrett (1987) specifically dealt with case reviews on the adverse effect of cervical manipulation where vertebrobasilar insufficiency was evident. Gutmann (1984), Terrett (1987), Theil (1991) and Schmitt (1991) have recently described or studied the biomechanical effects of head and neck movement and cervical manipulation in association with vertebral artery injury. Manipulation has been identified as only one of many activities or health care procedures that may result in damage to the vertebral artery. However, it has been the one most extensively reviewed and discussed. (Pratt-Thomas and Berger, 1947; Gutmann 1957, 1962, 1971, 1984; Smith and Estridge, 1962; Maigne, 1969; Houle, 1972; Lewit, 1972; Giles, 1977; Henderson, 1979, 1991; George et al., 1981; Terrett, 1982, 1983, 1987; Hulse, 1983; Fast et al., 1987; Henderson and Cassidy, 1988; Martienssen and Nilsson, 1989; Raskind and North, 1990).

It is thought that cervical rotation combined with extension and traction may have some obstructive effect on perfusion of the vertebral artery on the contralateral side of rotation. If the ipsilateral artery is diseased or hypoplastic, symptoms of hind brain ischemia may occur because the dominant healthy artery is under partial physiological compression, resulting in a loss of sufficient or compensatory blood flow. If trauma to the arterial wall does occur, thrombus formation may be the result. Further, this may lead to stroke or stroke-like complications in susceptible patients. While incidence figures vary, it is generally agreed that the risk of serious neurological complications is extremely low, and is approximately one or two per million cervical manipulations. Structural abnormalities, particularly where mechanical instability, pathological bone disorders, dislocations and fractures of the cervical spine are present may also lead to mechanical strain of the vertebral arteries (Terrett, 1987; Kleynhans, 1980; Jaskoviak, 1981; Ladermann, 1981).

Other cervical manipulative complications, which are rare but have either been reported or described in the literature, include Horner's syndrome, diaphragmatic paralysis, cervical myelopathy secondary to meningeal hemorrhage, pathological fracture of a cervical vertebra and cervical disc protrusions (Dabert et al., 1970; Rinsky et al., 1976; Krewalramani, 1982; Hefner, 1985; Grayson, 1987; Gatterman, 1991). Dislocation in the upper cervical spine due to inflammatory or traumatic rupture of the transverse adantal or alar ligaments warrants particular caution (Yochum and Rowe, 1980, 1987; Jeffreys, 1980; Sandman, 1981; Redlund-Johnell, 1984).

Though rarely reported in the literature, empirically the most common complaint of manipulation of the thoracic region occurs when forceful or poorly applied manipulations cause costovertebral strains, rib fractures and costochondral separations (Grieve, 1986). Excessive thoracolumbar torque in the side posture position as well as inappropriately applied posterior to anterior techniques may cause thoracic cage injuries particularly in the elderly.

Lower back injury alleged to have occurred following spinal manipulative therapy has been reported in patients with pre-existing disc herniation or prolapse (CCPA Claim Review, 1990; Bromley, 1989; Gallinaro and Cartesegna, 1983). While it is suggested that the forces required to cause a disruption of the annular fibers of the healthy intervertebral disc well exceed that of a rotational manipulative thrust (Adams and Hutton, 1981, 1983; Farfan, 1983; Gilmore, 1986; Triano, 1991), some disc herniation/protusion may certainly be aggravated by an inappropriately applied manipulative maneuver, as it may be by other simple activities of daily living such as bending, sneezing, lifting. The most frequently described severe complication is compression of the cauda equina by massive midline nuclear herniation at the level of third, fourth or fifth intervertebral disc (Lehmann et al., 1991; Malmivivaara and Pohjola, 1982; Kleynhans, 1980; Hooper, 1973).

Of the thirty cauda equina complications associated with manipulation reported in the French, German and English literature over an 80 year period, only eight were allegedly related to chiropractic treatment (Ladermann, 1980). Had these patients not been manipulated, the outcome may have been the

same with menial effort or impulsive strain replacing the rupturing effect alleged to arise from the manipulation. However, this clinical outcome does stress the need for particular care in this susceptible subgroup of patients.

Psychological factors including pain intolerance, hysteria conversion reactions, hypochondriasis, malingering, etc., require special consideration, since the presence of neuromusculoskeletal symptoms may be of secondary importance. Aside from the risk of creating a dependency for care that may or may not be indicated, treatment itself may aggravate or contribute to real or imagined harm.

V. ASSESSMENT CRITERIA

Complications may occur spontaneously or arise as a result of chiropractic treatment. The risk of these complications may vary within subgroups of patients based on their clinical presentation. The main focus for the prevention of complications is the recognition of well known and established indicators or "red flag" signs and symptoms, which may require careful assessment and reassessment, changes in treatment plan, or other appropriate action such as emergency care or referral to another health care specialist. Ignoring these "red flag" indicators increases the likelihood of patient harm.

The literature and clinical experience show that the most common therapeutic procedure in chiropractic practice, and the one most likely to result in complications, is the adjustment or high-velocity manipulative thrust. The following assessment criteria and recommendations relate to this procedure applied to, or adjacent to, the anatomical site of pathology.

Assessment criteria developed and used in this chapter relate to:

a) Rating of conditions
b) Severity of complication
c) Quality of evidence
d) Level of contraindication: based on the above factors and the probability of complication

A. Rating of Conditions:

Type I:

A condition for which high-velocity thrust procedures have been shown to be comparatively safe and effective so long as an adequate diagnosis has been made and a therapeutic trial is rationally applied (e.g., upper cervical dysfunction/subluxation associated with tension headaches).

Type II:

A type I condition is present but may be coincident with another related or unrelated condition requiring modification of procedures and/or further diagnostic assessment (e.g., upper cervical joint dysfunction/subluxation accompanied by widening of the atlantodental interval or inflammatory causes affecting the area). Careful clinical judgment is required as high-velocity thrust procedures may be relatively or absolutely contraindicated.

Type III:

Type I or II conditions are present but considered negligible compared with clinical evidence of another pathological problem requiring further diagnostic assessment and referral to another health care professional (e.g., cervical joint dysfunction/subluxation and local metastatic bone tumor). As the risk of serious harm far outweighs benefit, the therapeutic procedure may be absolutely contraindicated.

B. Severity of Complication:

Minimal Level:

Any complications of high-velocity thrust procedures may be considered minimal, with slight objective evidence of worsened signs usually lasting a maximum of several days. (Reactions such as short term pain and stiffness or, infrequently, a mild chronic pain disorder alleged to arise from aggravation of a pre-existing problem). These reactions are rarely reported in the literature/claim reviews, given the brief duration of mild symptoms experienced by patients and the superimposed natural history of the presenting complaint. High-velocity thrust procedures are not generally contraindicated. Treatment modifications may have to be anticipated in exceptional cases.

Moderate Level:

Level of harm is generally moderate, characterized by more-or-less serious but usually reversible harm lasting weeks to months. Effects are temporary and/or residual in nature (e.g., broken rib, uncomplicated disc herniation, radiculopathy, foot drop). Depending on all factors (e.g., frequency of complications, benefits) high-velocity thrust procedures may be relatively or absolutely contraindicated.

High Level:

Evidence suggests risk of a high level of harm. The complication or accident may be serious and/or permanent, particularly in susceptible patients. (e.g., stroke, cauda equina syndrome). High-velocity thrust procedures may be relatively contraindicated with careful treatment modification, or absolutely contraindicated given patient history, diagnostic tests and/or other information obtained during a trial of therapy.

C. Quality of Evidence:

Evidence on the risk of complication arising from chiropractic treatment and particularly high-velocity thrust procedures comes from case reports, surveys, literature reviews, and insurance and legal claims records. There needs to be further systematic study of the incidence, severity and man-

agement of complications. Present classification of quality of evidence is:

Class I:
Evidence provided by surveys, systematic studies, literature reviews, and detailed clinical case reports published in refereed journals.

Class II:
Evidence provided by other case studies or reviews, or consensus expert opinion from legitimate consensus-building efforts.

Class III:
Evidence provided by expert opinion and one or more case reports.

D. Level of Contraindication:

Having regard to all of the individual assessment criteria already discussed, the following overall ratings are used:

No Contraindication

Relative Contraindication: high-velocity thrust procedures may be used with appropriate care and/or modification.

Relative to Absolute Contraindication: careful clinical judgment dictates whether contraindication is relative or absolute with each specific patient.

Absolute Contraindication

Example: As an example of the complete rating system:

Noncomplicated Low-Back Pain:
No contraindication to high-velocity thrust procedures.

Risk-of-Complication Rating:
Severity (if harm did occur): Minimal
Rating of Condition: Type I
Quality of Evidence: Class I

This rating system assumes no negligence or error on the part of the practitioner. Tolerance to treatment may sometimes, but not always, be estimated by provocative or premanipulative testing.

In the examples below it is assumed that traditionally and commonly used high-velocity, low-amplitude thrusts (adjustment/manipulation) are administered to, or immediately adjacent to, the segmental level where both the manipulable subluxation/dysfunction and/or the condition has primarily manifested itself.

VI. RECOMMENDATIONS

Note: General health problems which have been described in the literature as either contraindications to or complications of high-velocity thrust procedures include the following conditions. It should be understood that the listed conditions are not necessarily those for which high-velocity thrust procedures are intended. Rather they may be coincidentally present in a patient undergoing treatment. The fundamental object of treatment is a manipulable joint lesion (subluxation, dysfunction, blockage).

A. Articular Derangements:

1. Acute rheumatoid, rheumatoidlike and nonspecific arthropathies including acute ankylosing spondylitis characterized by episodes of acute inflammation, demineralization, ligamentous laxity with anatomic subluxation or dislocation, represent an absolute contraindication to high-velocity thrust procedures in anatomical regions of involvement.

12.1.1 Risk-of-Complication Rating:
Severity: Moderate to High Condition Rating:
Type III
Quality of Evidence: Class II, III
Consensus Level: 1

2. Sub-acute and/or chronic ankylosing spondylitis and other chronic arthropathies in which there are no signs of ligamentous laxity, anatomic subluxation or ankylosis are not contraindications to high-velocity thrust procedures applied to the area of pathology.

12.1.2 Risk-of-Complication Rating:
Severity: Minimal
Condition Rating: Type I, II
Quality of Evidence: Class II, III
Consensus Level: 1

3. Degenerative joint disease, osteoarthritis, degenerative discopathy and spondyloarthrosis are not contraindications to high-velocity thrust procedures to the area of pathology but treatment modification may be warranted during active inflammatory phases.

12.1.3 Risk-of-Complication Rating:
Severity: Minimal
Condition Rating: Type I, II
Quality of Evidence: Class II
Consensus Level: 1

4. In patients with spondylolysis and spondylolisthesis caution is warranted when high-velocity thrust procedures are used. These conditions are not contraindications, but with progressive slippage they may represent a relative contraindication.

12.1.4 Risk-of-Complication Rating:
Severity: Minimal to Moderate
Condition Rating: Type I, II
Quality of Evidence: Class II
Consensus Level: 1

5. Acute fractures and dislocations, or healed fractures and dislocations with signs of ligamentous rupture or instability, represent an absolute contraindication to high-velocity thrust procedures applied to the anatomical site or region.

12.1.5 Risk-of-Complication Rating:
Severity: High
Condition Rating: Type III
Quality of Evidence: Class III
Consensus Level: 1

6. Unstable os odontoideum represents an absolute contraindication to high-velocity thrust procedures to the area of pathology.

12.1.6 Risk-of-Complication Rating:
Severity: High
Condition Rating: Type III
Quality of Evidence: Class III
Consensus Level: 1

7. Articular hypermobility, and circumstances where the stability of a joint is uncertain, represent a relative contraindication to high-velocity thrust procedures to the area of pathology.

12.1.7 Risk-of-Complication Rating:
Severity: Minimal
Condition Rating: Type I, II
Quality of Evidence: Class II, III
Consensus Level: 1

8. Postsurgical joints or segments with no evidence of instability are not a contraindication to high-velocity thrust procedures but may represent a relative contraindication depending on clinical signs (e.g., response, pretest tolerance or degree of healing).

12.1.8 Risk-of-Complication Rating:
Severity: Minimal
Condition Rating: Type II
Quality of Evidence: Class III
Consensus Level: 1

9. Acute injuries of osseous and soft tissues may require modification of treatment. In most cases, high-velocity thrust procedures to the area of pathology are not contraindicated.

12.1.9 Risk-of-Complication Rating:
Severity: Minimal to moderate
Condition Rating: Type I, II
Quality of Evidence: Class I, II
Consensus Level: 1

10. The presence of scoliosis is not a contraindication to high-velocity thrust procedure.

12.1.10 Risk-of-Complication Rating:
Severity: Minimal
Condition Rating: Type I, II
Quality of Evidence: Class II, III
Consensus Level: 1

B. Bone Weakening and Destructive Disorders

1. Active juvenile avascular necrosis, specifically of the weight bearing joints (e.g., Perthes' disease) represents an absolute contraindication to high-velocity thrust procedures to the area of pathology.

12.2.1 Risk-of-Complication Rating:
Severity: High
Condition Rating: Type III
Quality of Evidence: Class III
Consensus Level: 1

2. Demineralization of bone warrants caution with the use of high-velocity thrust procedures. This represents a relative contraindication to high-velocity thrust procedures to the area of pathology.

12.2.2 Risk-of-Complication Rating:
Severity: Minimal to Moderate
Condition Rating: Type II
Quality of Evidence: Class II, III
Consensus Level: 1

3. Benign bone tumors may result in pathological fractures and therefore represent a relative to absolute contraindication to high-velocity thrust procedures to the area of pathology.

12.2.3 Risk-of-Complication Rating:
Severity: Low to Moderate
Condition Rating: Type II, III
Quality of Evidence: Class III
Consensus Level: 1

4. Malignancies represent conditions for which high-velocity thrust procedures to the area of pathology are absolutely contraindicated.

12.2.4 Risk-of-Complication Rating:
Severity: Moderate to High
Condition Rating: Type III
Quality of Evidence: Class II, III
Consensus Level: 1

5. Infection of bone and joint represents an absolute contraindication to high-velocity thrust procedures to the area of pathology.

12.2.5 Risk-of-Complication Rating:
Severity: Minimal to High
Condition Rating: Type III
Quality of Evidence: Class II
Consensus Level: 1

C. Circulatory and Cardiovascular Disorders

1. Clinical manifestations of vertebrobasilar insufficiency syndrome warrant particular caution and represent a relative to absolute contraindication to cervical high-velocity thrust procedures to the region of pathology.

12.3.1 Risk-of-Complication Rating:
Severity: Minimal to High
Condition Rating: Type II, III
Quality of Evidence: Class I, II, III
Consensus Level: 1

2. When a diagnosis of a significant aneurysm involving a major blood vessel has been made, a relative to absolute contraindication may exist for high-velocity thrust procedures within the area of pathology.

12.3.2 Risk-of-Complication Rating:
Severity: High
Condition Rating: Type III
Quality of Evidence: Class III
Consensus Level: 1

3. Bleeding is a potential complication of anticoagulant therapy or certain blood dyscrasias. Patients with these disorders represent a relative contraindication to high-velocity thrust procedures.

12.3.3 Risk-of-Complication Rating:
Severity: Minimal to High
Condition Rating: Type II
Quality of Evidence: Class III
Consensus Level: 1

D. Neurological Disorders

1. Signs and symptoms of acute myelopathy or acute cauda equina syndrome represent an absolute contraindication to high-velocity thrust procedures applied to the anatomic site of involvement.

12.4.1 Risk-of-Complication Rating:
Severity: High
Condition Rating: Type II, III
Quality of Evidence: Class I, II
Consensus Level: 1

* Most dysfunctions or disease processes have variations or phases. Levels of severity and probability have been assigned on the basis that the condition displays usual and classical signs and symptoms. The difficulty in precisely detailing the degree or severity and probability of an individual patient's overall physical and psychological response both to the condition and therapeutic procedure (subtleties of force, amplitude, direction, patient positioning, etc.) is acknowledged. Nevertheless, ratings have been assigned based on the literature and the current consensus process. These provide a starting point which will require ongoing review and refinement.

Some conditions, such as scoliosis, are not level-specific and high-velocity thrust procedures used apply more to a region than a level.

VII. COMMENTS, SUMMARY OR CONCLUSION

This chapter provides an analytical framework and specific interim guideline recommendations with respect to complications of and contraindications to manipulative thrust procedures. At present, detailed systematic studies on this subject are lacking and the recommendations made are based on information from clinical reviews and case reports, as well as from expert opinion and consensus methods. One objective of this chapter is to encourage productive debate leading to firmer commitment on risk management protocols.

The recommendations made must be continuously re-evaluated in light of ongoing research and clinical experience. Cooperative intradisciplinary and interdisciplinary research will be necessary to determine the true extent of the nature and occurrence of iatrogenic complications in chiropractic practice. The development of a central registry system capable of generating comprehensive research data would be valuable, and would facilitate the establishment of more detailed and refined guideline recommendations in the future.

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IX. MINORITY OPINION

None.

13

Preventive/Maintenance Care and Public Health

Chapter Outline

I. OVERVIEW

The practice of chiropractic deals with acute therapeutic intervention and long-term care plans. This chapter focuses on the latter, which includes wellness or preventative care (designed to reduce the future incidence of illness or impairment) and health promotion (based upon optimal function).

Some confusion arises from the use of various terms to describe such care - including supportive care, maintenance care, and preventive care. In this chapter, it is called "preventive/maintenance care."

Long-term ongoing health management has been a significant component of the holistic chiropractic model of health. Surrounding this is a wellness paradigm that recognizes related influences on health, emphasizes drugless, non-surgical management, and takes a positive dynamic view of health. In addition to periodic passive care, the model looks to the whole individual and requires active patient participation.

Active care efforts emphasize patient responsibility and may include exercise programs, weight loss, dietary counseling, life style modifications, education on body postures and mechanics, coordination training, safety habits, modification of life stressors, etc.

This type of management program, which combines health promotion, preventive/maintenance care, and patient participation, is gaining much more widespread understanding and acceptance in today's more health conscious society.

II. DEFINITIONS

These definitions are intended to clarify inconsistency in professional, legal and contractual terminology. It is expected that they will become standard.

Active Care: Modes of treatment requiring "active" involvement, participation, and responsibility on the part of the patient.

Passive Care: Application of treatment procedures by the care giver to the patient who "passively" submits to and receives care.

Supportive Care: Treatment for patients who have reached maximum therapeutic benefit, but who fail to sustain this benefit and progressively deteriorate when there are periodic trials of withdrawal of treatment. Supportive care follows appropriate application of active and passive care including rehabilitation and life style modifications. It is appropriate when alternative care options, including home-based self-care, have been considered and attempted. Supportive care may be inappropriate when it interferes with other appropriate primary care, or when the risk of supportive care outweighs its benefits, i.e., physician dependence, somatization, illness behavior, or secondary gain.

Preventative/Maintenance Care: Any management plan that seeks to prevent disease, prolong life, promote health and enhance the quality of life. A specific regimen is designed to provide for the patient's well-being or for maintaining the optimum state of health.

Risk Factors: Health characteristics increasing the probability that an individual, or group of individuals will develop a given disease or disorder.

III. LIST OF SUBTOPICS

A. Preventive /Maintenance Care
   1. Disclosure
   2. Chiropractic adjustments used in preventive/maintenance regimen
   3. Health Screening
   4. Health Promotion
   5. Wellness Care

B. Public Health Considerations
   6. Community Based Screening
   7. Public Health Education

IV. LITERATURE REVIEW

From the very beginning, the chiropractic model of health has had as its foundation the maxim that a human being is an ecologically and biologically unified organism. The relationship between a patient's internal and external environment must be understood. A major premise is that the inherent recuperative power of the body aids restoration and maintenance of health. These assumptions comprise a wellness paradigm embraced by the great majority of the chiropractic profession. The spinal lesion, along with other factors such as poor nutrition, stress, trauma, heredity, congenital weaknesses, fatigue, environmental stressors and sedentary lifestyles, are viewed as lowering resistance and creating physical disharmony. The chiropractic model requires active patient participation.[1,2,3]

Patients presenting with a musculoskeletal problem often obtain a swift and favorable result. Then they may look to the practitioner for other health care needs.[4]

Some patients require ongoing long-term care; others choose it. Insurance constraints, however, mandate that the practitioner indicate when maximum therapeutic benefit has been achieved. The effectiveness of chiropractic preventive/maintenance care has not been subjected to study by randomized trial, a process that presents major methodological and financial challenges, but is supported by evidence from case studies.[5,6] However, its long-term benefits have not been clearly demonstrated.

Third party payers have typically resisted reimbursements for long-term preventive/maintenance care. Nonetheless, there is growing consumer demand for this and chiropractic care generally, despite increases in out-of-pocket expenses.[7,8,9]

Preventive/maintenance care is for patients without substantive manifestations. Therapeutic necessity is absent by definition. Clinically there is a need to distinguish for each

patient when therapeutic and supportive care stops, and when preventive/maintenance care begins. The latter is considered safe and effective when used discriminately, so as not to foster physician dependence and chronicity.

The overall efficacy of preventive health care is subject to considerable debate.[10] In addition, the chiropractic profession has a specific role in the prevention of complaints of spinal origin. This includes identifying principles of spinal hygiene, and therapeutic strategies to avoid the need for more radical interventions, such as surgery.

But enhanced public awareness of environmental, psychosocial, and physiological issues through education and community action has forced preventive care into the public health agenda as the number one priority. Smoking cessation, weight control, nutritional considerations, stress reductions, and advice about exposure to environmental pollutants are examples of initiatives affecting the chiropractic patient population.[11]

Coile [3] offers this historical input: "Thirty years ago, Rene Dubos, a research microbiologist, suggested in *Mirage of Health* that the advancements he and others had made in the development of antibiotics and therapeutics had less to do with the real health of populations than a variety of economic, social, nutritional, and behavioral factors. Five years later, the U.S. Surgeon-General's landmark report clearly revealed the links between smoking and diseases such as emphysema, chronic bronchitis, hypertension and lung cancer.

"A new awareness of the contribution of lifestyle, environment, and genetics infused medicine in the decade following. Sometimes called the 'wellness movement,' this new orientation broadened the paradigm of traditional biomedicine. Since Dubos' essay on health, a body of research findings has accumulated that demonstrates the validity of a more comprehensive approach to health, one which recognizes the many antecedents and co-factors in the disease and healing process.

"Although not fully accepted by all physicians, the holistic concept of health is gaining stature. Dozens of studies by employers have begun to quantify the beneficial impact of health promotion programs in terms of reduced health care utilization and lower health care costs."

Long-term care concepts and considerations in chiropractic have been discussed by a number of authors (Coulter, [1] Jamison,[2] Coile [3]). Jamison [12] offers a comprehensive overview of the current trends in chiropractic, and worksheets for health care assessment. McDowell and Newell [13] describe general health care indicators and instruments. Jamison [13] reviews the improvement of basic health status by alteration of behavior, especially through health education.

Some recent surveys focus upon musculoskeletal chiropractic practice (Phillips,[14] Wardwell,[8] Shekelle and Brook [4]), but other current literature takes a firm stance on the importance of maintaining a focus on prevention and health promotion (Coulter,[1] Sportelli,[9] Caplan [7]).

Areas with new significance for chiropractic long-term care include the management of osteoporosis (Stacey [5]), and hypertension and stress management (Yates, et al.[6]).

No study yet addresses what specific impact preventive/maintenance care has on overall health or health care costs, or if preventive care enhances longevity or quality of life. Now, however, research into such complex issues as these is becoming more feasible (Nyiendo,[15] Kassak,[16] Jose [17]).

Notwithstanding the challenges of research in the field of prophylactic care there must be publication of valid clinical studies before chiropractic long-term preventive/maintenance care gains widespread public acknowledgement as an important component of health maintenance and wellness.

V. ASSESSMENT CRITERIA

Procedure Ratings (System I)

Established: Accepted as appropriate by the practicing chiropractic community for the given indication in the specified patient population.

Promising: Given current knowledge, this appears to be appropriate for the given indication in the specified patient population. As more evidence and experience accumulates, this interim rating will change. This connotes provisional acceptance, but permits a greater role for the level of current clinical use.

Equivocal: Current knowledge exists to support a given indication in a specified patient population, though value can neither be confirmed or denied. As more evidence and experience accumulates this interim rating will change. Expert opinion recognizes a need for caution in general application.

Investigational: Evidence is insufficient to determine appropriateness. Further study is warranted. Use for a given indication in a specified patient population should be confined largely to research protocols. As more evidence and experience accumulates this interim rating will change.

Doubtful: Given current knowledge, this appears to be inappropriate for the given indication in the specified patient population. As more evidence and experience accumulates this interim rating will change.

Inappropriate: Regarded by the practicing chiropractic community as unacceptable for the given indication in the specified patient population.

Quality of Evidence

The following categories of evidence are used to support the ratings.

Class I:

Evidence provided by one or more well-designed controlled clinical trials; or well-designed experimental studies that address reliability, validity, positive predictive value, discriminability, sensitivity, and specificity.

Class II:

Evidence provided by one or more well-designed uncontrolled, observational clinical studies, studies such as case control, cohort studies, etc.; or clinically relevant basic science studies that address reliability, validity, positive predictive value, discriminability, sensitivity, and specificity; and published in refereed journals.

Class III:

Evidence provided by expert opinion, descriptive studies or case reports.

Suggested Strength of Recommendation Ratings

Type A. Strong positive recommendation. Based on Class I evidence or overwhelming Class II evidence when circumstances preclude randomized clinical trials.

Type B. Positive recommendation based on Class II evidence.

Type C. Positive recommendation based on strong consensus of Class III evidence.

Type D. Negative recommendation based on inconclusive or conflicting Class II evidence.

Type E. Negative recommendation based on evidence of ineffectiveness or lack of efficacy based on Class I or Class II evidence.

Safety and Effectiveness

Safety: A judgment of the acceptability of risk in a specified situation, e.g., for a given health problem, by a provider with specified training (at a specific stage of the disorder, etc.).

Effectiveness: Producing a desired effect under conditions of actual use.

VI. RECOMMENDATIONS:

A. Preventive/Maintenance Care

1. Disclosure:

Preventive/maintenance care is discretionary and elective on the part of the patient. When recommended, it is necessary for the practitioner to clearly identify the type and nature of this care and to give proper patient disclosure.

13.1.1 Rating: Established
Evidence: Class III
Consensus Level: 1

2. Use of Chiropractic Adjustments:

The clinical experience of the profession developed over a period of nearly 100 years suggests that the use of chiropractic adjustments in a regimen of preventive/maintenance care has merit.

13.1.2 Rating: Equivocal
Evidence: Class III
Consensus Level: 1

3. Health Screening:

The importance of health preventive strategies is widely recognized. These services may have value in identifying early or potential manifestations of a health problem.

13.1.3 Rating: Promising to Established
Evidence: Class II, III
Consensus Level: 1

4. Health Promotion:

Preventive orientation to health through health promotion is well established. Health promotion provides the opportunity for chiropractic practitioners to promote health through assessment, education, and counseling on topics such as nutrition, exercise, stress reduction, life style patterns, weight reduction, smoking cessation, and ergonomics, among others.

13.1.4 Rating: Established
Evidence: I, II, III
Consensus Level: 1

5. Wellness Care:

Chiropractic is the largest of the holistic-oriented professions. Wellness and health management lifestyle strategies have gained popularity and acceptance. Chiropractic practitioners may choose to expand their practices to include those interventions that may influence a person's attainment of optimum performance and behavior, and in so doing, improve health status. This kind of care is performance specific (i.e., quality of life) rather than condition (e.g., symptom) specific.

13.1.5 Rating: Equivocal
Evidence: Class III
Consensus Level: 1

B. Public Health Considerations

6. Community Screening:

Community-based screening programs are commonly used by all disciplines to promote public health. Spinal screening and blood pressure checks offer excellent examples of such programs.

13.2.1 Rating: Promising
Evidence: Class II, III
Consensus Level: 1

7. Public Health Considerations:

The chiropractic profession has recognized the need to engage in the local, state, national and international agendas of public health. Such programs provide opportunities for educa-

tion and understanding programs regarding spinal health, nutrition, exercise and life styles, drugs, alcohol, tobacco, and infectious disease, as well as environmental and other social issues.

13.2.2 Rating: Promising
Evidence: II, III
Consensus Level: 1

VII. COMMENTS, SUMMARY, OR CONCLUSION

In this chapter a distinction has been drawn between two kinds of long-term chiropractic care: supportive care which has therapeutic necessity; and preventive/maintenance care which is elective and focuses upon patient participation and wellness.

At present there has been insufficient research into the effectiveness and cost-effectiveness of most forms of preventive care. Better study methods and greatly increased public awareness of the importance of healthy lifestyle and health promotion have produced the climate in which the needed research can be started.

The chiropractic profession, which has always had a wellness paradigm and has stood at the forefront of the health promotion movement, must participate in this research and better evaluate the basis of preventive/maintenance care.

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IX. MINORITY OPINIONS

None

14

Professional Development

Chapter Outline

I. OVERVIEW

The chiropractic profession has evolved and continues to develop within a similar dynamic process as have other professions. Research in the areas of professional education and continuing education has delineated characteristics of professionalism. These characteristics focus upon the central themes of education, credentialing, professional organizations, ethical considerations and legal reinforcement. Each characteristic speaks to the dynamic development of a profession as it moves toward greater organization, influence, and responsibility to the public that it serves.

This chapter will relate these common characteristics of professionalism to the chiropractic profession and will present models to be used for future development.

II. DEFINITIONS

Assessment Outcomes: Assessment of the impact of a continuing education or postgraduate program on a practitioner's knowledge, attributes, practice performance and patient care.

Continuing Education: Voluntary and/or mandatory ongoing instruction for facilitation of clinical performance.

Credentialing: A formal means by which the capabilities of the individual practitioner to perform duties at an acceptable level are certified.

Graduate Education: Education beyond undergraduate degree level usually denoting a masters degree or Ph.D.

Postgraduate Education: Education beyond first professional degree usually leading to specialty or certification status.

III. LIST OF SUBTOPICS

A. Continuing Education
B. Postgraduate Education
C. Graduate Education
D. Professional Organizations
E. Ethics/Standards of Conduct
F. Research

IV. LITERATURE REVIEW

The literature search was conducted through primary sources, printed indexes, computerized bibliographic databases and in a library card catalog. Printed indexes searched included the *Index to Chiropractic Literature* 1980-1990, the *Chiropractic Literature Index* 1970-1979, and the *Chiropractic Research Archives Collection* (Vols 1-3). The computerized database searched was Medline, the National Library of Medicine's current medical literature database. Finally, searches for relevant materials were conducted in the card catalog of the David D. Palmer Health Sciences Library.

Both specific thesaurus terms and "keyword" terms were searched in these resources. A sampling of thesaurus, keyword terms and concepts searched included: professional development; continuing education; credentialing; continuing competency; life-long learning programs; diplomate/specialization programs; certification programs; extern programs; preceptorship; residency programs; performance measurement; licensure; licensure and reciprocity; professional associations; ethics and advertising; social responsibility; professional responsibility; peer review; information literacy.

A. Chiropractic Education

The practitioner is educated in the basic and clinical sciences as well as in related health subjects. Chiropractic science concerns itself with the relationship between structure and function as that relationship may affect the restoration and preservation of health. The purpose of chiropractic professional education is to prepare the practitioner to serve as a portal of entry to the health care delivery system. He/she must be well educated to evaluate and diagnose, to provide care, and to consult with or refer to other health care providers.

All applicants to chiropractic colleges must have successfully completed a minimum of 60 semester hours, or equivalent, of college credits from a nationally recognized accrediting body.

The Council of Chiropractic Education, a national accrediting agency for chiropractic colleges, produces a standards document specifying guidelines for chiropractic educational institutions and programs. However there is no CCE standard regarding residency specialty programs. At present, standards with regard to postgraduate education are at the discretion of the colleges, and the individual institutions hold the printed materials relevant to their postgraduate residency offerings. National organizations have established specialty councils but specific guidelines and requirements are then subject to determination by the council.

The needs of society require that chiropractic practitioners be able to carry out their duties according to the highest possible standards of character, competence and practice. Chiropractic is an art based on the application of a complex body of scientific knowledge. Competence in solving problems, capacity to use complex knowledge and a sensitive awareness of ethical problems are related to the entire lifelong learning process of the individual practitioner.

B. Credentialing

Credentialing is a formal means by which the capabilities of the individual practitioner to perform duties at an acceptable level are recognized. The major instrument for licensure within the chiropractic profession is the state government

which fulfills this function with guidance from the profession in setting examination policies and testing the applicants.

In all states an applicant for license to practice must supply evidence of successful completion of an approved program of chiropractic education leading to the doctor of chiropractic degree, and proficiency by passing required examinations to demonstrate mastery of basic and practical elements of chiropractic as defined in that state.

National testing for the profession is conducted by the National Board of Chiropractic Examiners. The National Board examinations address basic and clinical sciences. The examination scores are recognized by all states in partial fulfillment of licensure requirements. A subsequent component of licensure is continuing education. The purpose of continuing professional education is to update theoretical knowledge, technique skills and clinical applications. To be effective continuing education should enhance successful clinical performance of practitioners. In addition, continuing education must be truly "continuing," not sporadic or opportunistic, and must be self-directed, with each professional being the ultimate monitor of his or her own learning. The ultimate test of a continuing education program is in the improvement of clinical outcomes and thus the quality of service.

Currently most states (42) require evidence of board-approved continuing education for license renewal. This requirement may range from 24 to 40 hours every two years with some states requiring specific areas of focus for credit hours. While it is recognized that mandatory continuing education requirement for license renewal does not equate with continuing competency, it is the consensus of licensing boards that practitioners need to remain knowledgeable and maintain skills current with standards within the profession.

Postgraduate continuing education is offered in many fields including orthopedics, neurology, sports injuries, nutrition, and occupational health. These courses are taught and monitored by chiropractic educational institutions and have specific requirements for practitioners to meet board certification status. However, postgraduate specialty programs and credentialing requires individual evaluation with respect to reliability, standardization of education, and its implication regarding quality of care.

C. Professional Organizations

Formal association with other chiropractic professionals enhances creation of a professional identity, fostering a relationship which nurtures distinct attributes for its members. Membership in a professional association could be restricted to those who have met rigorously defined requirements or perhaps open to anyone who wishes to participate.

Practitioners should participate in interprofessional organizations that bring a variety of health care providers together. In this way practitioners can educate other health providers and at the same time have an opportunity to be aware of other health care services that may impact on chiropractic practice and the interests of patients. Communication and understanding between chiropractic practitioners and other health care professionals must be facilitated and enhanced for the benefit of the health care consumer.

D. Ethical Considerations

Ethical principles in chiropractic care focus on patient rights. A code of ethics addresses the professional principles each practitioner should adopt in all interactions with patients, the public, and other practitioners.

Fundamental values and ethical principles in health care focus around three main principles: beneficence, justice and respect for persons. Respect for persons encompasses a central theme of treating patients as individuals with rights. Patients have the right to know, the right to privacy, and the right to acknowledge and make choices about treatment. Central to this concept is informed consent, confidentiality and presenting patients with information regarding conditions and remedial treatment. This concept also speaks to the practitioner's need to maintain the patient's autonomy by sharing knowledge, providing self-help measures, and avoiding physician dependency. Justice demands universal fairness. Health care resources and opportunities for treatment should be available regardless of race, creed, and/or economic status. Inherent in this concept is the practitioner's responsibility to maintain standards of quality care, including the consistency of treatment. Beneficence focuses on the doctor's duty to care. Inherent in this responsibility is the duty "to do good and avoid doing harm."

Both national chiropractic associations and all state chiropractic associations have codified ethics for their members. State licensing boards have laws and administrative rules that include ethical considerations which the practitioner must adhere to for continued licensure.

The practitioner's demeanor and behavior impact greatly on the patient. There is a moral, ethical and professional obligation to treat each patient with skill, dedication and respect. Health care professionals should remain aware of those issues if they are to establish appropriate patient-provider relationships. A therapeutic relationship is generated by an honest, caring and concerned attitude.

Advertising and marketing are common within all health care professions. Promotion of chiropractic should be in a responsible, informative, and professional manner. State law dictates that advertising should not be false, misleading or deceptive. In addition, promises of cure or statements that would create unjustified expectations of beneficial treatment should be avoided.

E. Research

Chiropractic researchers, clinicians, and administrators have emphasized the paucity of well-designed research studies in the field of chiropractic practice, and the importance of

clinical research to the profession. Individual practitioners have important roles to play in research. Practice experience provides the opportunity to report on clinical phenomena and observations and propose diagnostic and treatment outcomes in the literature. Clinicians, professional organizations, and chiropractic academic personnel should continue to be involved in and supportive of research activities conjoint with other health care professionals.

V. ASSESSMENT CRITERIA

Procedure Ratings (System II)

Necessary: Strong positive recommendation based on Class I evidence, or overwhelming Class II evidence when circumstances reflect compromise of patient safety.

Recommended: Positive recommendation based on consensus of Class II and/or strong Class III evidence.

Discretionary: Positive recommendation based on strong consensus of Class III evidence.

Unnecessary: Negative recommendation based on inconclusive or conflicting Class II and Class III evidence.

Quality of Evidence

The following categories of evidence are used to support the ratings.

Class I:

A. Evidence of clinical utility from controlled studies published in refereed journals.
B. Binding or strongly persuasive legal authority such as legislation or case law.

Class II:

A. Evidence of clinical utility from the significant results of uncontrolled studies in refereed journals.
B. Evidence provided by recommendation from published expert legal opinion or persuasive case law.

Class III:

A. Evidence of clinical utility provided by opinions of experts, anecdote and/or by convention.
B. Expert legal opinion.

VI. RECOMMENDATIONS

A. Continuing Education

1. It is expected that every practitioner shall participate in continuing education.

14.1.1 **Rating:** Necessary
Evidence: Class I, II, III
Consensus Level: 1

2. Continuing education should be ongoing and should facilitate successful clinical performance.

14.1.2 **Rating:** Recommended
Evidence: Class I, II, III
Consensus Level: 1

3. Completion of mandatory continuing education requirements for license renewal does not necessarily assure continuing competency. Those requirements should include assessment of outcomes by administering institutions/organizations to evaluate the effectiveness of their programs.

14.1.3 **Rating:** Recommended
Evidence: Class I, II, III
Consensus Level: 1

4. Continuing education should allow for a variety of instructional formats.

14.1.4 **Rating:** Recommended
Evidence: Class II, III
Consensus Level: 1

5. Practitioners should continue to educate themselves through critical reading and review of clinical and/or scientific literature.

14.1.5 **Rating:** Recommended
Evidence: Class II, III
Consensus Level: 1

B. Postgraduate Education

1. All chiropractic colleges are encouraged to provide residency programs for qualified graduates for the purpose of advanced research, education and clinical practice.

14.2.1 **Rating:** Recommended
Evidence: Class II, III
Consensus Level: 1

2. Colleges should provide opportunities for postgraduate programs for professional development which may lead to certification or specialty status.

14.2.2 **Rating:** Recommended
Evidence: Class II, III
Consensus Level: 1

3. Practitioners are encouraged to participate in certification or specialty postgraduate education programs (e.g., specialty programs).

14.2.3 **Rating:** Discretionary
Evidence: Class II, III
Consensus Level: 1

4. Where such postgraduate programs exist the impact and outcome should be measured appropriately.

14.2.4 Rating: Recommended
Evidence: Class II, III
Consensus Level: 1

5. Proprietary programs should affiliate with accredited educational institutions for the purposes of development, evaluation and implementation.

14.2.5 Rating: Recommended
Evidence: II, III
Consensus Level: 1

C. Graduate Education

1. Practitioners are encouraged to participate in programs providing graduate education (e.g., masters or doctorate) offered by accredited educational institutions.

14.3.1 Rating: Discretionary
Evidence: Class II, III
Consensus Level: 1

D: Professional Organizations

1: Practitioners should be members of one or more professional associations.

14.4.1 Rating: Recommended
Evidence: Class II, III
Consensus Level: 1

Comment: Professional organizations and associations provide a structure of responsibility through which members develop and maintain awareness of professional developments and gain enhanced professional competence. Practitioners also develop leadership abilities by participating in sponsored conventions, conferences, workshops and other gatherings; receive publications pertinent to the profession; support and encourage legislative programs and otherwise influence public policy in the interests of the public and the profession.

E. Ethics/Standards of Conduct

1. Practitioners should conduct themselves in a manner consistent with a professional code of ethics which addresses morality, honesty and all aspects of professional conduct.

14.5.1 Rating: Necessary
Evidence: Class I, II, III
Consensus Level: 1

2. Practitioners who advertise should do so in a responsible, ethical and professional manner.

14.5.2 Rating: Necessary
Evidence: Class I, II, III
Consensus Level: 1

Comment: The responsibility for regulation of advertising lies with professional associations and licensing boards. Professional organizations can assist by enforcing guidelines established for the membership; the state licensing boards promulgate rules to aid the profession and safeguard the public. Violation of state or provincial laws can result in fines or suspension or revocation of a license.

F. Research

1. Practitioners are encouraged to participate in research and support institutions/organizations conducting research, for the purposes of professional development and improved patient care. Valid research requires appropriate research protocols as approved by recognized institutional review boards.

14.6.1 Rating: Recommended
Evidence: Class I, II, III
Consensus Level: 1

VII. COMMENTS, SUMMARY OR CONCLUSION

None.

VIII. REFERENCES

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IX. MINORITY OPINIONS

None.

Epilogue

EVOLUTION OF THE CONSENSUS PROCESS

The consensus process which resulted in the publication of these guidelines should be considered part of an ongoing process rather than a final prescription for the practice of chiropractic. The recommendations voted on at the Mercy Conference are the product of two years of literature review, consultation, debate and compromise. This resulted in the most comprehensive set of guidelines ever established for the chiropractic profession.

The guidelines outlined in this document can and will be used to assist practitioners to improve their practice parameters. They should not, however, be considered set in stone. The practice of chiropractic is dynamic. There is an increasing amount of research being done both at chiropractic colleges and within private practices, hospitals and universities. This research can be expected to impact the practice of chiropractic on a continuous basis ensuring that there is progression and growth in knowledge and understanding of the benefits and role of chiropractic in the health care delivery system. As the results of such research begin to have a practical impact, the practice of chiropractic will change and future guidelines will have to take such changes into account.

In addition, there are rapid changes in all fields of health care which are likely to affect the practice of chiropractic. Legislation and legal precedent can be expected to influence the expectations and responsibilities of the profession. The attitude of practitioners toward patients, insurance carriers and government agencies will have to adapt in response to these changes. In addition, there is increasing debate and emphasis on ethics by all health care professionals and future consensus processes within chiropractic should follow the example of this Commission and attempt to give guidance on these issues.

RESEARCH AND THE CONSENSUS PROCESS

It can be anticipated that additional consensus conferences will be held every few years to update these guidelines and bring the recommendations in line with the results of future research and the normal evolution of the role of the chiropractic profession in the delivery of health care. The primary rationale for such conferences and modification of these guidelines should be the incorporation of research knowledge into established chiropractic practice.

A number of practitioners may disagree with individual recommendations and specific guidelines which were included in these proceedings. The proper course for them to take is to accumulate research or literature which may not have been considered at the Mercy Conference. Where there is no published literature or research, then it is the responsibility of those practitioners with a specific opinion on the guidelines to initiate such research. It is only through published research that significant advances in the practice of chiropractic can occur. There are numerous techniques and diagnostic methods which have been discussed in these guidelines which could not be given a high rating due to the lack of research on the topic. Many of these techniques and methods are fairly widely practiced. The failure of these methods to gain a high recommendation rating can be expected to be of concern to those individuals who believe them to be of value. The guidelines should serve as an incentive to develop and finance the research necessary to establish the credibility of a greater number of techniques and procedures.

Many manufacturers and suppliers of diagnostic and therapeutic equipment, as well as practitioners who have developed methods of adjusting or treating patients, may feel that their particular procedure or method has value which was not recognized by the conference delegates. It is incumbent upon these individuals or companies to take the initiative to establish a research base for future consensus conferences. When such a conference is convened the justification for such procedures must be made available in the form of research papers published in peer reviewed journals. Failure to present research at future consensus conferences can lead to the dismissal of a technique or method from the chiropractic therapeutic armamentarium.

GUIDELINES FOR EVALUATION

The following are offered as guidelines for the evaluation of the appropriateness/clinical usefulness of tests and treatment procedures in chiropractic practice.

I. Guides for Determining the Clinical Usefulness of a Test:[10]

A. There have been independent, blind comparisons with an acceptable gold standard of diagnosis based on the best available methods of determination.

B. The test has been evaluated in a patient sample that included patients with an appropriate spectrum of mild and severe, treated and untreated disorders, plus individuals with different but commonly confused disorders.

C. The setting for the evaluation, as well as the criteria by which study patients were included, were adequately described.

D. The reproducibility of the test result (precision) and its interpretation (observer variation) have been determined.

E. The reference (normal) has been defined sensibly as it applies to the test being evaluated.

F. If the test is advocated as part of a cluster or sequence of tests, its individual contribution to the overall validity of the cluster or sequence has been determined.

G. The tactics for carrying out the test have been described in sufficient detail to permit their replication.

H. The utility of the test has been determined.

I. The test is documented by publication in refereed journals.

II. Guides for Determining the Clinical Usefulness or Appropriateness of a Treatment Procedure

An evaluator should consider the following points:

A. Design
   1. The strength of the study design (randomized, controlled, cohort, case-control, case studies; prospective, retrospective).
   2. Evaluation of the assignment of patients to intervention.
   3. Biases in the intervention.
   4. Biases in the outcome.

B. All clinically relevant outcomes (e.g., both morbidity and mortality) are reported.

C. Sample
   1. Biases in the sample.
   2. The characteristics of the sample are known for all intervention groups and their characteristics are comparable and appropriate for the interventions studied.

D. Significance
   1. Clinical significance is demonstrated.
   2. Statistical significance is demonstrated.
   3. There is appropriate review for Type I error and Type II error.

E. Dropouts and subjects lost to follow-up are acknowledged and dealt with appropriately.

F. The procedure is documented by publication in refereed journals.

FUTURE CONSENSUS CONFERENCES

It is unlikely that any substantial revision of these guidelines will occur and be sponsored by a credible portion of the profession within the next two or three years. It takes approximately two years from the time of the initial considering of a commission to the publication of the final document. This should be ample time for any group of practitioners or manufacturers to begin developing research projects to establish whether there is value in a particular method or technique. Such research is best performed by independent investigators in the chiropractic colleges or in recognized universities or research institutions. The research should then be submitted to peer reviewed journals in order that it can be debated and considered on its scientific merit.

Future consensus processes may be comprehensive or have limited scope. Because the guidelines produced by this commission were extremely comprehensive, addressing the entire practice of chiropractic, it was not possible to address each area of practice in the degree of detail which may be desirable. It may become necessary to develop consensus processes for specific areas of practice such as treatment of the elderly or children, rehabilitation, the use of specific adjusting techniques or the management of specific conditions such as cervical injuries or headaches. Guideline parameters on these topics would be of great value to practicing chiropractors treating specific groups of patients.

When the next commission is established to revise these guidelines there must be a sufficient period of time allowed for the profession to have input to any changes that may be considered. As was the case in the development of these guidelines, the process must be widely advertised and input from a wide cross section of the profession invited. At no time, however, must political consideration be allowed to supersede basic scientific principles and health care ethics. As was repeatedly stressed by the participants in this Commission, the only

justification for any guideline is the advancement of the health of the millions of patients who seek the care and advice of the chiropractic profession every year.

Anyone who would like to submit comments regarding these Guidelines please see Appendix C on page 217.

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Appendix A

Endorsement by the Federation of Chiropractic Licensing Boards

RESOLUTION #3

Myrtle Beach, South Carolina
April 11, 1992

WHEREAS, The establishment and continuing review of chiropractic practice guidelines is important with respect to quality of care and the public interest; and

WHEREAS, National guidelines are important to the regulation of chiropractic practice and the better coordination of the work of the chiropractic licensing boards; and

WHEREAS, In order to provide national practice guidelines the Congress of Chiropractic State Associations created a Commission for the establishment of guidelines for chiropractic quality assurance and standards of practice in December of 1989; and

WHEREAS, The work of the Commission was subsequently sponsored by most major chiropractic associations in North America including the American Chiropractic Association, the Canadian Chiropractic Association, International Chiropractors Association, Association of Chiropractic Colleges and the Federation of Chiropractic Licensing Boards; and

WHEREAS, The Consensus Panel established by the Commission included chiropractors who represent the chiropractic profession as a whole in a fair and equitable manner; and

WHEREAS, It is appreciated that the Commission was the first national effort by the chiropractic profession to establish comprehensive practice guidelines and that these guidelines are imperfect, incomplete and will require revision; and

WHEREAS, Due to the nature of the consensus process itself it is recognized that diversity of opinion exists, but that most chiropractors will agree with the majority of the guidelines. Now therefore, be it

RESOLVED, That the Federation of Chiropractic Licensing Boards hereby endorses the work of the Commission in the legitimate consensus process representing as closely as practicable the views of the entire chiropractic profession, and the Federation of Chiropractic Licensing Boards endorses the Guidelines appearing in the proceedings of the Commission and encourages the chiropractic profession to continue with the ongoing process of establishing valid and useful guidelines for the practice of chiropractic.

Appendix B

Summary of Recommendations (Guidelines)

The recommendations are the most important part of these proceedings. Each of these recommendations was voted on by the entire Commission with varying degrees of consensus. The practitioner who wishes to utilize the guidelines will want to read and understand the entire document but will be looking to the recommendations to evaluate specific aspects of his or her practice. At all times, however, it must be kept in mind that the recommendations should not be perceived as free floating statements. Each recommendation must be placed in the context of the entire document. The scientific and theoretical base of a recommendation must be kept in mind, as well as its relationship to other recommendations.

For easy reference the recommendations have been summarized in table format. The tables which follow list each of the recommendations under chapter titles. The first column lists the recommendation number. The second column lists the subject of each recommendation in abbreviated form. The actual recommendation or guideline is considerably longer in most cases and must be read in detail for a full understanding of its meaning.

The next three columns provide the ratings for the recommendations—the rating (e.g., "necessary"), the quality of evidence in support, and for Chapters 3 and 8 a strength of rating. The rating systems are discussed in detail at the beginning of this text. (See "Introduction and Guide to Use" Section C.) The evidence upon which these ratings were derived appears in the chapter discussion.

The final column lists the level of consensus. (For explanation of consensus levels see "Introduction and Guide to Use" Section E.) Any minority opinion or report is noted at end of the table. In the text minority opinions appear at the end of each relevant chapter.

In order to understand these tables fully it is necessary to read the "Introduction and Guide to Use of These Guidelines" and follow the procedure given in Section G.

CHAPTER 1
HISTORY AND PHYSICAL EXAMINATION

Rec #	Recommendation	Rating System I & II	Quality of Evidence	Strength	Consensus Level
	A. HISTORY				
1.1.1	The Process	Necessary	II,III	—	1
1.1.2	The Role	Established	I,II,III	—	1
1.1.3	The Components	Necessary	I,II,III	—	1
	B. EXAMINATION				
1.2.1	All DX Procedures	Necessary	II,III	—	1
1.2.2	Regardless of CC	Recommended	III	—	1
1.2.3	Cranial Complaints	Established	II,III	—	1
1.2.4	CNS Evaluation	Established	II,III	—	1
1.2.5	Neck & Adjacent	Established	II,III	—	1
1.2.6	Thoracic/Chest	Established	II,III	—	1
1.2.7	Low Back	Established	I,II,III	—	1
1.2.8	Extremity	Established	I,II,III	—	1
1.2.9	ICE	Recommended	II	—	1

CHAPTER 2
DIAGNOSTIC IMAGING

Rec #	Recommendation	Rating System I	Quality of Evidence	Strength	Consensus Level
2.1.1	Sequence of Services	Established	III	—	1
2.2.1	Patient Selection	Established	I,II,III	—	1
2.3.1	Interpretation & Report	Established	II,III	—	1
2.4.1	Legal Issues	Established	III	—	1
2.5.1	Technology & Protection	Established	I,II,III	—	1
2.6.1	Plain Film	Established	I,II,III	—	1
2.6.2	Postural & Biomech	Promising	II,III	—	1
2.7.1	Full Spine-Scoliosis	Established	I,II,III	—	1
2.7.2	Full Spine-Biomech & Postural	Promising	II,III	—	1
2.8.1	Stress—DJD, Trauma, or Instability	Established	I,II,III	—	1
2.8.2	Stress—Other Uses	Equivocal	II,III	—	1
2.9.1	V Fluoro Kinematic & Biomechanical	Promising	II,III	—	1
2.9.2	V Fluoro Instab Wrist & Contrast	Established	I,II,III	—	1
2.10.1	Plain Film Contrast	Established	I,II,III	—	1
2.11.1	CT Scanning	Established	I,II,III	—	1
2.12.1	MRI	Established	I,II,III	—	1
2.13.1	Radionucleotide BS	Established	I,II,III	—	1
2.14.1	Diag Ultrasound	Established	I,II,III	—	1

CHAPTER 3
INSTRUMENTATION

Rec #	Recommendation	Rating System I	Quality of Evidence	Strength	Consensus Level
3.1.1	Instrumentation Questionnaires	Established	I,II	A	1
3.1.2	Screening Questionnaires	Equivocal	II,III	C	1
3.1.3	Pressure Algometry	Promising	II,III	B	1
3.2.1	Plumbline Analysis	Established	II,III	B	1
3.2.2	Scoliometry	Established	I,II	A	1
3.2.3	Photogrammetry	Established	I,II,III	A	1
3.2.4	Moire Topography	Promising	II,III	B	1
3.2.5	Bilateral Weights	Equivocal	II,III	C	1
3.2.6	Automated Posture	Promising	II,III	B	1
3.3.1	Goniometry	Established	I,II	A	1
3.3.2	Inclinometers	Established	I,II	A	1
3.3.3	Optical Systems	Established	II	B	1
3.3.4	Computer ROM	Promising	II,III	B	1
3.4.1	Manual Strength Test	Established	I,II	A	1
3.4.2	Isometric	Established	I,II	A	1
3.4.3	Isokin-Sport	Established	II,III	B	1
3.4.4	Isokin-Post Injury	Promising	II,III	C	1
3.5.1	Isoinertial Thermocouples	Doubtful	II,III	D	3
3.5.2	Infrared Thermograph	Equiv/Prom	II,III	C	3
3.6.1	Galvanic Skin Resp	Investigational	II,III	D	1
3.6.2	GSR Acupuncture	Doubtful	II,III	E	1
3.7.1	EMG Scanning	Investigational	II,III	C	2
3.7.2	EMG Flexion-Relax/Mean-Median Freq	Promising	II,III	B	1
3.7.3	Surface Electro DX	Established	I,II	A	1
3.7.4	Needle Electro DX	Established	I,II	A	1
3.7.5	ECG	Established	I,II	A	1
3.8.1	Clinical Laboratory	Established	I,II,III	A	1
3.9.1	Doppler Ultrasound	Established	II,III	B	1
3.9.2	Plethysmog Diff Dx	Established	II,III	B	1
3.9.3	Plethysmog Monitor Spine	Investigational	II,III	D	1
3.9.4	Spirometry	Established	I,II	A	1
3.10.1	Thermocouples	Equivocal	II	C	Minority Report
3.10.2	Infrared Thermograph	Promising	II,III	B	Minority Report

CHAPTER 4
CLINICAL LABORATORY

Rec #	Recommendation	Rating System I	Quality of Evidence	Strength	Consensus Level
4.1.1	Role of Laboratory	Established	III	—	1
4.1.2	Lab Selection	Established	III	—	1
4.1.3	Office Laboratories	Established	III	—	1
4.1.4	Patient Preparation	Established	III	—	1
4.1.5	Specimen Collection	Established	III	—	1
4.1.6	Need for Lab Testing	Established	I,II,III	—	1
4.1.7	Test Selection-DX	Promising	I,II,III	—	1
4.1.8	Test Selection-Screen	Established	I,II,III	—	1
4.1.9	Test Selection-Patient Mgt.	Established	II,III	—	1
4.1.10	Interpretation of Reference Values	Established	I,II,III	—	1
4.1.11	Integration of Data	Established	I,II,III	—	1
4.1.12	Communication with Patients	Established	III	—	1
4.1.13	Recording Results	Established	III	—	1
4.1.14	Consultation	Established	III	—	1
4.1.15	Organ Profiles	Established	I,II,III	—	1
4.1.16	Investigational Tests	Established	I,II,III	—	1
4.1.17	Novel Applications	Established	I,II,III	—	1
	GUIDELINES FOR ORDERING:				
4.2.1	Urinalysis	Established	I,II,III	—	1
4.2.2	CBC	Established	I,II,III	—	1
4.2.3	ESR	Established	I,II,III	—	1
4.2.4	Biochem Profiles	Established	I,II,III	—	1
4.2.5	Serum or Plasma Glu	Established	I,II,III	—	1
4.2.6	Serum Urea Nitro & Creatinine	Established	I,II,III	—	1
4.2.7	Serum Calcium	Established	II,III	—	1
4.2.8	Serum Inorg Phos	Established	II,III	—	1
4.2.9	Serum Prot & Albumin	Established	II,III	—	1
4.2.10	Serum Cholesterol	Established	I,II,III	—	1
4.2.11	Alk Phos	Established	I,II,III	—	1
4.2.12	Prostatic Acid Phos	Established	I,II,III	—	1
4.2.13	Prostate Specific Antigen	Established	I,II,III	—	1
4.2.14	AST	Established	I,II,III	—	1
4.2.15	CK	Established	I,II,III	—	1
4.2.16	Thyroid Function	Established	I,II,III	—	1
4.2.17	Uric Acid	Established	I,II,III	—	1
4.2.18	Rheumatoid Factor	Established	I,II,III	—	1
4.2.19	ANA	Established	I,II,III	—	1

CHAPTER 4
CLINICAL LABORATORY - CONTINUED

Rec #	Recommendation	Rating System I	Quality of Evidence	Strength	Consensus Level
4.2.20	HLA-B27	Established	I,II,III	—	1
4.2.21	CRP	Established	I,II,III	—	1
4.2.22	Potassium	Established	I,II,III	—	1
4.2.23	Sodium	Established	I,II,III	—	1
4.2.24	Iron	Established	I,II,III	—	1
4.2.25	Fecal Occult Blood	Established	II,III	—	1
4.2.26	Ferritin	Established	I,II,III	—	1
4.3.1	Hair Analysis	Investigational	I,II,III	—	1
4.3.2	Live Cell Analysis	Investigational	III	—	1
4.3.3	Biochem Biopsy	Investigational	I,II,III	—	1
4.3.4	Optimal Values w/o accept. proced.	Investigational	I,II,III	—	1
4.4.1	Cytotoxic	Inappropriate	I,II,III	—	1
4.4.2	Reams Testing	Inappropriate	III	—	1

CHAPTER 5
RECORD KEEPING AND PATIENT CONSENTS

Rec #	Recommendation	Rating System II	Quality of Evidence	Strength	Consensus Level
5.1.1	Pt File, Initial	Necessary	I,II,III	—	1
5.1.2	Pt File, Archive	Recommended	II,III	—	1
5.1.3	Dr/Clinic ID	Necessary	I,II,III	—	1
5.1.4	Patient IDq	Necessary	I,II,III	—	1
5.1.5	Patient Demographs Sex & Occupation	Necessary	I,II,III	—	1
5.1.6	Marital Status, Race, Dependents, Employer, Spouse Occupation	Discretionary	I,II,III	—	1
5.1.7	Health Coverage	Discretionary	III	—	1
5.1.8	Health Hist Date, CC, Description, Rev Sys; Tx, Signature	Necessary	I,II,III	—	1
5.1.9	Questionnaires, Drawings and Other Patient Information	Recommended	I,II,III	—	1
5.1.10	Exam Findings	Necessary	I,II,III	—	1
5.1.11	Special Studies	Recommended	I,II,III	—	1
5.1.12	Misc Assess Outcome Instruments	Recommended	I,II,III	—	1
5.1.13	Clinical Impression	Necessary	I,II,III	—	1
5.1.14	Treatment Plan	Recommended	I,II,III	—	1
5.1.15	Chart/Progress Notes	Necessary	I,II,III	—	1
5.1.16	Clinical Info	Necessary	I,II,II	—	1
5.1.17	Adj/Man Tech	Necessary	II,III	—	1
5.1.18	Initials, Other than Attending	Necessary	I,II,III	—	1
5.1.19	Reexam/Reassess	Necessary	I,II,III	—	1
5.1.20	Financial Records	Necessary	I,III	—	1
5.1.21	Info Storage & Retrieval	Discretionary	III	—	1
5.1.22	Internal Memoranda	Discretionary	I,III	—	1
5.2.1	Direct Correspondence	Recommended	II,III	—	1
5.2.2	Health Records	Recommended	II,III	—	1
5.2.3	Dx Imaging	Recommended	II,III	—	1
5.2.4	External Reports	Recommended	II,III	—	1
5.3.1	Gen Chart File Org	Necessary	I,II,III	—	1
5.3.2	Preprinted Forms	Discretionary	II,III	—	1
5.3.3	Legibility & Clarity	Necessary	I,II	—	1
5.3.4	Abbreviations/Symbols	Recommended	II,III	—	1
5.4.1	Confidentiality	Necessary	I,II	—	1
5.4.2	Records Retention	Necessary	I,II	—	1
5.4.3	Beyond Legal Time Limits	Discretionary	III	—	1
5.4.4	Admin. Records	Necessary	I,II,III	—	1
5.4.5	Records Transfer	Necessary	I,II,III	—	1

CHAPTER 5
RECORD KEEPING AND PATIENT CONSENTS - CONTINUED

Rec #	Recommendation	Rating System II	Quality of Evidence	Strength	Consensus Level
5.4.6	Staff Responsibility	Necessary	I,II,III	—	1
5.5.1	Consent to Tx General	Necessary	I,II,III	—	1
5.5.2	Consent to Tx Competence	Necessary	I,II,III	—	1
5.5.3	Authorization	Necessary	I,II,III	—	1
5.5.4	Financial Assignments	Discretionary	III	—	1
5.5.5	Consent Research	Necessary	I,II,III	—	1
5.5.6	Consent Records Photo/Video	Recommended	I,II,III	—	1
5.5.7	Consent Research Pub/Photo/Video	Necessary	I,II,III	—	1
5.5.8	Consent Observers	Necessary	I,II,III	—	1

CHAPTER 6
CLINICAL IMPRESSION

Rec #	Recommendation	Rating System I & II	Quality of Evidence	Strength	Consensus Level
6.1.1	Necessity	Necessary	I,II,III	—	1
6.2.1	Initial Responsibility	Necessary	I,II,III	—	1
6.3.1	Subsequent Responsibility	Necessary	I,II,III	—	1
6.4.1	Terminology	Recommended	II,III	—	1
6.5.1	Content—Unrelated Impressions	Recommended	II,III	—	1
6.5.2	Content—Intensity & Region	Recommended	II,III	—	1
6.5.3	Content—Sub/Obj Findings	Established	I,II,III	—	1
6.6.1	Timely Diagnosis	Necessary	I,II,III	—	1
6.6.2	Appropriate Consultation	Recommended	II,III	—	1
6.6.3	Impression Recorded	Necessary	I,II,III	—	1
6.7.1	Working sypothesis	Necessary	I,II,III	—	1
6.8.1	Communication	Necessary	I,II,III	—	1

CHAPTER 7
MODES OF CARE

Rec #	Recommendation	Rating System I	Quality of Evidence	Strength	Consensus Level
	MAN MANIP & ADJ PROCEDURES SPECIFIC CONTACT THRUST				
7.1.1	Hi Vel-LBP	Established	I,II,III	—	1
7.1.2	Hi Vel Other NMS	Established	II,III	—	1
7.1.3	Hi Vel Type O	Equivocal	II,III	—	1
7.1.4	Hi Vel Recoil NMS	Prom to Estab	II,III	—	1
7.1.5	Hi Vel Recoil Type O	Equivocal	II,III	—	1
7.1.6	Low Velocity NMS	Equiv to Prom	II,III	—	1
7.1.7	Low Velocity Type O	Inv to Equiv	II,III	—	1
	NONSPECIFIC CONTACT				
7.2.1	Mobilization	Established	I,II,III	—	1
	MANUAL FORCE				
7.3.1	Mechanically Assist Drop Piece/Terminal Point NMS	Prom to Estab	III	—	1
7.3.2	Drop Piece/Terminal Point Type O	Inv to Equiv	III (II?)	—	3
7.3.3	Flexion Distraction	Established	II,III	—	2
7.3.4	Pelvic Blocks	Promising	III	—	1
	MECHANICAL FORCE, MANUALLY ASSISTED				
7.4.1	Fixed Stylus	Equivocal	III	—	1
7.4.2	Moving Stylus	Prom to Estab	I,II,III	—	1
	MANUAL NONARTICULAR				
7.5.1	Muscle Energy	Promising	II,III	—	1
7.5.2	Neurological Reflex Muscle Relaxation	Equivocal	III	—	1
7.5.3	Other	Investigational	III	—	1
7.5.4	TPT	Established	II,III	—	1
7.5.5	Misc Soft Tissue	Established	II,III	—	1
7.6.1	Neuro Retraining NMS	Equiv to Prom	II,III	—	1
7.6.2	Neuro Retraining Other	Investigational	II,III	—	1
7.6.3	Concep. Mind-Body Approaches	Inappropriate	III	—	1
7.6.4	Surrogate Testing	Inappropriate	III	—	1

Chapter 7
Modes of Care - Continued

Rec #	Recommendation	Rating System I	Quality of Evidence	Strength	Consensus Level
	NON-MANUAL PROCEDURES				
7.7.1	Exercise & Rehab	Prom to Estab	I,II,III	—	1
7.7.2	Strength & Cond	Prom to Estab	I,II,III	—	1
7.7.3	Passive Stretch	Established	I,II,III	—	1
7.8.1	Back School	Prom to Estab	I,II,III	—	1
7.8.2	Wellness & Health Promotion	Prom to Estab	II,III	—	1
7.8.3	Nutritional Counseling	Established	I,II,III	—	1
7.8.4	Bio-Feedback	Prom to Estab	II,III	—	1
7.9.1	Electrical Modalities	Prom to Estab	I,II,III	—	1
7.10.1	Thermal Modalities	Established	I,II,III	—	1
7.11.1	Ultraviolet	Established	II,III	—	1
7.12.1	Ultrasound & Phonophoresis	Established	I,II,III	—	1
7.13.1	Bracing, Casting, etc.	Prom to Estab	II,III	—	2
7.14.1	Traction	Prom to Estab	I,II,III	—	1
7.15.1	Manip.—Sedation/Anesthesia	Equivocal	II,III	—	1
7.16.1	Acupuncture	Promising	I,II,III	—	1
7.17.1	Homeopathic Remedies	Equivocal	II,III	—	1

CHAPTER 8
FREQUENCY AND DURATION OF CARE

Rec #	Recommendation	Rating System I	Quality of Evidence	Strength	Consensus Level
8.1.1	Preconsultation, Duration of Symptoms; Severity of Symptoms, # Previous Episodes, Injury Superimposed on Pre-existing Injury	Promising	II,III	B	1
8.2.1	Tx Care Frequency	Established	II,III	B	1
8.3.1	Patient Cooperation	Promising	II,III	B	1
8.4.1	Failure to Meet Tx, Obj (uncomplicated cases), Acute Disorders, Unresponsive Sub/Chronic, Systematic Interview, Written Tx Goals, Failure-Discharge MMI	Established	I,II,III	A	1
8.5.1	Uncomplicated Cases	Established	I,II,III	A	1
8.6.1	Complicated Cases Signs of Chronicity	Established	I,II,III	A	1
8.6.2	Subacute Episode	Promising	II,III	B	1
8.6.3	Chronic Episodes	Promising	II,III	B	1
8.7.1	Elective Care	Unrated	—	—	—

CHAPTER 9
REASSESSMENT

Rec #	Recommendation	Rating System II	Quality of Evidence	Strength	Consensus Level
9.1.1	Integral Component Case Mgt.	Necessary	II,III	—	1
9.2.1	Determined by Pt Response	Necessary	II,III	—	1
9.3.1	ASAP if Worse	Necessary	III	—	1
9.4.1	New Signs/Sx	Necessary	II,III	—	1
9.5.1	By Appropriately Trained Persons	Necessary	II,III	—	1
9.6.1	Same Manner as Initial Assessment	Recommended	I,II,III	—	1
9.7.1	Third Party Interests	Recommended	III	—	1
9.8.1	Interactive Reassessment	Necessary	III	—	1
9.9.1	Periodic Reassessment	Necessary	III	—	1
9.10.1	In Areas of Prior (+) Findings	Necessary	III	—	1

CHAPTER 10
OUTCOME ASSESSMENT

Rec #	Recommendation	Rating System I & II	Quality of Evidence	Strength	Consensus Level
10.1.1	Functional Outcome Assessment	Established	I,II,III	—	1
10.2.1	Pain Measurement	Established	I,II,III	—	1
10.2.2	Patient Satisfaction	Established	I,II,III	—	1
10.3.1	General Health	Established	I,II,III	—	1
10.4.1	ROM	Established	I,II,III	—	1
10.4.2	Thermography	Invest to Equiv	II,III	—	3
10.4.3	Muscle Function Inst	Established	I,II,III	—	1
10.4.4	Muscle Function Man	Equivocal	II,III	—	1
10.4.5	Posture	Promising	II,III	—	1
10.5.1	Malposition	Equivocal	II,III	—	1
10.5.2	Abnormal Motion	Equiv to Prom	II,III	—	1
10.5.3	Abnormal X-ray Motion	Investigational	II,III	—	1
10.5.4	Soft Tiss Texture & Tenderness	Promising	I,II,III	—	1
10.5.5	Tone Electrodes	Equivocal	I,II,III	—	1
10.5.6	Tone Scanning	Invest to Equiv	II,III	—	3
10.6.1	Subluxation	Recommended	II,III	—	1
10.6.2	Qualified Individuals	Necessary	II,III	—	1
10.6.3	Consideration	Necessary	II,III	—	1
10.6.4	Appropriate Intervals	Necessary	II,III	—	1
10.6.5	Generic Outcomes	Recommended	II,III	—	1
10.7.1	Thermography	Equivocal		—	Minority Report
10.7.2	Tone Scanning	Equivocal	I,II,III	—	Minority Report

CHAPTER 11
COLLABORATIVE CARE

Rec #	Recommendation	Rating-Mixed	Quality of Evidence	Strength	Consensus Level
11.1.1	Explanation	Necessary	II,III	—	1
11.2.1	Freedom of Choice	Necessary	III	—	1
11.2.2	Informed Decision	Necessary	III	—	1
11.3.1	Familiarity w/Med	Recommended	II,III	—	1
11.3.2	Familiarity w/Alt Hlth	Recommended	III	—	1
11.4.1	Consult or Refer	Necessary	I,II,III	—	1
11.4.2	Accept Referrals	Recommended	III	—	1
11.5.1	Provide Information	Recommended	III	—	1
11.5.2	Post Referral Comm	Recommended	III	—	1
11.5.3	Direct Comm	Recommended	III	—	1
11.5.4	Request for Records	Recommended	III	—	1
11.6.1	Develop Consensus	Recommended	III	—	1
11.6.2	Seek Access	Recommended	III	—	1
11.6.3	Concurrent Care	Recommended	III	—	1
11.6.4	Resolution of Disputes	Recommended	III	—	1
11.6.5	Facilitate Pt Access	Recommended	III	—	1
11.7.1	No Financial Relation	Necessary	III	—	1
11.7.2	Cooperation	Recommended	III	—	1

CHAPTER 12
CONTRAINDICATIONS AND COMPLICATIONS

Rec #	Recommendations	Condition Rating	Quality of Evidence	Strength	Consensus Level
	ARTICULAR DERANGEMENT				
12.1.1	Acute Inflammatory	III	II,III	—	1
12.1.2	Subacute/Chronic	I,II	II,III	—	1
12.1.3	DJD	I,II	II	—	1
12.1.4	Spondylolisthesis	I,II	II	—	1
12.1.5	Fx/Dislocation	III	III	—	1
12.1.6	Os Odontoidum	III	III	—	1
12.1.7	Hypermobility	I,II	II,III	—	1
12.1.8	Postsurgical Int	II	III	—	1
12.1.9	Acute Injuries	I,II	I,II	—	1
12.1.10	Scoliosis	I,II	II,III	—	1
	BONE WEAKENING DISORDERS				
12.2.1	Avascular Necrosis	III	III	—	1
12.2.2	Demineralization	II	II;III	—	1
12.2.3	Benign Bone Tumors	II,III	III	—	1
12.2.4	Malignancies	III	II,III	—	1
12.2.5	Infection	III	II	—	1
	CIRCULATORY/CARDIO				
12.3.1	V.B.I.	II,III	I,II,III	—	1
12.3.2	Aneurysm Inv Major Blood Vessel	III	III	—	1
12.3.3	Bleeding	II	III	—	1
12.4.1	Neurological Acute Myelopathy, Cauda Equina	II,III	I,II	—	1

CHAPTER 13
PREVENTIVE/MAINTENANCE CARE

Rec #	Recommendation	Rating System I	Quality of Evidence	Strength	Consensus Level
13.1.1	Disclosure	Established	III	—	1
13.1.2	Chiro Adjustments	Equivocal	III	—	1
13.1.3	Health Screening	Prom to Estab	II,III	—	1
13.1.4	Health Promotion	Established	I,II,III	—	1
13.1.5	Wellness Care Public Health	Equivocal	III	—	1
13.2.1	Community Screening	Promising	II,III	—	1
13.2.2	Public Health Ed	Promising	II,III	—	1

CHAPTER 14
PROFESSIONAL DEVELOPMENT

Rec #	Recommendation	Rating System II	Quality of Evidence	Strength	Consensus Level
14.1.1	Cont Ed Participation	Necessary	I,II,III	—	1
14.1.2	Ongoing	Recommended	I,II,III	—	1
14.1.3	Assess Outcomes	Recommended	I,II,III	—	1
14.1.4	Variety of Formats	Recommended	II,III	—	1
14.1.5	Critical Reading Postgraduate Ed	Recommended	II,III	—	1
14.2.1	Residency Programs	Recommended	II,III	—	1
14.2.2	Certification Programs	Recommended	II,III	—	1
14.2.3	Encouragement	Discretionary	II,III	—	1
14.2.4	Assess PG Outcomes	Recommended	II,III	—	1
14.2.5	Proprietary Grad Ed	Recommended	II,III	—	1
14.3.1	Encouragement Professional Organz	Discretionary	II,III	—	1
14.4.1	Membership Ethics/Std of Conduct	Recommended	II,III	—	1
14.5.1	Code of Ethics	Necessary	I,II,III	—	1
14.5.2	Advertising Research	Necessary	I,II,III	—	1
14.6.1	Encouragement	Recommended	I,II,III	—	1

Appendix C

Responses to Guidelines

All comments regarding these guidelines should be sent to:

Mercy Center Conference Advisory Committee
P.O. Box 6070
Huntington Beach, CA 92615

Please specify the chapter and specific guideline(s) to be addressed. All responses should be typed and double-spaced to facilitate accurate processing. Whenever possible, responses should include support material and references. Authors should include name, address and telephone number in case additional explanation is required.

Due to the number of responses anticipated, acknowledgment of submissions may not be possible. As future guidelines commissions are established, additional input will be solicited.

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Contents

Scientific Monograph of the Quebec Task Force on Whiplash-Associated Disorders:

Redefining "Whiplash" and Its Management

Walter O. Spitzer
Mary Louise Skovron
L. Rachid Salmi
J. David Cassidy
Jacques Duranceau
Samy Suissa
Ellen Zeiss

Editorial Coordinator, Scientific Monograph: J. David Cassidy

Statement and Editorial Board

This *Scientific Monograph of the Quebec Task Force on Whiplash-Associated Disorders* is an abridged version of the Official Report entitled *Whiplash-Associated Disorders (WAD)* of the Quebec Task Force on Whiplash-Associated Disorders, also entitled in French *Les Troubles Associés à l'Entorse Cervicale (TAEC)*. Throughout this monograph, we refer to the Official Report (Official Report of the Quebec Task Force on Whiplash-Associated Disorders) and the scientific monograph (Scientific Monograph of the Quebec Task Force on Whiplash-Associated Disorders).

The Official Report is the authorized and endorsed report of the Task Force. Readers of this scientific monograph who wish to explore selected issues in more detail can obtain the Official Report by writing to the Société d'assurance automobile du Québec, 333 boul. Jean Lesage, Tour nord, 6ième étage, Québec, Québec, G1K 8J6, Canada.

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THE QUEBEC CLASSIFICATION OF WHIPLASH-ASSOCIATED DISORDERS*

Grade	Clinical Presentation
0	No complaint about the neck No physical sign(s)
1	Neck complaint of pain, stiffness, or tenderness only No physical sign(s)
2	Neck complaint AND Musculoskeletal sign(s)†
3	Neck complaint AND Neurological sign(s)‡
4	Neck complaint AND Fracture or dislocation

* For explanation refer to Section 3.
† Musculoskeletal signs include decreased range of motion and point tenderness.
‡ Neurologic signs include decreased or absent deep tendon reflexes, weakness, and sensory deficits.
Symptoms and disorders that can be manifest in all grades include deafness, dizziness, tinnitus, headache, memory loss, dysphagia, and temporomandibular joint pain.
Dotted lines indicate limits of terms of reference of Task Force.

Introduction

In 1987, The Quebec Task Force, under the esteemed leadership of Dr. Walter Spitzer, presented us with a classic work on low back pain entitled "Scientific Approach to the Assessment and Management of Activity-Related Spinal Disorders: A Monograph for Clinicians." Today, that piece remains a significant reference to which many frequently refer.

The Quebec Task Force has again, in this issue, provided us with an objective review of whiplash-associated disorders (WAD). The work by the Task Force was sponsored by the Société d'assurance automobile du Québec (or SAAQ). It is our pleasure to have a brief introduction to this monograph by Dr. Nikolai Bogduk, Newcastle, Australia, an expert in cervical spine disorders and pain.

Dr. James N. Weinstein
Editor-in-Chief

Editorial

The report of the Quebec Task Force on Whiplash-Associated Disorders scores a victory for spine science. It will serve as one milestone applying clinical epidemiology to clinical practice: the rules that distinguish truth from fashion.

This report is an indictment of the literature. From an inception pool of more than 10,000 publications, the Task Force found only 346 worth of consumption. This reflects how the literature has been polluted by the fashion to publish biographical papers—"what I do in my practice"—that offer no proof of either the reliability, validity, or true efficacy of that practice.

A parallel fashion has been to dismiss calls for controlled studies as the ravings of obsessed academics: "research is for scientists, but I am a clinician." Proper research is not an indulgence of academics; it is the basis of best practice and quality assurance. You cannot know that what you are doing is best for the patient unless the practice has been rigorously tested. Peer endorsement is no longer a substitute for scientific proof and cannot prevail over rigorous disproof.

The Task Force found the literature wanting. It could not even complete a table of the number of good studies per topic as it did for low back pain.[10] On the topic of whiplash, there is no decent epidemiology, nothing written on diagnosis, and barely any treatment discussed works. Mobilization and manipulation seem to help for short periods of acute pain, but nothing helps for chronic pain.

Mercifully, it seems that the management of whiplash is not as riddled as the management of low back pain by medical excesses, such as expensive technologic investigations and controversial, major surgery. In stark contrast is the province of Quebec; the Task Force reports an extraordinary expense of some $1.5 million (Canadian dollars) for physiotherapy, when medical expenses were $230,000. Yet the report clearly finds no proven value for physiotherapy. A temporary moratorium on fees for physiotherapy would provide the funds needed to pursue the research called for by the report.

It is fascinating that the report from Canada (and Sweden) converges in time with similar initiatives elsewhere. The International Association for the Study of Pain has just published the second edition of its taxonomy, which streamlines the classification of spinal pain.[9] That taxonomy rejects supposed diagnoses but recognizes "cervical spinal pain of unknown origin," and "acceleration–deceleration injuries." The Quebec Task Force extends the latter by offering four grades. However, none of these rubrics is a legitimate diagnosis. They are not based on the cause or even source of pain, but do serve as convenient, descriptors of presentations and are more honest than supposed diagnoses, such as spondylosis or the ubiquitous and ambiguous "soft-tissue injury."

Unfortunately, the Quebec Task Force was not aware of other more modest initiatives instituted by the Motor Accidents Authority of New South Wales: However, this convergence reflects a worldwide recognition of the serious social, economic, and medical problem of whiplash.

The Quebec Task Force provides a cogent and exhaustive summary of the state of the art as of September 1993. What is not reflected, though expected, is the rapid progress that has been made since then. Whereas the Quebec study emphasized, in its findings and in its recommendations, the epidemiology, prognosis, clinical features, and treatment of whiplash, the Australian thrust has been on its pathology, pathophysiology, and diagnosis.[3] This literature appeared too late for inclusion in the Quebec report. Experimental studies and postmortem studies have yet to prove the "lesion" of whiplash, but they have set a spectrum of possibilities.[5] The likely lesions are tears to muscles, rim lesions of the discs, and occult fractures or injuries to the zygapophysial joints.[6,11] No clinical studies have addressed the validity of diagnostic or epidemiologic factors associated with muscle "lesions" and disc "lesions," but painful zygapopbysial joints have been studied.

Pain is not morphologic; it cannot be seen on radiographs, computed tomography, or magnetic resonance imaging. Pain can be pursued using diagnostic blocks. In this regard, the Australia studies have established the face validity,[1] construct validity,[2] and use of controlled, diagnostic blocks of the cervical zygapophysial joints. Under double-blind, controlled conditions, it has been shown that zygapopbysial joint pain is the single most common basis for chronic neck pain after whiplash,[5] and that at least 27% of the headaches after whiplash can be traced to the C2–C3 zygapophysial joints.[7] Although treatment with intra-articular steroids is not unreasonable,[4] results with percutaneous radiofrequency neurotomy have been promising but capricious.[8] Controlled studies are nearing completion.

The Quebec Task Force emphasizes that whiplash is essentially a benign condition with the vast majority of patients recovering, but it is the refractory minority that accounts for an inordinate proportion of the costs. With respect to these patients, the state of the art may not be as bleak as portrayed by the Task Force. Spine science is moving fast. Some of the research that the Task Force called for is already being done and has been done. We congratulate the Task Force on this much needed effort, and we hope it will guide us in the appropriate direction

to diagnose, treat, and research this most costly clinical problem.

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Section 1. Approach to the Problem

In the past few decades, communities have been repeatedly confronted with health-related dilemmas that are difficult to resolve. Individuals, on the one hand, seek cures or control for fatal and chronic diseases that science cannot provide. Policy makers and those who pay for health services question whether investments should go to aggressive preventive intervention or to high technology for treatment, or to a mix of both. The intensity of these dilemmas has been driven by recent international recession and virtually universal cost containment strategies in developed countries.

Since World War II, there has been pressure to depend more on sophisticated technology. Such technology often goes through a trendy "fad phase" and is not always subjected to rigorous scientific evaluation before its use becomes widespread. The price paid by society for such shortcomings is aggravated by procedure-oriented fee-for-service reimbursement schemes that reward "doing" much more than "thinking." Once such procedures become part of the mainstream of clinical practice, it becomes very difficult to evaluate them because of legitimate ethical concerns about withholding accepted interventions from patients whom might need them.

The Department of Epidemiology and Biostatistics at McGill University and its hospital-based Divisions of Clinical Epidemiology have been addressing controversial social and medical issues for governments and public agencies since 1976. Task forces have been formed to address such problems as the value of the periodic medical examination, the disproportionate disability and associated expense of occupational back injury, the congestion in Montreal-area emergency rooms, and possible causal associations between exposure to pesticides and Reye's Syndrome in children and exposure to sour gas emissions and respiratory disease and cancer.

This Task Force addresses the problem of whiplash and its associated disorders. Neck pain is to the automobile what low back pain is to the workplace. Whiplash-Associated Disorders (WAD) are becoming increasingly worrisome in the Western world. In Quebec alone, approximately 5000 whiplash cases annually account for 20% of all traffic injury insurance claims, and the average period for compensation has increased from 72 days in 1987 to 108 days in 1989.[34,35] In British Columbia and Saskatchewan, two other Canadian Provinces with single-payer motor vehicle insurance programs, claims for whiplash injury represent 68% and 85% of the automobile injury claims, respectively.[35,98] In addition, whiplash injury presents a substantial financial burden to society.

Mandate of the Task Force

During 1989–1990, the Quebec Automobile Insurance Society (Société d'assurance automobile du Québec [SAAQ]) approached Dr. W. O. Spitzer, of the Department of Epidemiology and Biostatistics, McGill University, about the possibility of an in-depth analysis of clinical, public health, social, and financial determinants of "the whiplash problem." The frequency of the clinical entity labeled as whiplash is high; the residual disability of victims appears significant in magnitude, and the costs of care and indemnity are high and rising. There is considerable inconsistency about diagnostic criteria, indications for therapeutic intervention, rehabilitation, and the appropriate role of clinicians at all phases of the syndrome. Little is known about primary prevention of the condition, and virtually nothing is known about tertiary prevention of serious disability.

The leaders of the SAAQ appreciated the need to understand the epidemiology; mechanisms of injury; clinical definitions and syndromes; natural history; evidence of effectiveness of prevention, treatment, and rehabilitation; the role of psychosocial factors; and the impact of the health services system in general to formulate a rational approach to the problem. The Task Force was charged to make specific recommendations to deal with these issues. The SAAQ was committed to a system that would provide fairness and compassion to persons with neck injury following motor vehicle collision, medical care of the highest scientific standards, realistic strategies of primary prevention, and judicious management of society's resources. Most importantly, the SAAQ acknowledged the preeminence of scientific evidence.

Basic Approach

Despite the expertise of the Task Force and our scientific advisors, opinion had to take a backseat to evidence. Thus, all conclusions and recommendations were based on scientifically admissible studies, when available. The general rules of evaluation of evidence were adopted in advance and fine-tuned to adapt them to the body of evidence as the work of the Task Force progressed. Experience in science, clinical judgment, and well-reasoned opinion were not totally disregarded, but they were always subordinate when admissible scientific evidence was available.

When confronting controversies of clinical diagnosis and management, a special challenge is to enable a process whereby methodologists are educated about the clinical issues, and clinicians are trained in the design and analysis of experimental and nonexperimental studies. Understanding the important issues is crucial when decisions about public health policy are under consideration. The strategy used by this Task Force to assemble valid data from the many published original studies evolved over two decades. First, it required adoption of criteria of eligibility for the type of publication to be considered. In this effort, we eschewed review articles

and reports of secondary analyses, except as background reading or as sources of references to primary reports. Only original research was considered as scientific evidence.

As described in detail in later sections, we standardized the process of evaluating original articles screened as eligible. This standardization ensured that all important features were weighed carefully each time by reviewers. The various types of experimental and nonexperimental studies required specific variants of the abstraction forms. The specific tactics and procedures were developed initially during the Canadian Task Force on the Periodic Health Examination,[26,101] and the methods of selecting, weighing, and synthesizing original data from multiple sources were refined during successive Task Forces (*e.g.*, the New Brunswick Task Force on Reye's Syndrome and Environmental Risk Factors,[102] the Inter-University Task Force on Passive Smoking,[103] the Working Group on Low Osmolality/High Osmolality Contrast Media,[55] and the Quebec Task Force on Vertebral Column Disorders in the Workplace[104]). In the current effort, we refined our methods, including extensive modifications of the forms for critical appraisal of articles.

In the educational field, Slavin coined the descriptive phrase "best evidence synthesis" and argued that a method of aggregating data is needed that avoids the constraints and pitfalls of meta-analysis and the haphazardness of unstructured literature review.[97] The key features of best evidence synthesis are predetermined explicit criteria of quality for articles, type of data used in the aggregating process, a diligent search for relevant unpublished material, and presentation of the results as ranges of estimates of effect with probability statements linked to the boundaries of the ranges, if necessary. Meta-analysis, in contrast, seeks a single estimate of effect. Because meta-analysis and best evidence synthesis are vulnerable to publication bias,[100] the search for unpublished material mentioned above is important in both types of undertakings.

After 3 years of deliberations by the Task Force, the evidence was found to be sparse and generally of unacceptable quality. The original research articles in the literature strained our capacity to adhere strictly to best evidence synthesis methodology. The following important elements of the method were retained: guidelines on the type of research papers that could be considered, a diligent search for relevant unpublished articles, a structured critical appraisal with predetermined checklists and rating scales, and an unwillingness to overinterpret the synthesized evidence with single estimates of effect. Applying *a priori* operational criteria of quality when accepting or rejecting studies could have resulted in rejection of virtually all articles considered. We used judgment to identify valid and useful components of published reports, which taken as a whole would not have met conventional standards. Therefore, this scientific monograph presents qualitative descriptions of the aggregate data, rather than ranges of estimates of effect.

■ Scope of the Report

The mandate of the Task Force included a broad variety of questions to be addressed. It was not feasible to have, in a single Task Force, sufficient representation of all areas of expertise needed to carry out a best evidence synthesis on all clinical questions and on all questions concerning prevention. Consequently, it was decided to focus the full Task Force on clinical issues, specifically risk, diagnosis, treatment, and prognosis of whiplash. Issues regarding mechanism of injury and prevention of whiplash were addressed by consensus in a subgroup that included an injury epidemiologist, orthopaedist, and engineer with outside consultants. This group conducted a review of the literature on road safety, biomechanics, and injury control with respect to the mechanism of whiplash injury, prevention of collisions, and the environment of moving automobiles.

Parallel to the Task Force review of the scientific evidence, a subgroup of clinicians was formed, with experts from the various specialties involved in diagnosis, treatment, and rehabilitation of WAD. They reviewed the basic anatomy, physiology, and semiology underlying clinical interventions for WAD. This permitted a better elaboration of the treatment algorithm and recommendations for professional education.

Because of the above consensus process, the entire Task Force was better prepared to describe, define, and classify the problem of whiplash, a process essential to the evaluation of the literature and to any subsequent recommendations. These results appear in Section 3 under the heading of "Consensus Findings." One of the most important contributions of the Task Force is the *Quebec Classification of Whiplash-Associated Disorders*. We hope our classification will allow more meaningful discussion of clinical issues and allow comparisons of future research studies through the adoption of standardized diagnostic criteria for WAD.

Surprisingly little evidence relevant to epidemiology, clinical decisions, preventive interventions, and rehabilitation was found. Accordingly, for many aspects covered by its mandate from the SAAQ, the Task Force was forced to invoke expert opinion to make recommendations in areas where the literature was weak. To supplement this process and to gain a better understanding of the epidemiology of WAD in Quebec, we identified a cohort of whiplash subjects from the injury claim files of the SAAQ and examined prognostic factors in the recovery process. These findings appear in Section 2 under the heading of "The Quebec Whiplash-Associated Disorders Cohort Study."

This Scientific Monograph presents the essential scientific background from relevant clinical, epidemiologic, basic science and engineering disciplines, the methods employed, conclusions and recommendations. Given the dearth of valid information in the international literature, it emphasizes research priorities in the near term and the longer term. These can be found in Section 6: Research Priorities for Whiplash-Associated Disorders.

Section 2. The Quebec Whiplash-Associated Disorders Cohort Study

CHAIRPERSON'S NOTE: This section is a discrete report of original research conducted by Samy Suissa, Susan Harder, and Martin Veilleux under the auspices of the Task Force in fulfillment of its mandate. Thus, he and his coauthors, with the agreement of the Editor of Spine, will also cite this report as a peer-reviewed article, when appropriate in support of further research.

Two previous reports produced by the SAAQ have presented analyses of data from subjects compensated for whiplash, indicating the growing importance of this problem in Quebec since 1978.[16,17] Close to 20% of claimants to the SAAQ are recognized as having whiplash, making it the most common type of injury for which claims are submitted.[34,35] In British Columbia and Saskatchewan, two other Canadian provinces with single-payer motor vehicle insurance programs, staggering proportions of 68% and 85% of the claims paid out, respectively, in these two provinces are for whiplash.[35,58] Finally, the cost of whiplash injuries sustained in motor vehicle collisions represents a substantial financial burden to the SAAQ.[58]

In this study, using the claims database of the SAAQ, we estimate the incidence of compensated whiplash injury in Quebec and describe its variation by age, gender, and geographic region. We identify the sociodemographic and collision-related prognostic factors associated with the duration of compensation and the risk of recurrence of whiplash injury, using a large, population-based cohort. The direct medical and compensation cost of whiplash injury is assessed, along with its association with duration of compensation.

Methods

Design. The source population for this epidemiologic study is made up of all persons who sustained a whiplash injury in a motor vehicle collision in 1987 in Quebec and who submitted a claim for compensation to the SAAQ. The study subjects were identified from the SAAQ's computerized information systems by searching for individuals with an international classification of diseases-version 9 diagnostic code of 847.0 (sprains and strains of the neck, including whiplash injury). The year 1987 was selected because in that year the SAAQ achieved virtually complete coding of claimant-injury data by professional medical archivists.

A historical cohort design was used. The primary source cohort was defined as all subjects for whom some form of compensation was received from the SAAQ (i.e., reimbursement for one or more collision-related expenses or compensation to replace regular income), rather than simply as those who submitted a claim to the SAAQ. This source cohort was used in all analyses not involving collision-related data, such as the analyses of costs. A source subcohort was formed of all subjects in the primary cohort for whom collision-related data from a police accident report were available in the SAAQ's computerized databases. This subcohort was used as the source in all analyses involving collision-related data, such as the analyses of duration of absence and of recurrence. The date of entry into the cohort was defined as the date of the collision. The exit date from the cohort was the earliest of either the date on which the whiplash subject's file was closed by the SAAQ or the date on which the data were extracted from the SAAQ's computerized databases (May 1993) for the purposes of this study. The cohort was followed for approximately 6 years.

Factors Under Study. The potential prognostic factors that were available in the SAAQ's computerized databases for all members were sociodemographic (gender, age, area of residence, marital status, employment status, net income, and number of dependents of the whiplash subject). For the subcohort for whom collision-related data from a police accident report were available, collision-related factors (severity, type of vehicle occupied by the subject, position of subject in the vehicle, type of collision, seatbelt use, direction of collision, number of vehicles involved, and the authorized speed limit at the collision location) were used. In addition, the presence of multiple injuries was indicated.

Outcome Variables. The first outcome of interest was the duration of absence from usual activities for which some financial compensation was given. This was defined as the number of days between the date of the collision and the last date for which compensation to replace regular income was made by the SAAQ. This outcome corresponded roughly to the amount of time taken off work by the whiplash subject (if the subject was employed) or the length of time during which the whiplash subject could not carry out his or her usual activities (if the subject was a student, homemaker, retiree, or unemployed). SAAQ policy dictates that motor vehicle collision subjects who can return to work or to their usual activities within 7 days of the collision are ineligible to receive compensation to replace regular income, but may receive reimbursements for expenses. Such subjects, whose injuries were presumably minor, were assigned a mean duration of 3.5 days, or one half of the 7-day waiting period required by the SAAQ. For all others, the absence was taken as the duration of compensation plus 7 days. Because the duration of compensation is measured cumulatively by the SAAQ and does not allow successive intervals of compensation to be distinguished in cases of recurrence, the study cohort for this first outcome excluded all subjects who experienced a recurrence.

The second outcome of interest was whether or not the

subject experienced a recurrence or relapse of the injury. For the purpose of this study, recurrence was defined as the return of apparently resolved symptoms after a single motor vehicle collision in which the subject was involved in 1987. It did not include "reoccurrences" of whiplash resulting from subsequent motor vehicle collisions. The study cohort for this second outcome included only those individuals diagnosed with whiplash as their sole injury. This was necessary to ensure that the recurrence was related only to the whiplash injury and not to another injury sustained during the collision.

The third outcome under study was the financial cost of whiplash injury to the SAAQ. For descriptive purposes, the distribution of costs according to the type of reimbursement or compensation was determined for all subjects who submitted a claim to the SAAQ for a whiplash injury sustained in 1987. The medical cost associated with whiplash injury (besides those costs covered by Quebec's universal health insurance plan or other private insurance plans) comprised the fees and expenses that are routinely reimbursed by the SAAQ, such as expenses for medical apparatus necessary for the social and professional integration of whiplash patients undergoing rehabilitation; expenses for professional services used in the development of a rehabilitation plan (*e.g.*, psychologists, psychiatrists); expenses for medical and paramedical care not covered by the provincial or other health insurance plans; hospital expenses not covered by the provincial or other health insurance plans; medical expenses (prescriptions); ambulance fees; expenses for orthoses, prostheses; physiotherapy fees; and fees for medical examinations or expert medical consultations and evaluations not covered by the provincial or other health insurance plans. The study cohort for this cost outcome was the entire cohort of subjects who received some compensation from the SAAQ in 1987 for a whiplash injury.

Analysis. Using all whiplash patients who received some compensation from the SAAQ in 1987, the age- and gender-specific incidence rates for whiplash injury in Quebec were calculated using the 1987 stratum-specific Quebec population figures in the denominator.[39] The resulting rates are thus of the incidence of *compensated* whiplash injury. Region-specific incidence rates were also calculated for the 16 administrative regions in the province. These rates were based on the region of residence of the whiplash subjects rather than the region in which the collision occurred because the collision location information was frequently unavailable from the computerized databases. Driver-specific incidence rates using the number of licensed drivers in the province as the denominator[39] could only be calculated by extrapolation because of the lack of collision-related data on many of the whiplash cases. It was therefore assumed that the proportion of drivers among whiplash cases for whom collision-related data were available was equal to the proportion of drivers among whiplash cases whose collision data were missing from the databases.

Duration of absence and costs were analyzed using simple methods for continuous data. Comparisons were based on the Wilcoxon two-sample nonparametric test. Distributions of the duration of absence were described using standard techniques for survival data, such as Kaplan-Meier curves. Methods for proportions were used to analyze the rate of relapse or recurrence of whiplash symptoms.

Results

Study Cohorts

A total of 4766 subjects submitted claims for compensation to the SAAQ after whiplash injury in a motor vehicle collision in 1987. Nine of these 4766 individuals were found to have received no compensation or reimbursement of any sort from the SAAQ and were therefore deemed ineligible for inclusion in the study cohort. The remaining 4757 individuals formed the primary source cohort. Of these, 1743 did not have police collision report data entered in the computerized databases and were therefore excluded, leaving a total of 3014 whiplash subjects in the source subcohort aimed at assessing the role of collision-related factors. Reasons for the lack of police report data for 1743 individuals may include the possibility that police may not have been called to the scene of the collision or that the SAAQ may have been unable to link the police report with the subject's claim for compensation.

The study cohort for the analysis of the duration of absence had 2810 members because it excluded the 204 subjects with a recurrence from the 3014 members. The study cohort for the analysis of the rate of recurrence had 1666 members because it excluded the 1348 subjects with multiple injuries along with whiplash from the 3014 members to ensure that the recurrence was related only to the whiplash injury and not to another injury sustained during the collision. The study cohort for the analysis of costs comprised all 4757 members.

Incidence

Based on the Quebec population figures from 1987 and considering that the 4757 claimants represented the total number of compensated whiplash cases in the province in that year, the annual incidence of compensated whiplash in Quebec in 1987 was 70 per 100,000 inhabitants. The age- and gender-specific incidence rates of whiplash in Quebec in 1987 are shown in Figure 1A. The annual incidence of whiplash among female sufferers (86 per 100,000) was more than 1.5 times greater than among males sufferers (54 per 100,000). This difference in incidence was less marked in very young and in older age groups. For the 5–9- and the 65-year age groups, the incidence rate of whiplash among male patients exceeded the observed rate among female patients. The highest incidence of whiplash for both genders occurred in the 20–24 age group. For comparative purposes, the age- and gender-specific population-based incidence of all injuries combined that were reported by police in Quebec in 1987 is shown in Figure 1B.

The driver-specific annual incidence rate of whiplash, calculated by extrapolating from the data, showed that among those whiplash cases for whom collision-related data were available (3014 of 4757 cases), the percentage who were driving the vehicle at the time of their injury was 76.3 (2300 of 3014 cases). Assuming that an equal proportion and distribution of the whiplash subjects

with missing collision data were also driving their vehicles at the time of the event, the total number of whiplash subjects who were drivers was 3613 of 4757. Therefore, using the total number of licensed drivers in Quebec as the denominator,[99] the driver-specific incidence rate of whiplash in 1987 was 96 per 100,000 licensed drivers per year. Among male and female drivers, the incidence rates were 73 and 126 per 100,000 licensed drivers per year, respectively. The incidence of whiplash can be alternatively expressed in terms of the number of registered motor vehicles rather than in terms of population. Because there were 3.65 million registered vehicles in Quebec in 1987 and 4757 compensated claims for whiplash paid by the SAAQ, there were approximately 131 whiplash injuries per 100,000 vehicles per year in 1987.

Region-specific incidence rates for the 16 administrative regions in the province are shown in Figure 2. These rates are based on the region of residence of the whiplash subjects rather than the region in which the collision occurred because the collision location information

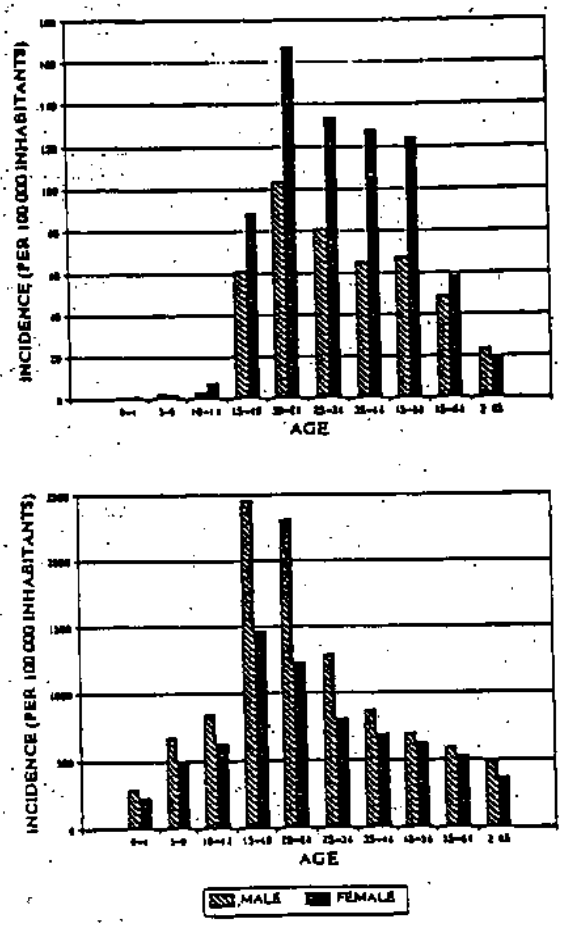


Figure 1. (A) Incidence rate of compensated whiplash injury by age and gender in Quebec (1987). (B) Incidence rate of all motor vehicle injuries by age and gender in Quebec (1987).

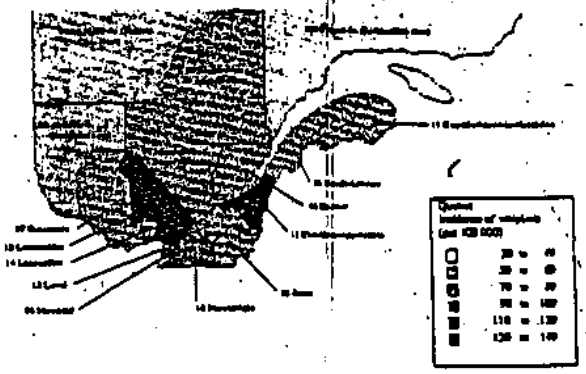


Figure 2. Incidence rate of compensated whiplash injury by geographic region of Quebec (1987).

was frequently unavailable from the computerized databases. The highest incidence rate, 141 per 100,000 inhabitants, was observed in the Lanaudière region, which is located on the north shore of the St. Lawrence River between Montreal and Trois-Rivières. Other regions with high whiplash incidence rates were the Laurentides (112 per 100,000 inhabitants), Laval (97 per 100,000 inhabitants), and Chaudière-Appalaches (91 per 100,000 inhabitants) regions. The lowest incidence rates occurred in the sparsely-populated northern regions of the province: Abitibi-Témiscamingue (47 per 100,000 inhabitants) and Nord-du-Québec/Côte Nord (34 per 100,000 inhabitants). It should be noted that for 2786 out of the 3591 (77.6 %) people for whom the region of residence *and* the region of the collision were known, the event occurred in the region where the subject resided.

Sociodemographic and Collision-Related Factors

A comparison of the sociodemographic characteristics of the 3014 subcohort members with the 1743 members of the cohort who were excluded because of the lack of collision-related data is provided in Table 1. Table 1 also provides a breakdown of the sociodemographic characteristics according to whether the cohort members sustained only a whiplash injury (n = 1666) or other injuries in addition to whiplash (n = 1348). Information on employment status was available for only 80% of the study cohort members.

Collision-related information for the study cohort is provided in Table 2, along with a breakdown according to whether the cohort members sustained only a whiplash injury or other injuries in addition to whiplash. Among the members of the study cohort, only 1.3% were involved in collisions in which at least one person was fatally injured. None of the cohort members died as a result of the motor vehicle collision. Six hundred fifty-two of the 3014 cohort members (21.6%) were reported to have been involved in a collision in which there were no injuries apparent when the police were at the scene. For subjects with whiplash only, 27.4% per-

Table 1. Sociodemographic Characteristics of Whiplash Subjects in Quebec, 1987

	Study cohort members	Whiplash only	Whiplash plus other injuries	Whiplash subjects excluded from study cohort*
Number	3014	1666	1348	1743
% Female	59.7	64.2	54.1	58.7
Age (mean ± SD)	34.7 ± 12.1	35.3 ± 12.6	34.1 ± 12.8	38.3 ± 13.8
% Married or living with common-law spouse	49.3	51.3	46.7	55.6
% With no dependents	78.9	75.6	78.4	78.4
Employment status				
% Employed fulltime	45.8	45.0	46.8	28.9
% Not employed fulltime but capable of working†	30.4	29.1	32.0	31.7
% Other (students, disabled, minors)	3.6	2.1	4.2	2.0
% Missing data	20.1	22.7	16.8	29.4
Income ($)‡				
Mean ± SD for those with employment status	15,666 ± 10,768	15,881 ± 11,028	15,419 ± 10,484	14,278 ± 11,094

* Excluded because they lacked a police collision report (n = 1743).
† Includes home makers and part-time, casual, and volunteer workers.
‡ Canadian dollars.
SD = standard deviation.

cent of the collisions were recorded as having no injuries apparent at the scene compared with 14.5% of collisions in which subjects sustained other injuries in addition to whiplash.

Table 2. Collision-Related Factors for Whiplash Subjects in Quebec, 1987

	Study cohort members	Whiplash only	Whiplash plus other injuries
Number	3014	1666	1348
% Involved in collisions resulting in			
Fatal injury	1.3	0.8	2.2
Serious injury	11.4	7.1	16.8
Minor injury	65.8	64.8	66.5
Material damage only	21.6	27.4	14.5
Vehicle type (%)			
Car or taxi	89.5	92.7	85.6
Truck	5.4	4.7	6.2
Other/missing data	5.1	2.5	8.2
Function of whiplash subject (%)			
Driver	76.0	76.2	73.2
Passenger	22.0	20.9	23.4
Pedestrian	1.8	0.7	2.7
Missing data	0.4	0.2	0.7
% Involved in collision with			
Moving object	78.3	84.4	70.8
Stationary object	12.0	8.8	15.7
Other (no collision or missing data)	9.7	6.7	13.4
% Involving one vehicle only	23.5	17.2	31.2
Direction of collision (%)			
Rearend	30.7	38.5	19.8
90°	19.1	18.0	20.4
Head-on	14.5	11.8	17.7
Other/missing data	35.8	30.7	42.1
Seat belt (%)			
Used	61.7	62.8	60.2
Not used	6.7	5.4	12.8
Missing data	29.6	31.8	26.9
Authorized speed limit (%)			
< 60 km/h	53.8	59.0	47.4
60–90 km/h	19.8	19.1	20.7
≥ 90 km/h	24.3	20.0	29.6
Missing data	2.1	1.9	2.3

Table 2 also shows the distribution of vehicle types for the whiplash subjects in the study cohort. A large majority (89.5% or 2699 of 3014 subjects) were occupants of passenger cars (including station wagons and four-wheel drive vehicles) or taxis at the time of the collision. Trucks were the second most frequently occupied vehicle type at 5.4%. Less than 4% of the whiplash subjects were using other vehicles, such as buses, motorcycles, mopeds, snowmobiles, and bicycles at the time of the event. Forty-eight (1.6%) of the subjects were pedestrians. Most of the pedestrians (77% or 37 of 48 cases) sustained other injuries in addition to whiplash, whereas only 43% of car and taxi occupants sustained multiple injuries. The majority of whiplash subjects (76%) were driving a vehicle at the time of the collision. Most of the whiplash subjects (78.3% or 2361 of 3014 cases) were involved in events in which a motor vehicle collided with another moving object, usually another motor vehicle. Collisions with other moving objects, such as pedestrians, trains, nonmotorized vehicles, and animals, were rare, accounting for only 3.6% (107 of 3014 cases) of collisions. Other types of events included collisions with stationary objects, such as lampposts, guardrails, and trees (12.0% or 361 of 3014 cases), and events not involving collisions, such as rollovers, submersions, and leaving the roadway (8.8% or 265 of 3014 cases). A total of 707 events (23.5%) that resulted in whiplash injury in 1987 involved only one vehicle, and the remainder were multiple-vehicle events, with the number of vehicles involved ranging from two to 10. The single-vehicle collisions appeared to be the most severe, as they resulted in a disproportionately high number of whiplash subjects with multiple injuries. Single-vehicle events accounted for 31.2% of whiplash subjects with multiple injuries compared with only 17.2% of subjects with whiplash

Table 3. Distribution of the Duration of Absence for Members of the Study Cohort, Excluding Those With Recurrence

Duration of absence (days)	All subjects		Subjects with whiplash only		Subjects with whiplash and other injuries	
	Number	%	Number	%	Number	%
≤ 7	621	22.1	383	24.7	238	18.9
8–14	227	8.1	126	8.1	101	8.0
15–28	482	17.2	234	15.1	248	19.7
29–42	281	9.3	135	8.7	126	10.0
43–56	161	5.7	88	5.7	73	5.8
57–84	222	7.9	136	8.8	86	6.8
85–112	187	6.7	102	6.6	85	6.8
113–140	133	4.7	79	5.1	54	4.3
141–365	439	15.5	239	15.3	197	15.6
365–1095	87	2.6	27	1.7	40	3.2
1096–1825	9	0.3	2	0.1	7	0.6
> 5 years	5	0.2	1	0.1	4	0.3
Total	2810	100.0	1551	100.0	1259	100.0

only. Of the multiple-vehicle events, 81% (1861 of 2307 cases) involved two vehicles.

The direction of collision was not recorded very accurately by the police who were called to the scene of the events. For 16 whiplash subjects, the direction of collision was not recorded on the police report. Among those events where something was recorded on the collision report, the direction of collision was coded as indicating an "other" direction of collision in 34.3%. Thirty-one percent of events were recorded as being rear-end collisions, and 14.5% were head-on collisions. Compared with those who were injured in rear-end collisions, whiplash subjects involved in head-on collisions were more likely to have sustained multiple injuries.

Although information regarding seatbelt use was missing for almost 30% (892 of 3014 cases) of the cohort, among those for whom this information was available, 87.6% (1859 of 2122 cases) were wearing seatbelts at the time of the collision. Of those wearing seatbelts, most were using a three-point lap-shoulder belt (98% or 1822 of 1859 cases), rather than a lap belt only. Based on the results shown in Table 2, there seemed to be a greater tendency for multiple injuries at higher speed limits. More than half of the whiplash injuries (53.8% or 1622 of 3014 cases) occurred on roads where the speed limit was less than 60 km/h.

Duration of Absence

For the analysis of absence duration, the study cohort has 2810 members because it excludes from the 3014 members the 204 subjects with a recurrence. Among these study cohort members, more than one fifth (22.1%) recovered within 1 week of the collision (Table 3). Fifty-three percent took more than 4 weeks to recover from their injuries. One year after the event, 2.9% were still absent from usual activities or work. Among those who sustained only a whiplash injury, 1.9% had an absence of longer than 1 year. The longest absence among those study cohort members who did not experience a recurrence was 1920 days. This corresponded to an exit date from the cohort of July 2, 1992.

The estimated Kaplan-Meier return to activity curve for the 2810 whiplash subjects in the study cohort who did not experience a recurrence of symptoms is shown in Figure 3 (truncated at 365 days). Twenty-three of 2810 observations (0.8%) were censored because the files on these whiplash subjects were not yet closed at the time when the data were extracted from the SAAQ's computerized databases. The return to activity curve, which is a graphic representation of the data contained in Table 3, reveals that approximately 50% of the 2810 whiplash subjects recovered within 1 month of the collision, and 64% recovered within 60 days. At 6 months and 1 year after the collision date, the proportion of subjects who had recovered was 87% and 97%, respectively. Return to activity curves stratified by gender and age are shown in Figures 4 and 5, respectively.

Duration of Absence and Recurrence

Analyses of the mean duration of absence and rate of recurrence are shown in Table 4 for sociodemographic factors and in Table 5 for the collision-related factors. Thus, female gender, older age, increased number of dependents, married status, multiple injuries, greater collision severity, vehicle other than car or taxi, collisions other than rearend, and nonuse of seatbelt are associated with a longer absence. Recurrences, defined as the recurrence of symptoms of collision-related injuries, were found to have occurred in 204, or 6.8%, of the study subjects. When those cohort members who sustained injuries in addition to whiplash were excluded from the analyses, the rate of recurrence was higher with

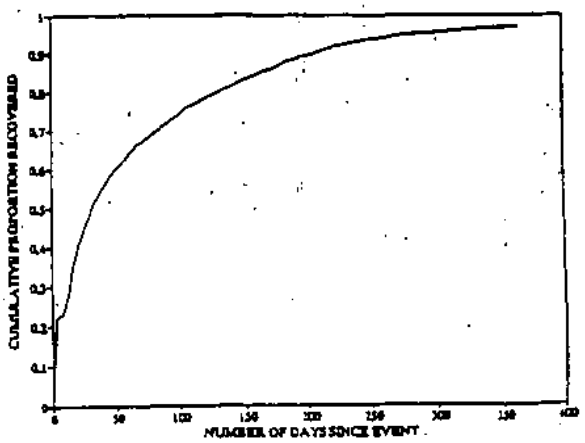


Figure 3. Overall one-year cumulative return to activity curve for cohort of whiplash subjects.

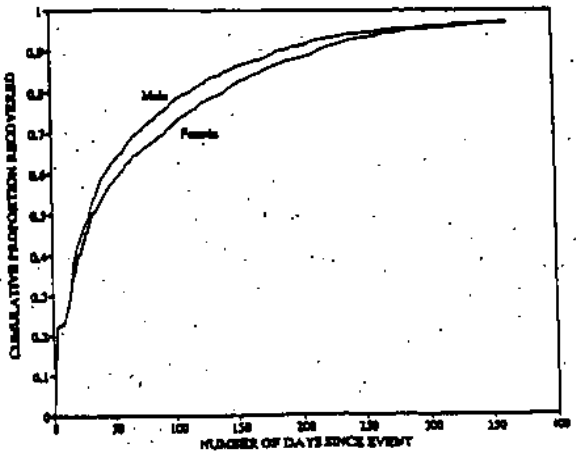


Figure 4. One-year cumulative return to activity curve by gender.

rearend collisions and the presence of dependents at home.

Because information on seatbelt use was missing for nearly 30% of the subjects, these individuals were included in the group to which they were most similar with respect to time to return to activity. That is, they were reassigned to the group that was using a seatbelt at the time of the collision, thus resulting in a 91% seatbelt use rate.

Costs Related to Whiplash

An itemized breakdown of the collision-related expenses compensated by the SAAQ to the 4757 whiplash claimants is shown in Table 6, with all amounts provided in Canadian dollars. This cohort cost the SAAQ a total of over $18 million in reimbursements and compensation or an average of more than $3800 per whiplash subject. Approximately 75% ($13 million) was paid to subjects for the replacement of their regular income while they were unable to work or carry out their usual activities. The total amount of payments made to people with whiplash as their only injury (2802 of 4757 cases) was more than $9 million, with replacement of regular in-

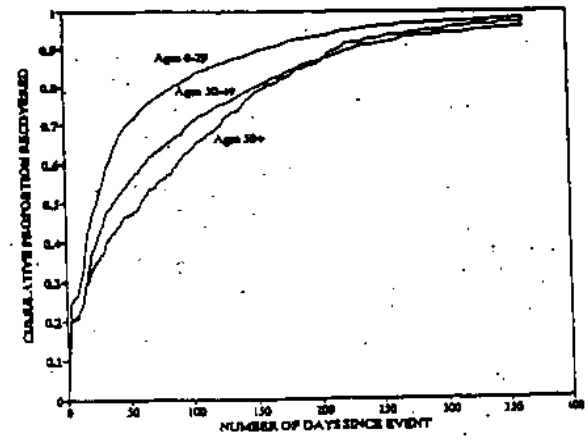


Figure 5. One-year cumulative return to activity curve by age.

Table 4. Duration of Absence and Recurrence of Symptoms by Sociodemographic Factors

	Duration of absence (n = 2810)				Recurrence of symptoms (n = 1668)		
	N	Mean	SD	*P* value	N	Rate	*P* value
Gender							
Female	166	85.7	150.6	0.014	1089	7.8%	0.148
Male	114	77.0	155.2		597	5.7%	
Age (years)							
< 35	157	68.8	141.1	0.0001	884	6.5%	0.148
35–55	575	94.8	152.7		634	8.2%	
≥ 55	285	115.4	201.2		148	4.1%	
Number of dependents							
0	217	74.3	140.5	0.0001	1259	6.0%	0.039
1–2	545	105.4	175.0		353	9.9%	
≥ 3	89	132.1	234.9		54	7.4%	
Marital status							
Married/cohabiting	137	93.3	149.8	0.5001	855	7.7%	0.177
Other	143	71.5	154.4		811	6.0%	

N = number, SD = standard deviation.

Table 5. Duration of Absence and Recurrence of Symptoms by Collision-Related Factors

	Duration of absence (n = 2810)				Recurrence of symptom (n = 1668)		
	N	Mean	SD	*P* value	N	Rate	*P* value
Multiple injuries							
Yes	1259	93.8	183.9	0.018	—	—	—
No	1551	72.7	112.8		—	—	
Collision severity							
Fatal or serious	345	133.5	258.2	0.0001	128	10.2	0.13
Other	2465	74.9	128.7		1538	6.6	
Vehicle type							
Car or taxi	2492	79.6	148.4	0.011	1529	6.9	0.65
Other	318	102.3	174.1		137	7.3	
Function of subject							
Driver	2127	78.7	142.6	0.56	1303	7.2	0.34
Other	683	92.7	179.8		363	5.8	
Collision with							
Moving object	2159	81.9	146.8	0.95	1408	7.0	0.80
Other	611	82.9	172.3		280	6.5	
Number of vehicles							
One only	664	89.4	178.5	0.20	288	8.3	0.68
Other	2148	79.9	144.2		1280	7.0	
Direction of collision							
Rearend	850	73.9	131.5	0.001	858	8.7	0.02
Other*	1960	85.7	108.8		1008	5.8	
Seatbelt use							
Yes*	2560	81.2	155.5	0.01	1578	7.0	0.34
No	250	91.8	117.8		90	4.4	
Speed limit (km/h)							
< 60	1509	76.0	131.9	0.23	983	6.9	0.98
≥ 60	1301	89.3	173.2		683	6.9	

* These categories including missing data.
N = number, SD = standard deviation.

Table 6. Types and Amounts of Compensation Paid by the SAAQ to Whiplash Claimants, 1987

Description of reimbursed expense or type of compensation	Total cost (n = 4757)	Cost for whiplash only (n = 2802)	Cost for whiplash plus other injuries (n = 1955)
Replacement of regular income	13,052,932.18*	5,716,667.01	8,338,265.17
Compensation for disfigurement	407,449.81	5505.08	401,943.73
Compensation for anatomicophysiologic deficit	984,733.40	294,309.32	870,424.08
Compensation for pain, loss of enjoyment of life	536,590.85	218,408.31	338,181.54
Physiotherapy	1,512,483.65	951,879.59	560,808.06
Medical, paramedical care	111,489.41	40,581.90	70,887.51
Hospital expenses not covered by health insurance	2851.18	108.88	2744.30
Medical expenses (i.e. prescriptions)	115,360.27	66,223.04	49,137.23
Ambulance	9812.98	3393.52	6419.38
Orthoses, prostheses	154,081.09	65,222.72	88,858.37
Replacement of damaged clothing	258,708.41	90,296.89	165,411.52
Travel expenses for subjects not assigned to rehabilitation program	822,891.85	414,895.34	407,996.51
Reimbursement of expenses for homemakers who choose not to receive compensation to replace regular income	38,092.64	22,163.24	15,929.40
Other expenses	111,030.87	57,324.70	53,706.17
Rehabilitation expenses	160,345.24	52,611.15	108,734.08
Total	18,279,633.83	9,000,338.39	9,279,247.44

* All numbers in table body represent figures in Canadian dollars.

come payments accounting for $6.7 million of the total. The average cost per subject with whiplash alone was over $3200.

The mean amount of reimbursement for prescriptions filled at a pharmacy by whiplash subjects in the cohort was $24.20. Only 19 of the 4757 whiplash claimants, or 0.4%, were assigned to a rehabilitation program by the SAAQ. These 19 individuals received an average of $74,958 in compensation and reimbursements from the SAAQ, totaling over $1.4 million. This amount represented 7.8% of the total amount of money paid out by the SAAQ to members of the cohort.

Costs and Duration of Absence

Of the 4757 subjects who sustained a whiplash injury in Quebec in 1987, 303 individuals experienced at least one recurrence related to the injuries they sustained in the motor vehicle collision and cost the SAAQ $2,876,964.37. This amount includes the costs incurred both before and after the recurrence because it was not possible to distinguish between these time periods from the computerized data obtained from the SAAQ. These individuals, who represented 6.4% of the full study cohort, accounted for 15.7% of the total costs paid out by the SAAQ to members of the study cohort.

Of the cohort of 2801 patients who sustained only a whiplash injury, 61.5% whose absence lasted 2 months or less accounted for only 15.5% of the total costs paid out by the SAAQ for all patients in this cohort. The 26% whose absence lasted between 2 and 6 months accounted for 38.5% of the costs; the 10.6% whose absence lasted between 6 and 12 months accounted for 32.3% of the costs; and the remaining 1.9% of patients still compensated 12 months after the collision accounted for 13.7% of the total costs paid by the SAAQ.

For the cohort of 1956 patients who sustained a whiplash injury along with other injuries, the corresponding proportions are similar except that the 10.5% whose absence lasted between 6 and 12 months accounted for only 24.3% of the costs, whereas 4.8% were still compensated 12 months after the collision, and they accounted for 36.1% of the total costs paid by the SAAQ.

■ Discussion

The variation in the incidence of whiplash in different parts of the world is considerable.[56] For example, we found that the population-based incidence of compensated whiplash injury in Quebec was 70 per 100,000 inhabitants in 1987; the incidence rates of whiplash in New Zealand and Australia's State of Victoria were 13 and 106 per 100,000 inhabitants, respectively, during a 12-month period from 1982–83.[67] Although the incidence appears very high in Australia, the actual rate of *compensated* whiplash injury in that region was only 39 per 100,000 inhabitants.[67] That is, not all of the whiplash claimants in Australia received compensation for their injuries, whereas in New Zealand and Quebec there were few or no differences between the number of claimants and the number of individuals who received some form of compensation. This means that of the three regions, Quebec had the highest population-based incidence of compensated whiplash injury. Additionally, because the incidence rates for whiplash injury reported in this study represent the incidence of compensated claims made to the SAAQ by whiplash subjects, the rates are conservative estimates of the actual incidence of whiplash injury in Quebec. Many subjects with injuries of this nature probably do not

bother submitting claims for compensation to the SAAQ, leading to an underestimate of the true incidence of whiplash.

Yet, in British Columbia and Saskatchewan, two other Canadian provinces with single-payer motor vehicle insurance programs, 68% and 85% of the claims paid out, respectively, for motor vehicle injuries are for whiplash[35,91] compared with 20% for Quebec. For Saskatchewan, with its one million inhabitants and approximately 9000 claims paid per year, this proportion would translate to a staggering incidence rate of compensated whiplash of over 700 per 100,000 inhabitants, 10 times the rate in Quebec. A possible explanation for this may be, despite their universality, in the different insurance systems of these two Canadian provinces, namely the no-fault system in Quebec versus the tort system in Saskatchewan.

The incidence of whiplash claims was notably higher among female subjects than among male subjects in most age categories. One hypothesis proposed to explain the consistent observation that the majority of whiplash subjects are women is that given the same head size, men have more neck musculature than women, making them less prone to whiplash injury.[58,105,108] Another possibility is that women may be more inclined than men to file an insurance claim for whiplash. The age- and gender-specific incidence of whiplash injury was found *not* to correspond to the age- and gender-specific incidence of all injuries combined that were reported by police in Quebec in 1987. This distribution shows that male subjects have a higher incidence of all injuries combined than female subjects in each age category, and the peak incidence of injuries occurs to those aged 15–24 years. The peak incidence of whiplash injuries occurs to those aged 20–24 years.

The regional variation in the incidence of claims for whiplash appears to be dependent on population density and the number of commuters in each region. For example, the regions to the north of Montreal and to the south of Quebec City were found to have a high incidence of whiplash claims. This probably reflects that many people who live in these regions spend a great deal of time commuting to the city for work or recreational reasons. With the increased amount of time and distance traveled, the likelihood of being involved in a collision and sustaining a whiplash injury increases. The northern regions of Quebec had a very low incidence of whiplash claims, probably because these regions are sparsely populated and there is less traffic on the roads, resulting in a lower number of collisions.

The fact that 21.6% of the whiplash subjects did not appear to be injured at the scene of the collision agrees with the findings reported by Deans et al,[18] who found that the onset of neck pain in 22% of collision subjects with neck injuries did not occur until 12 hours or more after the collision. The data showed that longer time to return to activity after whiplash injury was found in subjects with additional injuries besides whiplash, female gender, older age, greater number of dependents, married/cohabital status, being in a collision involving fatality or severe injury, being in a collision other than rearend, and being in a vehicle other than a car or taxi at the time of the collision. Seatbelt use was found to result in a shorter absence from activity in contrast with a previous study by Deans et al.[18] The finding that whiplash subjects who were occupants of vehicles other than cars or taxis had a poorer prognosis than those in cars or taxis at the time of the collision may reflect that trucks and other vehicles lack certain useful safety features incorporated into the design and construction of cars and taxis.

The itemized and total costs of whiplash injury paid by the SAAQ calculated in this study have already been reported elsewhere.[8,54,58] Relating total costs to duration of absence, the 61.5% of subjects with only a whiplash injury whose absence lasted 2 months or less accounted for only 15.5% of the total costs, whereas the 26% whose absence lasted between 2 and 6 months accounted for 38.5% of the costs, and the 12.5% of patients still compensated 6 months after the collision accounted for 46% of the total costs paid out by the SAAQ.

■ Summary and Conclusions

1. The population-based overall annual incidence rate of compensated insurance claims for whiplash injury in Quebec in 1987 was 70 per 100,000 inhabitants. The incidence rate was generally higher among female subjects and people aged 20–24 years. The overall incidence rate was generally comparable with that of other countries, but much lower than that found in Saskatchewan where the rate may be as high as 700 per 100,000. A possible explanation for this difference between the two provinces may be because of the contrasting no-fault insurance system in Quebec and tort system in Saskatchewan.
2. Female gender, older age, married/cohabital status, and a greater number of dependents were the sociodemographic factors associated with a longer time of absence for whiplash. Being in a severe collision, in a vehicle other than a car or taxi, in a collision other than rearend, and not using a seatbelt were the collision-related factors associated with a longer time of absence. The presence of multiple injuries was also an important prognostic factor.
3. Rearend collisions and having one or more dependents were associated with a higher rate of relapse or recurrence of symptoms of whiplash subjects.
4. Of the more than 18 million Canadian dollars paid out by the SAAQ to the 1987 cohort of 4757 whiplash subjects, over 70% was paid for the replacement of regular income. Thus, the main portion of the total

cost incurred by the SAAQ for whiplash is directly related to the duration of compensation.

5. The 26% of subjects with only a whiplash injury whose absence lasted between 2 and 6 months accounted for 38.5% of the costs, whereas the remaining 12.5% of patients still compensated 6 months after the collision accounted for 46% of the total costs paid out by the SAAQ. For the patients with multiple injuries besides whiplash, 15.3% of patients were still compensated 6 months after the event, and they accounted for 60.4% of the total costs. Therefore, the financial burden of whiplash injury to the SAAQ results from the small number of persons who became chronic.

Section 3. Consensus Findings

The work product of the consensus groups is not a series of results in the conventional sense, nor is it appropriate to present it as such. Rather, the consensus process was essential background work to proposing the Quebec Classification of Whiplash-Associated Disorders (WAD), which appears at the end of this section. The Task Force, with the help of special consultants, systematically considered anatomic, physiologic, and pathologic factors in WAD and information on the mechanism and prevention of injury from various text books, technical reports, and other relevant literature. In this scientific monograph, we present a summary of the consensus groups' findings and the Quebec Classification of Whiplash-Associated Disorders; the reader should refer to the Official Report of the Quebec Task Force for more details.

Mechanism of Injury and Prevention

Our understanding of what happens to the cervical spine during low-velocity, rearend collisions is limited, despite a wealth of experimental studies on the biomechanics of the cervical spine.[63] Most of these studies focus on the injury mechanisms in severe cervical spine injuries. Mathematical modeling and extrapolation from cadaver, animal, and mannequin studies of collisions are of limited value to define thresholds of injury in low-velocity collisions. Studies of human volunteers in controlled conditions cannot be easily extrapolated to real collisions.

For the purposes of this report, the Task Force recommends the study by McConnell et al[61] for its description of the kinematic response of human test subjects to low-velocity, rearend impacts. This study suggests that a 6 to 8 km/h impact, which subjects the cervical spine to as much as 4.5 G, constitutes the threshold for mild cervical strain injury. The test subjects experienced a rapid compression–tension cycle directed axially through the cervical spine as a result of the torso ramping up the seatback. Extreme hyperextension–hyperflexion of the cervical spine, commonly reported in cadaver and mannequin experiments, was not observed. The authors theorize that mild clinical symptoms experienced after low-velocity, rearend collisions might result from forces directed axially through the cervical spine rather than by the classic hyperextension–hyperflexion mechanism. There is a need for more research in this area.

An extensive body of literature on prevention exists, and a review of this literature could easily be a subject of a separate Task Force. This literature appears in highly diversified publications, depending on whether one is interested in the precollision phase (specialized road safety literature), the collision phase (road safety, engineering, and biomechanical literature), or the postcollision phase (medical and trauma care systems literature). Consequently, our best evidence synthesis was deliberately limited to the postcollision phase (see Section 4 titled "Best Evidence Synthesis"). The precollision and collision phases were addressed by the consensus group.

There is a relative scarcity of studies dealing specifically with whiplash in the prevention literature, and the consensus group was forced to extrapolate from the general road safety literature.

Interventions designed to reduce the risk of collision, and therefore, whiplash injuries include

1) interventions designed to reduce driving while intoxicated, such as automatic licence suspension,[41,70,124] enforcement of minimum age for purchase and consumption of alcohol,[19,33,40,50,88,94,121] and legal accountability of merchants who sell alcoholic beverages to people who are intoxicated;[44,66]
2) measures designed to decrease the risk for teenagers, such as increasing the legal age for license,[59,91,92] graduated access to unaccompanied driving,[45,77,79] and curfew;[80,81]
3) limiting access to driving for individuals on certain medications or with certain medical conditions;[117]
4) vehicle-related interventions, such as improvement in tires, antilock brakes, improved visibility and lighting,[21,25,71] and speed control devices;[22] and
5) interventions related to the road environment, such as widening, improving surfaces, increasing visibility of the road environment,[114,124] reducing highway speed limits,[32,90] not allowing right turns on red lights,[90] and the elimination of hazardous areas or death traps.[23]

Unfortunately, the efficacy of some of the above measures is not certain, and none have been studied specifically with whiplash prevention in mind.

With respect to prevention during the collision phase, most studies deal with headrests and seatbelts.[13,31,74,75,107,110,118–120] A headrest should protect the occupant by preventing hyperextension of the neck. Many headrests are ineffective because of poor design and improper positioning. If the headrest and seatback are composed of materials with different stiffness or deformation and energy absorption characteristics, the energy returned to the occupant's torso and neck after a rearend collision will differ. Headrests are often covered with slow recovery foam, whereas seatbacks often have springs that return energy much faster. If the torso rebounds earlier and faster than the head (differential rebound), cervical extension will be amplified. In other instances, instead of being stopped by the headrest, the

head is projected forward. At the time of the collision, the head may be too far forward or too high above the headrest for it to prevent hyperextension. A properly positioned headrest should be located so that the horizontal distance to the head is as small as comfortably possible, and its top edge should extend about 70 mm vertically above the occupant's eye level. These problems could be avoided if all seats and headrests were made in a single piece, high enough to provide fixed and absorbent support for both the head and torso.

Wearing a seatbelt may be a risk factor for whiplash and WAD (see Section 4 titled "Risk"). The three-point belt can prevent torso rebound, thus increasing the flexion moment at the cervical spine. The single-shoulder restraint may induce rotation of the torso and neck when the unrestrained shoulder moves forward. Cervical problems from the use of seat belts are minor compared with the morbidity and mortality avoided by their use. We emphasize that there is no evidence that individuals who are exempted from wearing seat belts for medical or professional reasons derive more benefits than disadvantages.

■ Clinical Consensus

Apart from anatomic studies, much of the scientific understanding of soft-tissue injury and healing is derived from animal models, and there is little information on the normal recuperation period. In the animal model of soft-tissue healing, there is a brief period (less than 72 hours) of acute inflammation and reaction, followed by a period of repair and regeneration (approximately 72 hours to up to 6 weeks), and finally by a period of remodeling and maturation that can last up to 1 year. Starting from this model, it is reasonable to estimate a healing period of between 4 and 6 weeks in cases of WAD with partial tear of soft tissues. Many cases are mild and will heal in a much shorter time. The model may not apply to WAD with neurologic signs or symptoms because nerve injury could prolong recovery.

Prolonged immobilization of WAD injuries may increase scar tissue and reduce cervical mobility. Normal function of the patient must be encouraged when possible. A return to regular activities, starting at the stage of fibroplasia and throughout the maturation phase, can enhance optimal healing.

The Task Force is also aware that the manifestations and prognosis of WAD are influenced by psychosocial factors. The relationship and interactions between the patient and the clinician may themselves affect the evolution of WAD, as has been described for other disorders. The patients' own psychologic make-up and psychosocial environment may also affect the prognosis and should be considered. The clinician should be alert to these possible influences when evaluating and treating the patient. Opinions from consultants with expertise in the behavioral sciences or from multidisciplinary groups experienced in WAD management may be helpful for atypical evolutions of WAD. It should be noted that the efficacy and effectiveness of psychologic or psychiatric interventions in WAD have not been demonstrated (See Section 4 titled "Best Evidence Synthesis").

■ Definitions and the Quebec Classification of Whiplash-Associated Disorders

A striking finding from the reviews of biomedical and other literature was the heterogeneity of definitions and classifications of all clinical aspects related to WAD. Accordingly, it became an early priority and a central challenge for the Task Force to propose definitions and classifications that would facilitate the evaluation of original research and would be unambiguous and helpful to the clinician. After extensive discussion of the anatomic, pathologic, and clinical relationships and drawing from the best groupings encountered in the literature,[42,73] certain important terms and definitions were adopted by the Task Force to be presented to the international scientific and clinical community.

The most important contribution of the Task Force may be the *Quebec Classification of Whiplash-Associated Disorders* proposed herein. The classification provides categories that are jointly exhaustive and mutually exclusive, clinically meaningful, stand the test of common sense, and are "user-friendly" to investigators, clinicians, and patients. Future research will decide whether refinement is required to enhance the discriminating properties of the classification and to establish the validity of the categories proposed.

One difficulty in evaluating the whiplash literature is that the term "whiplash" is used to describe a mechanism of injury, the injury itself, the various clinical manifestations consequent to the injury, and constellations of signs and symptoms designated as "whiplash syndrome." Typically, authors reporting studies do not specify the time after a collision (or in the evolution of the injury) when certain treatments or diagnostic tests are being evaluated. In other cases, it is unclear whether the underlying condition is complicated or uncomplicated (without objective aggravating signs) or whether comorbidity is present. The Task Force adopted the following definition of whiplash.

Whiplash is an acceleration–deceleration mechanism of energy transfer to the neck. It may result from rearend or side-impact motor vehicle collisions, but can also occur during diving or other mishaps. The impact may result in bony or soft-tissue injuries (whiplash injury), which in turn may lead to a variety of clinical manifestations (Whiplash-Associated Disorders).

"Whiplash-Associated Disorders" is the term adopted by the Task Force to describe the clinical entities associated with the injury. We propose a classification of WAD on two axes: 1) a clinical–anatomic axis and 2) a time axis.

The clinical–anatomic axis has five grades that correspond roughly to severity. Of the five grades, the Task

Table 7. Proposed Clinical Classification of Whiplash-Associated Disorders

Grade	Clinical presentation
0	No complaint about the neck No physical sign(s)
I	Neck complaint of pain, stiffness, or tenderness only No physical sign(s)
II	Neck complaint AND Musculoskeletal sign(s)*
III	Neck complaint AND Neurological sign(s)†
IV	Neck complaint AND Fracture or dislocation

* Musculoskeletal signs include decreased range of motion and point tenderness.
† Neurologic signs include decreased or absent deep tendon reflexes, weakness, and sensory deficits.
Symptoms and disorders that can be manifest in all grades include deafness, dizziness, tinnitus, headache, memory loss, dysphagia, and temporomandibular joint pain.
Dotted lines indicate limits of terms of reference of Task Force.

Force did not consider two. Namely, when there are "no complaints about the neck" and "no signs," either immediately or within a short time, no disorder manifests (Grade 0). We also excluded spinal cord injury and bony tissue injury, such as fracture or dislocation (Grade IV). The latter were not within the mandate of the Task Force. There remain three grades of WAD associated with soft-tissue injury: I) general, nonspecific complaints or symptoms about the neck without objective signs, II) neck complaints plus signs limited to musculoskeletal structures, and III) neck complaints with neurologic signs (Table 7). The footnotes in Table 7 clarify the classification, to simplify use by clinicians during patient care. Certain symptoms and disorders, such as deafness, dizziness, tinnitus, headache, memory loss, dysphagia, and temporomandibular joint disorders, may manifest in any grade. These associated findings may be highly relevant in the evaluation of individual patients by clinicians designing a treatment plan, planning judicious referrals, or contemplating a rehabilitation strategy.

Turning to the time axis, patients are classified within each grade as those less than 4 days from the time of the injury, those 4–21 days from the date of injury, those from 22–45 days, those from 46–180 days, and those with durations more than 6 months. This time axis guides the clinical management of WAD (See Section 5 titled "Conclusions"). By consensus, patients still symptomatic or with residual disability 6 months or more after the injury are designated as "chronic." We deem the status of chronic or the inception of chronicity as a serious clinical development with public health implications. We believe that it is important to try to prevent chronicity at all stages of WAD.

Continued complaints and residual disability after 45 days are important warnings of chronicity, justifying vigorous clinical intervention and mandatory interdisciplinary clinical consultation. Identifying the subgroup of patients at risk of chronicity within each of the three grades is crucial to efforts to prevent chronicity.

Clinical colleagues in the Task Force identified common clinical manifestations and commonly used terms that correspond to the grades defined. In Table 8, we present a brief summary of these items to assist clinicians in adapting designations already in use as well as those new classifications intended to be more rational and easier to use.

Table 8. Clinical Spectrum of Whiplash-Associated Disorders

I. Neck Complaint of Pain, Stiffness, or Tenderness Only; No Physical Sign(s)
Common synonyms
Whiplash injury
Minor whiplash
Minor cervical sprains or strains
Presumed pathology
Microscopic or multimicroscopic lesion
Lesion is not serious enough to cause muscle spasm
Clinical presentation
Usually presents to a doctor more than 24 hours after trauma
II. Neck Complaint and Musculoskeletal Signs
Common synonyms
Whiplash
Cervical sprain
Cervicalgia with headaches
Headache of cervical origin
Traumatic cervicalgia
Cervicoscapulalgia
Minor intervertebral dysfunction
Sprained cervical facet joints
Sprained cervical ligaments
Presumed pathology
Neck sprain and bleeding around soft-tissue (articular capsules, ligaments, tendons, and muscles)
Muscle spasm secondary to soft-tissue injury
Clinical presentation
Usually presents to a doctor in the first 24 hours after trauma
Nonspecific radiation to the head, face, occipital region, shoulder, and arm from soft-tissues injuries
Neck pain with limited range of motion due to muscle spasm
III. Neck Complaint and Neurologic Signs
Common synonyms
Whiplash
Cervicobrachialgia
Cervical herniated disc
Cervicalgia with headaches
Headache of cervical origin
Cervicoscapulalgia
Presumed pathology
Injuries to neurologic system by mechanical injury or by irritation secondary to bleeding or inflammation
Clinical presentation
Presents to a doctor usually within hours after the trauma
Limited range of motion combined with neurologic symptoms and signs

Section 4. Best Evidence Synthesis

Methods

In response to the mandate from the SAAQ, the Task Force focused on risk factors, diagnosis, treatment, and prognosis of soft-tissue injury to the neck from whiplash. In terms of the Quebec Classification of WAD, Grade 0 was not considered because no disorder manifests. Grade IV, involving bony tissue or spinal cord injury, was not considered except for studies evaluating diagnostic procedures for differentiating between bony tissue and soft-tissue injuries. Manifestations of soft-tissue injuries of the neck from other causes, such as "shaken baby syndrome" and diving mishaps, were also excluded. Although this definition limited the generalizability of the Task Force recommendations, it allowed a focused review of the literature on a clinical entity homogeneous in cause and directly relevant to motor vehicle collisions. Unfortunately, very little acceptable material was found.

Studies Reviewed. In the first stage of identifying material for review, a wide net was cast to optimize our ability to find relevant articles. A bibliography of thousands of titles was amassed from the sources described below.

1. A broad search of computerized bibliographic databases (Medline, TRIS, NTIS) was conducted for articles on head, neck, spinal cord problems, and specific problems such as cervicobrachialgia, with or without mention of traffic collisions. This search was updated through September 1993.
2. Task Force members suggested investigators contact and supply unpublished and published reports of studies of which they were aware.
3. Agencies, such as the Insurance Institute for Highway Safety and others, were contacted and provided information on studies that they had conducted or supported.
4. Reference lists of review and original articles included in the Task Force Review were scanned for relevant articles.

References resulting from the above search strategy were subjected to a two-stage screening process by the Task Force Secretariat. The purpose of this screening was to reduce the pool of articles, selecting for review those articles dealing with the content areas identified by the Task Force mandate.

The inclusion criteria for the pool of potentially relevant articles (preliminary screening) from the sources described above were:

1. an article or report published from 1980 to September 1993 and appearing in Medline or found by other means (important articles or "seminal papers" published earlier were included as exceptions);
2. an English or French language report;
3. an original research report, brief report, work in progress, or letter;
4. an article published in a journal, conference proceedings, or technical report, or an unpublished manuscript;
5. the study subjects included subjects with acceleration–deceleration injury to the neck from motor vehicle collisions;
6. the study examined risk factors, prognosis, diagnostic methods, efficacy of treatments, and clinical manifestations.

The following exclusion criteria were used at the preliminary screening.

1. The study subjects did not include subjects with neck injuries resulting from motor vehicle collisions. Such studies were occasionally not excluded, as exceptions, when the substantive area clearly included clinical manifestations similar to those arising in WAD.
2. The study subjects were restricted to those with bony tissue injury of the neck, spinal cord injury, head trauma, penetrating wounds, infections, multiple injuries, or with other comorbidities.
3. The study subjects were animal, cadaver, or simulation studies. A few cadaver and simulation studies were considered as background reading. They were not candidate studies for full Task Force review.

Articles that passed the preliminary screening were subjected to a second screening to select articles for in-depth review. The purpose of this screening was to identify articles whose substantive area was informative and within the focus of the Task Force. This involved confirmation that the article met the inclusion and exclusion criteria of the preliminary screening and invoked the following exclusion criteria: review articles or clinical reviews (these were excluded from the best evidence synthesis but were, as "seminal" papers cited in a number of articles reviewed, distributed as background reading), single case reports, and laboratory and simulation studies.

After the closing date for the search strategies, we continued to monitor the literature and to receive articles from Task Force members, with the goal of identifying recently published highly meritorious articles for the Task Force review. Current Contents was scanned in October 1993, and in February 1994 an additional Medline search was conducted for specific treatments because of concern regarding the dearth of articles on specific treatments for WAD. Articles identified by these means through April 1994 were included in the Task Force review process described below.

A final search of Medline using the broad search strategy was conducted in July 1994. Articles identified by these searches or supplied by Task Force members through September 1994, if deemed highly relevant on preliminary screening, were reviewed by the Secretariat or by individual Task Force members. The objective of this review was to identify any highly relevant and meritorious articles that would enhance the knowledge base for the Task Force Recommendations, even though they were found too late for the best evidence synthesis. Such late-find articles are footnoted in the "Results" part of this section.

Critical Review Process. The articles identified by the two-stage screening process described above were subjected to critical appraisal by the Task Force. Before undertaking the critical review of the literature, the principles of research de-

sign, hypothesis testing, and causal inference were reviewed by the Task Force. These principles formed the basis for assessment of the robustness of evidence from individual studies and for synthesizing evidence from the studies reviewed. To ensure a common understanding of the relevant substantive issues (*e.g.*, anatomy, pathophysiology), a clinicians' subgroup, with representation from several subspecialties, prepared and presented didactic sessions on the basic clinical sciences before the critical review of the literature.

The critical appraisal of the articles was guided by using structured critical appraisal forms adapted and augmented from forms used by the Canadian Task Force on the Periodic Health Examination, the Quebec Task Force on Spinal Disorders, and the Working Group on Passive Smoking. These forms prompt the reviewer to record information regarding the study design, methodologic features, analysis, clinical relevance, scientific merit, strengths, and weaknesses of the study. Each selected article was reviewed independently by two Task Force members. The articles were then presented by their reviewers and discussed by the entire Task Force. A consensus review was developed as a result of the discussion. When consensus as to relevance, quality of evidence, or key results could not be reached in discussion, a third reviewer did a critical appraisal. The article was returned for discussion at a later date.

Each article was classified as to its substantive relevance and scientific acceptability. Because the review of the literature took place during a 2-year period, there was an evolution in the Task Force definition of clinical relevance and acceptability. At the time that the synthesis of acceptable evidence took place (*i.e.*, during the drafting of the report), any Task Force member could return an article for reconsideration if he or she was dissatisfied with its classification. Thus, an early consensus decision could be affirmed or changed based on the matured consensus of the Task Force.

The references identified from all search strategies described above (first screening) were compiled and stored using a computerized bibliographic database management system. The critical appraisal and consensus information on articles reviewed were stored in a proprietary database. The database structure, data entry interface, error checking, and other features were developed for the Task Force with commercially available database management software.

■ Summary of Process

Over an approximately 2-year period, the 16 Task Force members were paired to review not more than four studies at a time (known as a critique round), and the pairs were changed three times. Task Force members were requested to appraise studies for their clinical relevance to the Task Force objectives and scientific merit. The following terms were adopted and defined for this process. *Accepted study*: a study rated both relevant and scientifically meritorious. Reviewers were requested to complete a critical appraisal form for studies they rated both relevant and scientifically meritorious. *Rejected study*: a study rated either irrelevant (*i.e.*, the information reported was not considered relevant to Task Force objectives) or lacking in scientific merit (*i.e.*, the results were not considered valid) was considered a rejected study. Reviewers were requested to complete rejection and clinical relevance forms (referred to below as the rejection form) for studies they rejected. The forms requested reasons for rejecting the study, *i.e.*, either methodologic flaws or clinical relevance. For a study rejected on scientific grounds, but rated relevant by the independent reviewer or later by Task Force consensus, the independent reviewer was requested to complete both a critical appraisal and a rejection form. This requirement was added in October 1992, and reviewers retrospectively completed critical appraisal forms for studies classified relevant, but rejected from earlier critique rounds.

Table 9. Literature Searches, Screening, and Review

Collected titles and abstracts	10,382
Studies eligible for screening by the Scientific Secretariat	1204
Studies selected by the Scientific Secretariat for independent review	294

Table 10. Sources of Studies Reviewed by the Task Force

Bibliographic database searches and research team contributions	248
Task Force members' contributions	32
Concurrent contributions by both	16

Results

From November 1991 through September 1993, supplemented by searches through April 1994, the Research Team of the Secretariat collected bibliographic information on 10,382 titles and abstracts, of which 1204 studies met the criteria for the preliminary screening. These were reviewed by one of the scientific secretaries who selected 294 studies for independent reviewing (Table 9). Table 10 provides information on the source of the reviewed studies. Both independent reviewers' structured forms with ratings were received for 254 studies, and at least one rating was received for 294 studies. Sixty percent (24 of 40) of the missing ratings from the independent reviewers came from one reviewer who did not complete his term on the Task Force.

Table 11 reports the Task Force consensus decisions on acceptance and rejection of studies. Sixty-two studies (21% of those reviewed) were accepted by the Task Force as both relevant and scientifically meritorious. The clinical relevance of rejected studies is described in

Table 11. Consensus Decisions

	Consensus decision		
Substantive area	Accepted, N (%)	Rejected, N (%)	Total, N
Risk	13 (21.7)	47 (78.3)	60
Diagnosis	21 (20.4)	82 (79.6)	103
Treatment	17 (25.2)	48 (73.8)	65
Prognosis	11 (16.7)	55 (83.3)	66
Total	62 (21.1)	232 (78.9)	294

Table 12. Relevance of Rejected Studies

Substantive area	Rejection category: Relevant, N (%)	Rejection category: Irrelevant, N (%)	Total, N
Risk	37 (78.7)	10 (21.3)	47
Diagnosis	52 (63.4)	30 (36.6)	82
Treatment	40 (83.3)	8 (16.7)	48
Prognosis	48 (87.3)	7 (12.7)	55
Total	177 (76.3)	55 (23.7)	232

Table 12. Approximately 76% of the studies rejected were considered relevant. The tables also provide results according to the substantive areas of the studies (risk, diagnosis, treatment, and prognosis). The percentage of accepted studies ranged from 16.7% (prognostic studies) to 26.2% (studies on treatments).

■ Results of Best Evidence Synthesis

Risk

Very little is known about the epidemiology of WAD. We did not find any population-based studies that provide estimates of the risk of WAD. Some studies deal with other clinical entities, such as cervical disc disease,[52] chronic neck pain,[59] or cervical trauma, but do not provide enough detailed information to assess whether the studied patients were suffering from WAD. Another limitation of most accepted studies is that the population under study is seldom the true population at risk of presenting with the clinical entity of interest. It is seldom possible to compute risk estimates or to compare groups of people having different characteristics. We have very little information about the true determinants of the risk for WAD.

The only population-based study on the frequency of WAD comes from insurance data provided by the Folksam Company in Sweden.[57] This study of all rear-seat occupants of vehicles involved in a collision during a 19-month period is population based, as it included damage-only and injury-producing collisions. The paper does not give incidence rates. Considering all neck injuries reported by people who answered the mail questionnaire and the denominator provided, the rate of neck injury in rear-seat occupants can be estimated to be 1.52% in children up to age 14 years and 3.53% in adults. Unfortunately, the paper does not provide the response rate of the questionnaire survey. Another study by Gustafsson et al[36] is also based on Folksam data but deals only with injuries in children. Although numbers of soft-tissue injuries resulting from all car collisions are provided, no rates can be computed.

In another population-based study, Björnstig et al[5] included soft-tissue injuries from causes other than whiplash. In this study of all injuries that occurred in one catchment area of northern Sweden during a one-year period, the incidence of neck injuries was 1 per 1000 inhabitants and occurred more frequently in young male subjects. Because the report does not provide any information on the number and characteristics of people involved in collisions or other potentially injuring events, we cannot conclude that this information applies to the risk of suffering whiplash injury only. The overrepresentation of young male subjects probably reflects their higher risk of being involved in a collision. In a study of 886 patients who suffered head trauma, Neifeld et al[72] suggested that neck injuries were more likely to occur in association with head trauma. This study looked at major cervical trauma only. Unfortunately, no other reviewed study provides acceptable information on who is injured, when, and where in terms of risk.

Wearing of a seatbelt at the time of the collision has been extensively studied as a risk factor for whiplash or soft-tissue injury of the neck. Several studies of the effect of implementing a seatbelt law on the patterns of injury suggest that the frequency of WAD is higher after the law has been in effect.[2,95,106,112] Only one study[95] estimates the number of people at risk and the people injured in one geographic area during similar 12-week periods, 3 years before and 1 year after the law was implemented in France. Although the study was not a very robust time series, it provides some evidence that the law increased the incidence of soft-tissue neck injuries. Another limitation of this study is that it dealt with a regional aspect of the impact of the French law. The study by Bodiwala et al,[7] although accepted for its information on prevalence of neck injuries, was not population based. Other studies reviewed were not based on the total population at risk.

Headrests have also been extensively studied, especially in the biomechanical literature,[109] which was not addressed in our best evidence synthesis. The only accepted study that provides information about the effect of headrests is that by Nygren et al.[75] Although the true population at risk cannot be deduced, there is evidence that the risk of WAD varies with the make of vehicle and whether or not there is a headrest. The role of the type of headrest is inconclusive in this study.

Several studies suggest the type of collision is a risk factor for soft-tissue neck injuries. Whiplash injuries may be more likely to occur in rearend collisions.[5] Although this seems obvious and compatible with biomechanical models of neck injuries, there are no studies based on an acceptable denominator, thus precluding estimation of relative risks. It is difficult to assess the true effect of circumstances supposedly associated with an increase of the frequency of rearend collisions, such as the use of daytime running lights, on the risk of WAD.[21]

Diagnosis

As part of its effort to summarize the consensus of the Task Force, the Methods and Reporting Secretariat met to construct a grid on diagnostic methods. The full Task Force had already agreed on the rows (enumerating

important diagnostic tests to be considered), the columns (classifying the patients by category of WAD), and the chronologic stage in the natural history of the problem. To our astonishment, a diligent attempt to complete the grid resulted in no entries (see Table 5.3.2.1 in the official report).

We also contemplated changing the grid to show the diagnostic tests in the rows and attributes, such as predictive value, sensitivity, specificity, and acceptability, in the columns. These are the attributes that are essential to a scientific and clinically relevant approach to the evaluation of diagnostic tests. We were also unable to find any accepted papers that allowed one single judgment regarding such characteristics of diagnostic tests.

This highlights a substantial gap in a very large area to which we have given a high order of priority, namely the diagnostic tests that provide information essential to cost-effective treatment of patients sustaining WAD. Accuracy and reliability must be shown and the predictive value of the tests must be confirmed before the acceptability of these diagnostic methods can be documented.

We did accept some studies on diagnosis of WAD. These only address the use of radiography, magnetic resonance imaging (MRI), measurement of cervical range of motion, strength, and neurobehavioral tests. We did not find any accepted articles on other potentially relevant diagnostic procedures.*

Only one paper[6] addressed relevant aspects of the use of MRI of the cervical spine. Although the study did not deal specifically with WAD patients, it had important information about the specificity of the technique. Multiplane MRIs were done on 63 asymptomatic volunteers and interpreted independently by three neuroradiologists. The scans were interpreted as showing an abnormality (herniated disc, bulging disc, foraminal stenosis) in as many as 19% of the asymptomatic subjects; the frequency of abnormalities was 28% in subjects aged 40 years or older. Consequently, as MRI becomes more popular in the assessment of soft-tissue injuries, it can be expected that its use in patients with WAD will be impeded by this high proportion of false-positive findings.

A single accepted study[76] has addressed behavioral findings in WAD patients. This study compared the results of an array of neuropsychologic tests in 34 "whiplash cases" with chronic symptoms examined 6 to 12 months after the initial injury and 21 nonhospitalized patients with chronic pain in the neck and arm but no history of trauma. The groups did not differ regarding gender, age, and education. There were no clinically nor statistically significant differences in the results of the neuropsychologic tests. The study, however, does not provide any comparative information on subjects without whiplash or with other sources of acute neck pain. We cannot draw conclusions concerning the potential usefulness of neurobehavioral tests in the evaluation of WAD patients.

Accepted papers on history or physical examination dealt with only two aspects: the development of a neck disability index and the development of rules or algorithms for predicting the presence of bony-tissue injuries. No accepted studies have dealt with the use of the medical history or physical examination to make a diagnosis of WAD.

The neck disability index has been developed to help classify patients with WAD.[115] The neck disability index includes ratings of pain intensity, personal care, lifting, reading, headaches, concentration, work, driving, sleeping, and recreation. Its reliability and validity have been assessed in only 48 subjects, 70% of whom had sustained whiplash injury within the past 4 to 6 weeks and two of whom had sustained injury within the past 6 months. This study suggests good test–retest reliability, good internal consistency, and construct validity. The authors show good concurrent validity, as assessed by correlations of the index and a visual analog scale rating improvement in activity. Reliability and validity of the neck disability index need more study in larger samples of patients and an assessment of the validity of the index for predicting recovery from whiplash injury.

Seven studies provide information on the value of the history or the physical examination to predict the presence of bony-tissue injury,[43,47,53,68,72,87] including one study in children.[68] The objective of these studies was to classify patients seen in an emergency room or trauma center into those who do or do not need cervical radiographic examination. The studies were made in selected populations that did not represent the spectrum of patients relevant to the study of whiplash injury; specifically, the samples were skewed toward the most severe patients. These studies indicate that a prediction algorithm with high sensitivity but low specificity can be achieved. Two of the studies suggest that radiographs are not necessary of patients who are alert and do not complain of neck symptoms.[53,68] Neifeld et al[72] and Roberge et al[87] suggest that radiographs are not necessary of patients who are alert and have no neck tenderness on physical examination, even if they have cervical pain. The study by Jacobs and Schwartz[47] suggests that clinical prediction is not sufficient to rule out the presence of bony-tissue injury.

A study by Hoffman et al[43] also assessed criteria for ordering radiographs. The authors suggest that radio-

* Barnsley et al[3] studied single versus comparative blocks for diagnosing zygapophysial joint pain in patients with chronic WAD. Subjects were randomly assigned to either short-acting (lignocaine) or long-acting (bupivacaine) injections on the first block and the complementary anesthetic on the second block. A concordant response was defined as shorter-duration relief from the lignocaine than from the bupivacaine. Only 34 of 45 subjects who had pain relief from the first block had a concordant response to the second injection. Because of the high proportion of discordant responses, this study suggests that positive response to a single nerve block is not adequately predictive of consistent response. Additional evaluation of single versus comparative nerve blocks on substantially larger samples of subjects is needed.

graphs are not necessary for patients who are alert, are not intoxicated, have an isolated blunt trauma, and have no neck tenderness on physical examination. The results of this study must be taken with some caution. The estimate of "no false negatives" is based on 27 patients with fractures who had at least one of the following four characteristics: midline neck tenderness, evidence of intoxication, abnormal level of alertness, or several painful injuries elsewhere, and who would have had radiographs taken using the decision criteria. This is a small number of fracture patients on which to base a conclusion. Moreover, the study was carried out on 974 patients receiving cervical spine radiographs for blunt trauma, but only 283 had a whiplash mechanism without a direct blow to the head or neck. The authors report that none of these latter patients had a fracture (0 of 283 cases) but do not provide confidence intervals. This study also suggests that false-positive findings are frequent on radiographs.

The study by Jaffe et al[48] was done in a select sample of 206 children including 59 (29%) with bony injury of the cervical spine. The authors propose indications for radiographs, including history of neck trauma, neck pain, abnormal sensation, abnormal reflexes, limitation of neck mobility, neck tenderness, abnormal strength, and abnormal mental status. The authors did not attain perfect sensitivity even when the specificity was very low.

Other studies on the use of radiographs in cervical spine injury patients did not address the issue of validity of diagnosis of these injuries. These studies, however, provide some useful information about the reliability and variability of radiography or measurement. The study by Annis et al[1] suggests that interpretation of radiographs is dependent on the level of training of the interpreter. The study by Sistrom et al[96] illustrates that most of the variation in usual measures of soft tissue on cervical radiographs is related to variations in age and gender of the subjects, rather than variations in symptomatology and objective findings. Studies by Templeton et al[111] and Young et al[123] suggest that there are a number of false-positive radiographic findings in the measurement of soft tissue and the laminar space in WAD patients. The study by Freemyer et al[31] suggests that there is no benefit of adding a supine oblique view to the three-view series used in emergency rooms. The study by Dvorak et al,[20] although specifically done on whiplash patients, does not provide useful information about radiographs; there are not enough details in the paper about the type of manifestations or about the comparison with the control group of healthy adults to make conclusions on radiography's predictive validity of range of motion assessment in whiplash patients.† Another study by Jackson et al[46] suggests that the use of a marking system on radiographs is a reliable way to assess the upper cervical spine; unfortunately, the paper does not provide any information on the study population, which precludes our using this information for WAD patients.

Devices to measure range of motion of the cervical spine have been assessed by Foust et al,[30] Rheault et al,[86] and Youdas et al.[122] These studies were reliability assessments carried out on healthy subjects[30] or on a group with very few whiplash patients.[86,122] The reliability varies considerably depending on the direction of movement. Gender and age are major sources of variation in the measurements. None of these studies address issues of validity of the devices to predict clinical findings or the course of the disorder. Variation resulting from sources other than clinically relevant variables is also reported by Vernon et al,[116] in a study of the modified dynamometer to evaluate neck muscle strength in whiplash patients.

Interventions

The Task Force identified a number of specific treatments for WAD. This section synthesizes the evidence regarding efficacy and effectiveness of these treatments, based on the results of studies judged acceptable by Task Force consensus. A table describing the accepted randomized control trials (RCT) of treatments for WAD can be found in Appendix II.

Immobilization. Collars. Cervical collars are often prescribed to immobilize the neck in patients with WAD. Several accepted studies have shown that the soft foam collar, the Philadelphia collar, and the Queen Anne collar have little effect on cervical range of motion in healthy adults.[17,24,49]

Although prescription of cervical collars is common practice in WAD, no research was found addressing their independent efficacy or effectiveness for WAD. The information that is available comes from studies where collars were part of the treatment regimen prescribed for control patients in studies evaluating other interventions. Soft collars were prescribed as part of the control treatment in three RCTs evaluating mobilization[62,63,64] and electrotherapies.[27,28] In all these studies, the group receiving soft collars in combination with the other control interventions had delayed recovery in terms of pain rating (by McGill Pain Questionnaire, Visual Analog Scale, or other validated method) and range of motion (by several methods) compared with that of the groups receiving the interventions the studies were conducted to evaluate.

Soft collars do not restrict the range of motion of the cervical spine. Collars may promote inactivity, which can delay recovery in patients with WAD.

Prescription of Rest. Prescription of rest in the first few days is a common recommendation for WAD. There are

† A recent study by Helliwell et al[34] suggests that a finding of a straight cervical spine after radiography is not specific to muscle spasm caused by pain.

accepted RCTs in which prescription of rest for 10–14 days along with soft collars and analgesia was the control treatment. This recommendation was compared with mobilization or advice for WAD presenting within 72 hours[62,63] or in the acute phase.[64] We found no studies designed to evaluate the independent effect of rest on WAD. The cumulative evidence suggests that prolonged periods of rest are detrimental to recovery from WAD.

Cervical Pillows. There were no studies found regarding cervical pillows for WAD.

Activation. Manipulation. Nansel et al[69] addressed the duration of effect of a single manipulation (adjustment) in volunteers with or without a history of neck trauma and with cervical range of motion asymmetry of greater than 10°. There was an equivalent immediate reduction in range of motion asymmetry in both groups. This effect lasted less than 48 hours. In a RCT comparing the efficacy of a single manipulation with a single mobilization, Cassidy et al[14,15] found that after controlling for pretreatment differences, there were equivalent immediate (less than 5 minutes) improvements in pain and range of motion in neck pain patients, including Grade I and II WAD. There were no other accepted studies regarding the short- or long-term effectiveness or efficacy of manipulation. Because manipulation is a common treatment in WAD, its value must be established in randomized controlled trials.

Mobilization. There were no studies found that addressed the independent effects of mobilization. There are several accepted RCTs of the efficacy of mobilization in combination with other physiotherapeutic modalities in WAD.[9,10,62,63,64] McKinney et al[62] found that 1 week after completion of a 2-week course of physiotherapy (including mobilization by McKenzie and Maitland techniques in combination with passive modalities, analgesics, and collars), mobilized subjects (physiotherapy group) showed significantly greater improvement in summary range of motion and pain than subjects who were prescribed rest, analgesics, and soft collars (rest group). The improvement in the physiotherapy group was equivalent to that of subjects who received advice on posture, on early activation, a program of home exercises, and a prescription of soft collars and analgesics with advice to limit use of both. At follow-up, 2 years after completion of treatment, the physiotherapy group and rest group had similar proportions recovered (defined as absence of symptoms).[62] The advice group had a significantly higher proportion recovered than either the rest or the physiotherapy group. These results are consistent with the work of Mealy et al,[64] who reported that the Maitland mobilization technique, in combination with passive modalities and advice for home exercises and analgesics, had a significantly better short-term effect on pain and range of motion than the prescription of 2 weeks rest, soft cervical collar, and analgesia in acute WAD. Brodin[9,10] found that a 3-week course of passive mobilization combined with a brief information session and analgesics was more effective in reducing pain and improving range of motion 1 week after treatment than was "mock therapy" with education and analgesics, or simply analgesics with instruction to wait for treatment. The duration of symptoms before treatment initiation was not specified in these reports.

The cumulative evidence suggests that mobilization techniques can be used as an adjunct to strategies that promote activation. In combination with activating interventions, they appear to be beneficial in the short term, but long-term benefit has not been established.

Exercise. The independent effect of exercise has not been evaluated. Active exercises were included as part of the interventions in the McKinney et al,[62,63] Mealy et al,[64] Foley-Nolan et al,[28] and Zybergold and Piper[125] trials (see section titled "Traction"). The cumulative evidence suggests that active exercise as part of a multimodal intervention may be beneficial in the short and long term. This suggestion should be confirmed in future studies.

Traction. There was no research found regarding the independent benefit of traction in any grade of WAD. The literature yielded one accepted paper focused primarily on traction,[125] a RCT in patients with cervical spine disorders including WAD. There were four treatment groups: static traction, intermittent traction, manual traction, and control (no traction). All four groups received neck care instruction, moist heat treatments, and a program of exercises. For all three types of traction combined, there was a significantly greater change over the control group only in forward flexion and in right rotation. There were no clinically or statistically significant differences in range of motion change in extension, left or right lateral bending, left rotation, or in change of pain severity. Although the authors advocate intermittent traction, there were no clinically or statistically significant differences in outcome (change in pain by the McGill Pain Questionnaire and range of motion at 6 weeks) between any of the traction types and the control treatment.

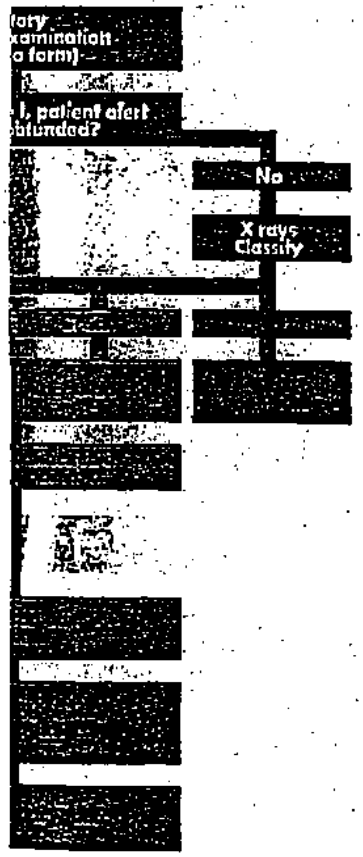
Postural Alignment and Advice. There was no research found regarding postural alignment. Advice on posture was part of the intervention for the "advice" group in the studies of McKinney et al[62,63] (see section titled "Mobilization").

Spray and Stretch. There were no studies found regarding spray and stretch.

Passive Modalities and Electrotherapies. Transcutaneous Electrical Nerve Stimulation. There were no accepted

PLASH-ASSOCIATED DISORDERS

FOR PATIENT CARE



Name: Record #:

WHIPLASH-ASSOCIATED DISORDERS (WAD)
Minimum data/Initial visit (FORM B)

To be completed by the Clinician

A. SPINE EXAMINATION

1. Date of examination: Day ___ Month ___ Year ___
2. Pain/limitation in cervical spine

	No	Pain	Limitation
Flexion	☐	☐	☐
Extension	☐	☐	☐
Right rotation	☐	☐	☐
Left rotation	☐	☐	☐
Right lateral flexion	☐	☐	☐
Left lateral flexion	☐	☐	☐

3. Palpatory tenderness ☐ No ☐ Yes

If yes	Left	Midline	Right
Cervical spine	☐	☐	☐
Thoracic spine	☐	☐	☐

Other, specify: _____

B. NEUROLOGICAL EXAM

1. ☐ Normal or _

	Sensory deficit		Motor weakness		Decreased deep tendon reflexes	
	Right	Left	Right	Left	Right	Left
C5	☐	☐	☐	☐	☐	☐
C6	☐	☐	☐	☐	☐	☐
C7	☐	☐	☐	☐	☐	☐
C8	☐	☐	☐	☐	☐	☐
T1	☐	☐	☐	☐	☐	☐

Other, specify: _____

C. DIAGNOSTIC TESTS

1. Plain X-rays (cervical spine)
   - ☐ Normal
   - ☐ Degenerative changes, specify levels: _____
   - ☐ Fracture/dislocation/subluxation, specify levels: _____
   - ☐ Not indicated
4. Other specialized tests, specify: _____

D. DIAGNOSIS

7. Whiplash-Associated Disorder (WAD) Grade ☐ I ☐ II ☐ III ☐ IV
8. Other injuries, specify: _____
9. Other important medical conditions, specify: _____

E. MANAGEMENT PLAN

10. Reassurance
    - ☐ Yes
    - ☐ Not applicable
11. Activities
    - ☐ Return to usual activities A.S.A.P.
    - ☐ Delayed return to usual activities, specify days: ____
12. Other treatments
    - ☐ Medications, specify: _____
    - ☐ Exercise, specify: _____
    - ☐ Mobilization/manipulation, specify: _____
    - ☐ Other, specify: _____
13. Referral to specialized advice, specify: _____

F. REMARKS: _____

G. CLINICIAN IDENTIFICATION: _____

THE QUEBEC TASK FORCE ON WHIPL

THE QUEBEC CLASSIFICATION OF WHIPLASH-ASSOCIATED DISORDERS

Grade	Clinical Presentation
0	No complaint about the neck No physical sign(s)
I	Neck complaint of pain, stiffness or tenderness only No physical sign(s)

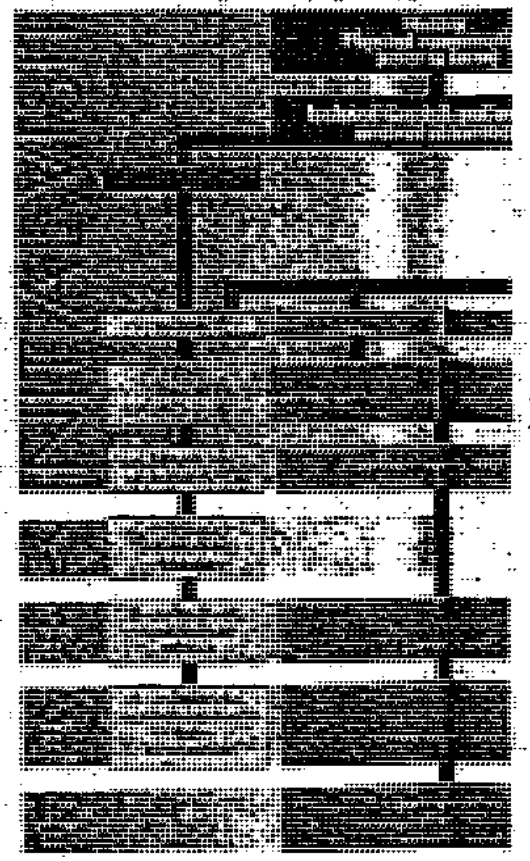
a Musculoskeletal signs include decreased range of motion and point tenderness.

b Neurologic signs include decreased or absent deep tendon reflexes, weakness, and sensory deficits.

Symptoms and disorders that can be manifested in all grades include deafness, dizziness, tinnitus, headache, memory loss, dysphagia and temporomandibular joint pain.

—— Dotted lines indicate terms of reference of the Task Force

THE QUEBEC GUIDELINES FOR



studies regarding transcutaneous electrical nerve stimulation.

Pulsed Electromagnetic Treatment. There were two accepted RCTs on pulsed electromagnetic treatment, one in neck pain patients[27] and one in patients with WAD Grades I and II referred from an emergency department within 72 hours of a motor vehicle collision.[28] The pulsed electromagnetic treatment device in a soft cervical collar (treatment group) was compared with a sham pulsed electromagnetic treatment device in a soft cervical collar (control group). The treatment course was 12 weeks; patients could elect to add physiotherapy beginning at 4 weeks. The treatment group showed a greater improvement in pain and range of motion in the first 4 weeks than the control group. Use of analgesics declined in the treatment group up to 4 weeks but not in the control group. At 4 weeks, approximately half of each group (45% of treatment vs. 60% control group—not significant by secondary analysis) added physiotherapy to their treatment. After then, the control group improved more quickly than the treatment group, so that at 12 weeks there were no differences between the groups. Because the pulse electromagnetic treatment device is in a soft collar, which tends to encourage inactivity, it cannot be recommended until it is shown to be superior or at least equivalent to mobilizing interventions.

Electrical Stimulation. There were no accepted studies regarding electrical stimulation in WAD.

Ultrasound. There were no accepted studies regarding ultrasound in WAD.

Laser, Short Wave Diathermy, Heat, Ice, Massage. There were no accepted studies regarding the independent effect of any of these treatments for WAD or neck pain. They were part of the combination of passive modalities in the studies of McKinney et al,[62,63] Mealy et al,[64] and Brodin.[9,10]

Surgical Treatment. There were no accepted studies of disc surgery or nerve block in managing WAD or cervical disorders. No research was found concerning the benefit of rhizolysis in WAD.

Injections. No accepted studies were found addressing epidural or intrathecal steroid injections for management of WAD. Accepted studies were found addressing intra-articular steroid injections for chronic WAD (one study)[4] and subcutaneous sterile water trigger point injections for chronic neck and shoulder pain (one study).[12]

Intra-articular Steroid Injection. The results of injection with beramethasone (treatment group) were no better that 0.5% bupivacaine (control group) for relief of cervical zygapophysial joint pain of greater than 3-months duration attributed to a motor vehicle collision.[4] The short duration of pain relief overall and the lack of a substantial difference in duration of efficacy between steroid and local anesthetic, leads to the conclusion that intraarticular steroid injection is not justified in the management of cervical zygapophysial joint pain after whiplash injury.

Subcutaneous Sterile Water Injection. One accepted RCT conducted in patients with chronic neck and shoulder pain 4 to 6 years after whiplash injury found a greater improvement in reported pain and cervical range of motion in patients receiving sterile water injections compared with patients receiving saline injections.[12] A major limitation of this study is that it was not a blind study. The immediate pain associated with sterile water injection is such that neither patients nor treating physicians were blind to the treatment received.

Pharmacologic Interventions. No research was found regarding the benefit of narcotic analgesics or psychopharmacologic therapeutics in WAD.

Analgesics[9,62,63,64] and nonsteroidal anti-inflammatory drugs[27,28] combined with other treatment modalities were associated with short-term benefit for WAD Grades I and II that presented in the acute phase or less than 72 hours postcollision.

No accepted studies were found regarding muscle relaxants in management of WAD.

Psychosocial Interventions. No research was found regarding the psychosocial interventions in the management of WAD.

Other Interventions. Of all the other interventions cited, there were accepted studies for only three.

Prescribed Function. In a RCT of the efficacy of prescribed function on individuals suffering from Grade I and II WAD within 72 hours of a motor vehicle collision, McKinney et al[62,63] found that advice to mobilize, exercise, limit inactivity, and avoid dependence on collars and analgesics was effective. This regimen of prescribed function was at least as effective short term in improving cervical range of motion and more effective long term in improving symptoms than physiotherapy, including McKenzie and Maitland mobilization techniques.

Acupuncture. No research was found concerning acupuncture in the management of WAD. One study was accepted comparing acupuncture with sham transcutaneous electrical nerve stimulation in rheumatology outpatients with chronic neck pain of at least 6-month duration.[78] Acupuncture was not shown to be superior to the sham transcutaneous electrical nerve stimulation. Because this study was not conducted in patients with WAD, the efficacy of acupuncture for treatment of WAD remains to be established.

Magnetic Necklace. There was one accepted study regarding the efficacy of the magnetic necklace in chronic neck pain.[64] Patients with neck and shoulder pain for more than 1 year were randomly assigned to an active or sham magnetic necklace. There were no differences in reported pain or other outcomes between the two groups at baseline examination and after 3 weeks of treatment.

Although there were no accepted studies supporting its efficacy in any grades of WAD at any time, the magnetic necklace appears to be widely advertised in the lay media. It is not common practice among mainstream health care providers.

Prognosis

The best source of subjects for prognostic studies would be all persons in a population who experienced a motor vehicle collision that included an acceleration–deceleration event, and thus had the potential to produce a whiplash injury and its clinical manifestations. No reports on prognosis in subjects thus identified were accepted. The next best source for prognostic studies of this problem would be subjects identified by insurance claims with clinical examinations occurring almost immediately after the motor vehicle collision or by visits to health care providers almost immediately after the motor vehicle collision. From sources of this type information can be gathered very early in the evolution of the disorder on all potential WAD subjects who had been sufficiently concerned to report their condition to either an insurance representative or health care provider. The reports of Norris and Watt,[73] Heise et al,[37] Radanov et al,[12,65] Burke et al,[11] and Hildingsson and Toolanen[39] fall into this category. Excluded from this type of study are people who did not consider themselves in need of emergency medical attention or of indemnity immediately after the motor vehicle collision.

Initial Presentation. Severity. Norris and Watt,[73] in a prospective study of 61 patients presenting to an emergency department after a motor vehicle collision in England, classified subjects based on symptoms and signs at the initial examination. Forty-four percent had symptoms but no reduction in range of motion (Group 1), 29% had neck pain and a reduced range of motion (Group 2), and 16% had neurologic signs (Group 3). These groupings roughly parallel the Quebec Grades I–III, with the exception that fractures and subluxations could be included in any of the three groups rather than forming a separate group. After radiographic examination, one subject in Group 1 was found to have a fractured transverse process, and three subjects in Group 3 had other cervical spine fractures.

Burke et al[11] reported that of 39 WAD subjects presenting to an emergency department within 7 days of the motor vehicle collision, 41% had an initial presentation corresponding to Quebec Grade I, 56% to Quebec Grade II, and 3% to Quebec Grade III.

Heise et al[37] also studied patients coming to emergency departments with neck pain after a motor vehicle collision but did not exclude patients with multiple injuries or bony-tissue injuries of the cervical spine. Of the 155 patients included in their study, 41% had fractures, dislocations, or subluxations of the cervical spine (Quebec Grade IV). The remaining 59% of patients were Quebec Classification Grades I–III.

Table 13. Presentation of Symptoms at Baseline*

Symptoms	Study: Norris and Watt,† 1983 %	Radanov et al,† 1991 %	Hildingsson and Toolanen, 1990 %
Neck Pain	100	100	88
Neck stiffness	–	–	69
Headache	66	57	54
Shoulder pain	–	42	40
Arm pain/numbness	–	–	14
Paresthesias	62	13	–
Weakness	18	–	–
Dysphagia	15	–	–
Visual	8	23	9
Auditory	18	–	4
Dizziness	25	17	23

* Baseline in various studies: Norris and Watt[73]—cannot be determined; Radanov et al[65]—mean approximately 7 days; Hildingsson and Toolanen[39]—less than 3 days.
† Secondary analysis.

Presenting Symptoms. The study of Hildingsson and Toolanen[37] (patients referred to an orthopedic service from an emergency department in Sweden) and the secondary analyses of the studies of Radanov et al[82] ("common whiplash" patients in Switzerland identified a mean time of 7 days after motor vehicle collision) and Norris and Watt[73] (patients presenting to an emergency department in England) revealed that the most common presenting symptoms were neck pain (88–100%) and headache (54–66%) (Table 13). Other symptoms, such as paresthesias, weakness, dysphagia, visual symptoms, auditory symptoms, and dizziness, varied considerably in frequency, possibly reflecting the different patient sources and health care system influences.

Among the 92 Grade I–III WAD patients in the study of Heise et al,[37] 14 (15%) reported masticatory muscle and temporomandibular joint pain, including one reporting a temporomandibular joint click.

Radiologic Findings. The radiologic findings at baseline examination were directly reported or ascertainable by secondary analysis in the studies by Norris and Watt[73] and Hildingsson and Toolanen (Table 14).[39] Fifty percent or less of the subjects had completely normal cervical spine radiographs. Forty-six percent of subjects in the former study and 39% of subjects in the latter study had straight or kyphotic cervical spines. Degenerative spondylosis was noted in 31% of Norris and Watts' and 8% of Hildingsson and Toolanen's subjects. The prev-

Table 14. Radiologic Findings at Baseline*

Findings	Study: Norris and Watt,† 1983 N (%)	Study: Hildingsson and Toolanen, 1990 N (%)
Normal	21 (35)	45 (51)
Straight/kyphotic cervical spine	28 (46)	33 (38)
Degenerative spondylosis	19 (31)	7 (8)

* Studies from orthopedic departments with the patients referred from the emergency department.[30,73]
† Secondary analysis.

alence of radiologic abnormalities was observed to increase with severity grouping in one of the studies.[73]

Prognosis Overall. In the study by Norris and Watt,[73] the prevalence of every symptom had declined somewhat by 6 months or more after the motor vehicle collision (Table 15). The only exception was visual symptoms, which had been reported initially by only 8% of the subjects. The data, however, were not presented such that the total number of subjects reporting any symptoms at follow-up could be reconstructed.

In the early study of Radanov et al,[82] a reanalysis of the data shows that 27% of the subjects were still symptomatic at the 6-month follow-up. The distribution of symptoms at baseline was similar to that reported by Norris and Watt,[73] except for paresthesias. The later report of Radanov et al[85] described predictors of recovery from headache in subjects with "common whiplash." Trauma-related headache (arising in the occiput and radiating to the frontotemporal region) resolved over time; 35% had headache persisting at 3 months, and 27% had headache persisting at 6 months.‡ This frequency is lower than that reported by Norris and Watt.[73] The mean time to follow-up in the Norris and Watt study was approximately 2 years.

At follow-up, an average of 2 years after the motor vehicle collision, 39 (42%) subjects in Hildingsson and Toolanen[39] reported themselves completely recovered, 13 (14%) reported mild discomfort, and 41 (44%) continued to have major complaints. The authors found no relationship between the potential predictors ascertained at baseline and persisting symptoms at follow-up. By comparison, Rosomoff et al[93] found that 100% of chronic neck pain patients attending a pain clinic had tender trigger points, 54% had a decreased range of motion, 53% had nondermatomal sensory changes, and 15% had rigid contracted muscles. With respect to temporomandibular joint symptoms, Heise et al[37] found that at 1-month follow-up no new symptoms were reported, and that the patients with initial symptoms "reported a decrease in these symptoms." At 1-year follow-up "no new cases of temporomandibular joint pain and clicking were reported."

Prognostic Factors. In this section, the prognostic importance of single or grouped determinants is described. The studies of Norris and Watt[73] and Radanov et al[82,85] suggest that the severity of the initial injury is a predictor of the persistence of symptoms.

Signs and Symptoms. Radanov et al[82] found that finger paresthesia was predictive of persistence of symptoms for 6 months after the injury in a series of 78 patients who attended primary care practices within 7 days after a whiplash injury (Table 16).§

In the Radanov et al[85] report examining predictors of persistence of headache in subjects with "common whiplash," the authors conducted a multiple logistic regression analysis to determine predictors of trauma-related headache at baseline, 3 months, and 6 months. Initial neck pain intensity, time of onset of neck pain, and depression and well-being scores were associated with headache at baseline. Pretrauma headache and concurrent severity of neck pain were predictive of headache at 3 and 6 months. This report suggests that pretrauma headache and neck pain are associated with a delay in recovery from trauma-related headache after whiplash injury.

The central finding of the study by Norris and Watt[73] is that the presence of musculoskeletal or neurologic signs within 3 days of a motor vehicle collision, as indicated by

Table 15. Prevalence of Symptoms at Follow-Up*

	Study: Norris and Watt,† 1983 N (%)	Study: Radanov et al,† 1991 N (%)	Study: Radanov et al,‡ 1993 N (%)	Study: Hildingsson and Toolanen, 1990 N (%)
Symptomatic	–	21 (27)	–	41 (44)
Neck pain	40 (66)	–	–	27 (29)
Neck stiffness	–	–	–	23 (25)
Headache	28 (43)	–	32 (27)	14 (15)
Shoulder pain	–	–	–	16 (17)
Arm pain/numbness	23 (38)	–	–	6 (9)
Paresthesias	2 (3)	–	–	–
Weakness	0 (0)	–	–	–
Dysphagia	8 (13)	–	–	8 (8)
Visual	8 (13)	–	–	5 (5)
Auditory	0 (0)	–	–	4 (4)
Dizziness	–	–	–	–

* Time from motor vehicle collision to follow-up: Norris and Watt[73]—at 6 months, mean approximately 2 years; Radanov et al[82,85]—6 months; Hildingsson and Toolanen[39]—6–43 months, mean approximately 2 years.
† Secondary analysis.
‡ Symptom of interest: headache only.

‡ In a report addressing a larger number of symptoms in the same cohort, Radanov et al[84] reported that 44% of subjects were symptomatic at 3 months, 31% at 6 months, and 24% at 1 year after entry to the study; 11% were still disabled at 3 months, 6% at 6 months, and 4% at 1 year.
§ In the Radanov et al[84] cohort, symptoms of radicular irritation were found, by multiple logistic regression, to be predictive of symptom persistence at 3-, 6-, and 12-month follow-up. Other signs and symptoms predictive of delayed recovery were intensity of initial neck pain and headache as a result of the current trauma.

Table 16. Percent Prevalence of Initial Characteristics of Subjects Asymptomatic and Symptomatic at Follow-Up

Symptom	Symptomatic (N = 21)	Asymptomatic (N = 57)
Headache	71	52
Shoulder pain	57	37
Blurred vision	33	18
Dizziness	24	14
Finger paresthesias	29	7
Fatigue*	88	54
Sleep disturbances*	65	28
Sensitivity to noise*	38	28
Irritability*	38	16
Forgetfulness*	29	7

* Self-report on interview.
Initial prevalence of self-reported neck pain, back pain, difficulty swallowing, and anxiety not different in the two groups.
Adapted from Radanov et al.[82]

Table 17. Percent Prevalence of Symptoms Initially and at Final Follow-Up

	Group 1 (N = 27)		Group 2 (N = 24)		Group 3 (N = 10)	
	Initial	F/U	Initial	F/U	Initial	F/U
Neck pain	100	44	100	81	100	90
Headache	48	37	78	37	80	70
Dysphagia	19	0	10	0	30	0
Paresthesias	33	37	43	29	100	60
Weakness	15	0	10	0	50	0
Visual symptoms	0	19	0	10	30	10
Auditory symptoms	0	11	0	14	30	20
Dizziness	0	0	5	0	10	0

Adapted from Norris and Watt.[79]
F/U = follow-up.

severity group, is predictive of outcome 6 or more months later. Headache was common across all groups and resolved equivalently in all groups. Neck pain resolved in half of Group 1 subjects but persisted in the other groups. Paresthesias resolved somewhat by the end of the follow-up in Groups 2 and 3 but not in Group 1. Dysphagia, weakness, and dizziness all resolved within 6 months. Auditory and visual symptoms were rare in Groups 1 and 2 but tended to appear late in the evolution of the disorder. Dizziness was uncommon initially and not present at baseline in Group 1. Table 17 summarizes the core results regarding prognosis within groups classified according to signs and symptoms in this study.

In a small study examining visual complications of whiplash, Burke et al[11] followed 39 emergency room subjects for 6 weeks. At initial examination (less than 7 days after the motor vehicle collision), 10 patients (26%) had visual symptoms, and 16 (41%) had ophthalmologic abnormalities. At the time of follow-up, ophthalmologic abnormalities remained in five of the original 16 subjects.

Radiologic Findings. The prognostic importance in WAD of radiologic findings, including osteophytes, endplate sclerosis, angular deformity, and preexisting degenerative changes, was not examined in any accepted studies.‖ It should be noted that in the cross-sectional study of Van der Donk et al,[113] radiographic evidence of disc degeneration was associated with nonspecific neck pain in men and not in women, and osteoarthritis was not associated with neck pain.

Sociodemographic and Economic Factors. Sociodemographic and economic factors have been explored in several studies. In the earlier Radanov et al study[82], the symptomatic and asymptomatic groups at 6 months did not differ in sex, education, injury mechanism, collision fault, or time from injury to initial study examination.

‖ Radanov et al[84] reported that baseline radiologic evidence of preexisting osteoarthritis was predictive of symptom persistence at 3 months but not at 6 or 12 months.

Older age was associated with persistent symptoms. All the studies reviewed addressing the influence of financial compensation and legal action on the prognosis of WAD were flawed by substantial selection and information biases. The association of compensation and legal action with outcome in whiplash injury, therefore, remains to be shown.

Psychologic Factors. Several psychologic and behavioral factors, such as psychosocial stress, personality characteristics, and depressive symptoms have been examined. In the study by Radanov et al,[82] there was no statistically significant association of life history, personality traits, and "current psychosocial stress" with persistence of symptoms at 6 months. Self-report of cognitive impairment was associated with symptom persistence. This study included only 78 patients and therefore had limited statistical power.

Radanov et al[83] reported that there was no evidence for differences in attentional processing between "common whiplash" patients (mean duration 24.6 months) and patients with Barré-Liéou syndrome (mean duration 63.5 months), although whiplash patients tended to report more disturbance of cognitive function. The authors suggest that the self-reported cognitive impairment may have been related to the sudden nature of whiplash injury, whereas in Barré-Liéou syndrome there is a gradual onset, allowing time for adaptation. This suggestion requires further testing.¶

Van der Donk et al[113] have suggested that neurotic personality traits are associated with neck pain in the general population. This was a cross-sectional study, and it is not possible to determine whether the presence of neck pain negatively affected personality or if personality was a determinant of persistent neck pain.

¶ In their later report on a larger cohort, Radanov et al[84] found an association of cognitive disturbances (self-report of forgetfulness and poor concentration), speed of information processing from the personality inventory, and variables interpreted as indicating the intensity of the initial reaction to the trauma (sleep disturbances, score on nervousness), with persistence of symptoms. Contrary to expectation, neuroticism as measured on the personality inventory was associated with earlier recovery.

Section 5. Conclusions

Major Findings and Recommendations

The systematic review of the original research literature yielded little scientifically rigorous information addressing the mandate to the Task Force by the SAAQ. The consensus recommendations that follow are based on the best available evidence, or where evidence was lacking, on the combined experience and judgment emerging after extended in-depth discussions of the Task Force members. Consultation with external experts, information from a study initiated during the deliberations, and inference from relevant literature that does not address WAD specifically were also invoked. We have also put forward some controversial courses of action in the belief that public debate would be of value. Although commissioned in Quebec for Quebeckers, we believe that the conclusions and recommendations are appropriate to other populations.

Social Impact of Whiplash-Associated Disorders

Findings. The incidence of WAD is highly variable. The 1-year incidence rate of compensated claims for WAD in Quebec in 1987 was 70 per 100,000 inhabitants. Incidence rates in other provinces of Canada differ considerably from this. The marked variation in WAD claims from province to province raises the possibility that system differences, such as no fault insurance in Quebec and the tort system in Saskatchewan, may affect the frequency of claims and chronicity of cases.

Whiplash-associated disorders are usually self-limited. In a cohort of persons compensated for whiplash injuries occurring in 1987 in Quebec, the median time to recovery (end of disability compensation) was 31 days. Fifty-five percent of the cohort filed claims for whiplash only; 1.9% of these were still disabled 1 year after their injury.

Cases lasting more than 6 months and cases of 2 to 6 months duration are responsible for most of the disability costs from WAD. Of persons with compensated claims for whiplash injuries in a cohort followed for 5 years in Quebec, 12% received disability compensation for more than 6 months following the collision episode. These 12% of patients accounted for 46% of the costs paid by the SAAQ. Another 38% of costs paid by the SAAQ are associated with disabilities of 2 to 6 months duration. This finding is analogous to findings of the economic costs of other musculoskeletal disorders, notably low back pain in the workplace.

Diagnostic criteria and nomenclature used in WAD are confusing and are not standardized. This is a major barrier to a better understanding of WAD. Inconsistent definitions, descriptions, and classifications used in reports of WAD and in common clinical use make it impossible to compare and synthesize the findings of published studies. A lack of systematic stratification of severity similarly limits the usefulness of both administrative data and research reports.

The prevention of chronic WAD is an important challenge for society and the health care system. A major challenge for the health care system, the insurance industry, health professions, and the public is to prevent chronic disability related to WAD and to provide effective care to reduce chronicity. Risk factors for chronicity have had little study.

Recommendations. All reports of WAD should conform to a standardized classification scheme. Building on previous work of others, we propose the Quebec Classification of Whiplash-Associated Disorders (see Section 3 titled "Consensus Findings"). This clinical classification scheme describes mutually exclusive and collectively exhaustive categories of WAD, which should facilitate research and administrative reporting. Its reliability, comprehensiveness, and prognostic utility should be tested formally.

All new incidents of WAD should be reported on a standardized form. All persons involved in an acceleration–deceleration collision with possible WAD and who are seeking care for the first time or initiating an insurance claim should complete a standardized form that provides basic personal, sociodemographic, clinical, vehicular environmental data, and information on the dynamics of the collision (see Appendix I). This requirement will enhance the quality of follow-up evaluations, permit epidemiologic surveillance of the population and foster the pursuit of the research priorities set forth in this scientific monograph. Health professionals not reporting standardized data should not be reimbursed, and patients who do not provide information should be ineligible for benefits from SAAQ.

Patients should be reassured that WADs are almost always self-limited. Health professionals caring for patients with WAD should emphasize that most incidents of WAD are self-limited, involving temporary discomfort and rarely resulting in permanent harm. All interventions, particularly at inception of the episode, should be accompanied by reassurance about the favorable prognosis and the need to resume usual activities as soon as possible. The key message to the WAD patient is that pain is not harmful, is usually short-lived, and is controllable.

The effect of different social and insurance policies, such as no-fault insurance on incidence, and chronicity of WAD should be studied. The possibility that the

marked variation in WAD claims from province to province may in part be attributed to insurance system differences, such as no-fault insurance, should be investigated by means of formal evaluative studies incorporating health economics.

Prevention of Whiplash-Associated Disorders

Findings. The effectiveness of seatbelts in preventing neck injury has not been clarified. There are suggestions from the literature that seatbelts may increase the incidence of neck injuries (Grades I, II, and III in our classification), especially when not worn properly. This increase is minor and is largely offset by the demonstrated effectiveness of seatbelts in decreasing overall fatality and the incidence of severe head, face, and other injuries. There are no studies of the effect of airbags or other automatic protection devices on the frequency and severity of WAD. Controversy exists about whether the use of seatbelts affects the recovery of WAD patients.

Properly fitted headrests reduce severity of WAD. In rearend collisions, there is evidence that a headrest, which is in line with the seat, positioned close to the individual at the level of the occiput, made of the same material as the seat, and strong enough to resist impact but yielding enough to avoid rebound of the occupant, will reduce the incidence and severity of neck injuries.

Recommendations. Promoting general road safety measures to decrease the risk of motor vehicle collisions will be the most effective strategy to prevent WADs and their sequelae. There are many proven primary prevention measures for decreasing the risk and severity of motor vehicle collisions and injuries, but their implementation, dissemination, and enforcement are still incomplete. We recommend that major efforts be made to promote road safety to decrease the risk and severity of WAD. Priority should be given to measures directed at making vehicles and the road environment safer, without neglecting educational and behavioral interventions. For example, the maximum possible speed of all vehicles should be reduced, and retailers who sell alcoholic beverages to persons already intoxicated and likely to drive a vehicle should be held legally accountable.

All vehicles should be equipped with adequate headrests and restraints. Motor vehicles should be equipped with headrests for all occupants. These must be integrated in the seat and high enough to protect individuals of all heights. The seat and headrest should be of the same material to avoid differential rebound of the head and the body. All seatbelts should incorporate at least three-point shoulder/lap devices and retraction mechanisms so that forces are transmitted evenly. Seatbelt and restraint use should be required for all occupants of motor vehicles without exception.

In the interest of safety of both the person affected by WAD and the public on the roads, it may be necessary for the injured person to suspend or restrict driving activities temporarily. To operate a motor vehicle in a safe manner, a person should not be affected by conditions that prevent adequate perception of the road and its environment or which alter judgment, decision making, or reaction time. Persons with WAD who have limited range of vision resulting from restricted cervical range of motion or exhibit associated symptoms like equilibrium dysfunction, uncontrolled vertigo, diplopia, or who are obtunded by psychotropic medications or narcotic analgesics should be advised by their physicians to limit or discontinue the operation of a motor vehicle until the medications are discontinued and signs and symptoms resolve to a point at which the safe operation of the vehicle is again possible. It is the consensus of this Task Force that a recommendation by a physician for full disability status implies limitations of the ability to operate a motor vehicle in the absence of clear evidence to the contrary.

Diagnosis of Whiplash-Associated Disorders

Findings. The diagnosis of WADs can usually be made clinically. An evaluation including personal information, careful medical history, and directed physical examination can be used to classify patients and to assess the extent and severity of injury. There is no evidence that specialized diagnostic testing or imaging is needed on a routine basis for presumptive Grade I WAD when a subject is not obtunded and has no physical signs. Radiographs may be used selectively to rule out structural damage.

Recommendations. Patients with Grade I WAD usually do not require radiographic evaluation. Patients with presumptive Grade II and III WAD need a baseline radiologic examination. The clinical evaluation of a patient with apparent Grade I WAD, who is alert and not obtunded by alcohol or drugs and has no physical signs, generally does not require a radiographic evaluation. All other patients with WAD should have a radiologic examination, consisting of plain films with anteroposterior, lateral, and open-mouth views. All seven cervical vertebrae and the C7–T1 motion segment should be visualized. Flexion and extension views and tomography, computer-assisted tomography, and other imaging techniques are indicated when the three-view plain films are equivocal.

Diagnostic tests and imaging for WAD should be evaluated critically. There is a need for formal evaluation of history taking, physical examination, and plain radiographs for the diagnosis of WAD. The marginal additional value of other tests, procedures, and imaging techniques for Grade II and III WAD also need assessment. These studies should be large enough to estimate precisely the frequency of false positives and false negatives and should include assessments of costs and benefits, including considerations of adverse side effects such as prolonging disability.

Treatment of Whiplash-Associated Disorders

Findings. Most therapeutic interventions currently used in patients with WAD have not been evaluated in a scientifically rigorous manner. These unproven therapies include cervical pillows, postural alignment training, acupuncture, spray and stretch, transcutaneous electrical stimulation, ultrasound, laser, short-wave diathermy, heat, ice, massage, epidural or intrathecal injections, muscle relaxants, and psychosocial interventions.

Treatments evaluated in a scientifically rigorous manner show little or no evidence of efficacy. There is little or no evidence of efficacy for soft cervical collars, corticosteroid injections of the zygapophysial joints, pulsed electromagnetic treatment, magnetic necklace, and subcutaneous sterile water injection. Use of soft cervical collars beyond the first 72 hours probably prolongs disability in WAD.

Interventions that promote activity such as mobilization, manipulation, and exercises in combination with analgesics or nonsteroidal anti-inflammatory agents are effective on a time-limited basis. Based on limited evidence and reasoning by analogy, it is the Task Force consensus that the use of nonsteroidal anti-inflammatory agents and analgesics, short-term manipulation and mobilization by trained persons, and active exercises are useful in Grade II and III WAD, but prolonged use of soft collars, rest, or inactivity probably prolongs disability in WAD.

Recommendations. Early return to usual activities for WAD patients should be vigorously encouraged by clinicians. Immediate return to usual activities is recommended for Grade I WAD; work restrictions are not indicated. For Grades II and III WAD, return to usual activity as soon as possible should be encouraged, typically in less than 1 week for Grade II WAD. Work alterations may be prescribed for Grades II and III WAD, but should be temporary, except for clinical circumstances justified as unusual by the attending clinician or for atypical work environments. The work alteration prescription should be reassessed within 3 weeks.

Soft collars in the management of WAD are not recommended and should be discouraged. Even in Grade III WAD, soft collars should not be used because they do not adequately immobilize the spine. In the majority of cases, early return to mobility is important, and the use of a collar may prolong disability.

Prescription drugs have a limited role in the management of WAD and should be used sparingly. No medication should be prescribed in Grade I WAD. In Grade II and III WAD, non-narcotic analgesics and nonsteroidal anti-inflammatory agents can be used to alleviate pain for a period of less than 1 week. In Grade III WAD, narcotic analgesics may occasionally be needed for pain relief, particularly in the acute phase. Whenever narcotics are prescribed, the patient should be cautioned about possible sedative effects and advised not to drive motor vehicles or operate heavy equipment. Psychopharmacologic drugs are not recommended for WAD. They may be used occasionally for symptoms, such as insomnia or anxiety, as an adjunct to other interventions promoting greater activity of the patient. In chronic cases of WAD (at 3 months or more after inception) minor tranquilizers and antidepressants may be a necessary part of multidisciplinary management. Muscle relaxants should not be used in the management of WAD.

Prescribed rest is seldom indicated and should always be limited to a short duration. The prescription of bed rest is not indicated for any Grade of WAD. The prescription of rest for the neck by restricting activity in Grade I WAD is not indicated. In the few cases with Grade II and III WAD in which rest for the neck might be indicated, it should be limited to less than 4 days and followed by early activation. Longer periods of rest require clinical reassessment.

Practitioners of manipulative therapy should emphasize early return to usual activity and the promotion of mobility. The Task Force consensus is that manipulative treatments by trained persons for the relief of pain and facilitating early mobility can be used in WAD. All such treatments should be accompanied by reassurance about the good prognosis of WAD, should discourage extended dependence on the health professional, and promote resumption or continuation of usual activities and work. Long-term, repeated manipulation without multidisciplinary evaluation is not justified.

Physiotherapy should emphasize early return to usual activity and the promotion of mobility. Treatments given for relief of pain and promoting early mobility are recommended primarily on the basis of consensus. All interventions by physiotherapists in WAD patients of any grade or stage should be accompanied by reassurance about its good prognosis and should promote resumption of usual activities including work. Long-term physiotherapy without multidisciplinary evaluation is not justified.

Surgery for WAD patients is rarely indicated. Surgery is only indicated for WAD Grade III patients with progressive neurologic deficit or persisting arm pain.

Current Practice

Findings. Widely accepted, standardized guidelines for the management of WAD are not available.

Recommendations. A patient care guideline for WAD is proposed. The clinical management of WAD patients should recognize that most cases unassociated with other injury, *i.e.*, isolated WAD, are self-limiting. Thus reassurance, promotion of activity, and conservative management are recommended in early treatment for all three grades. The most important principle is to prevent chronicity. Unresolved disability in Grade I WAD patients requires a specialized consultation at 3 weeks after

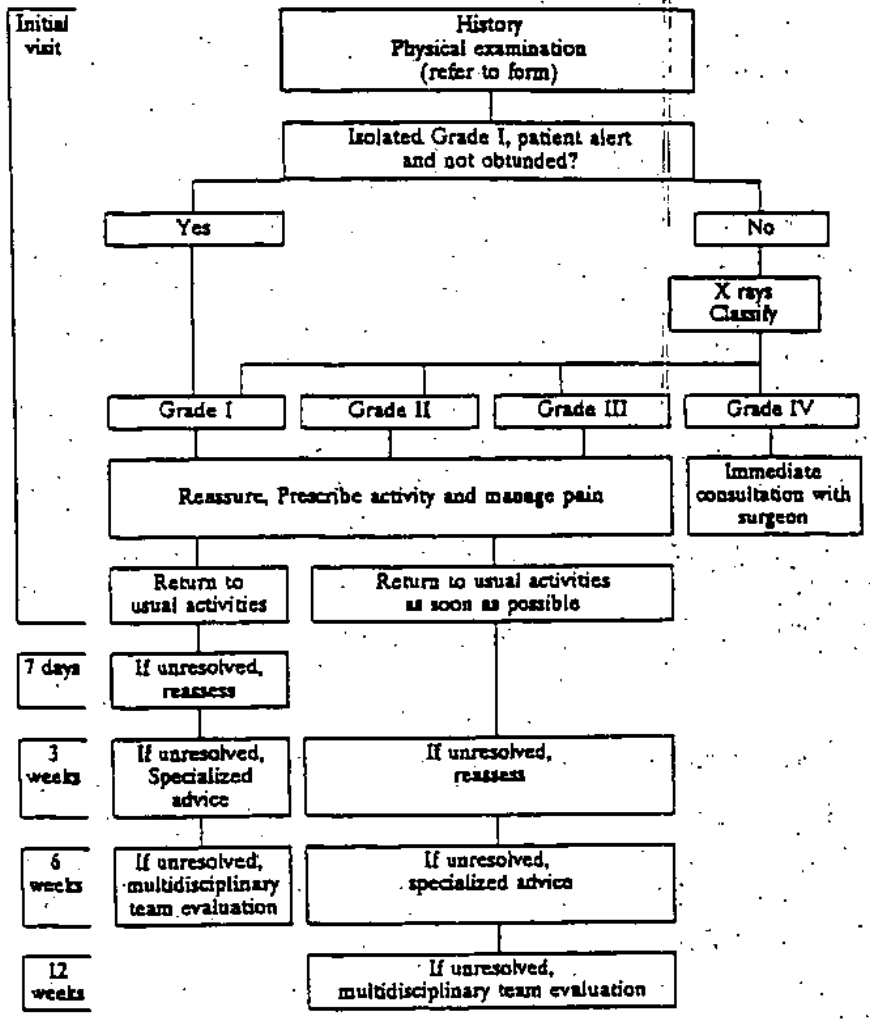


Figure 6. The Quebec Guidelines for Patient Care.

* See Table 18 for explanation of terms.

inception and a mandatory, multidisciplinary consultation after 6 weeks. For Grade II and III WAD, specialized consultation for unresolved cases should take place at 6 weeks and mandatory multidisciplinary consultation at 12 weeks. Grade I WAD patients with persisting problems should be reassessed in 7 days, and Grade II and III WAD patients who have not returned to usual activity in 3 weeks should be reassessed. Health professionals must provide essential clinical data at baseline, and patients should be required to provide personal data and information on the collision to enable good follow-up. Guidelines must always be individualized for the particular patient.

Professional Education Related to Whiplash-Associated Disorders

Findings. Training of practitioners and health science students in the management of WAD is deficient. Educational opportunities for clinicians in all health science faculties, including medical students, provide insufficient preparation for the management of WAD.

Recommendations. Health care professionals, particularly those involved in primary care and trauma care, should have improved training in the management of WAD. Traditional teaching programs should be enriched with multidisciplinary clinical content relevant to WAD. There should be more continuing educational programs, teaching materials, and aids to the education of health care professionals in the prevention, clinical evaluation, care, and rehabilitation of patients with WAD. Training programs should be targeted to clinicians in trauma and primary care. These initiatives should be implemented directly and through the faculties of health sciences in the university setting.

Table 18. Operational Definitions

Isolated	Not associated with other injuries.
Obtunded	Dulled consciousness.
Form	Recording information from the history and physical examination, management decisions, and grading of the WAD should be completed for all initial visits and for all reassessment visits for Grade I–III and preferably on a standardized form (Appendix I).
History	Includes characteristics of patient, previous history of medical and other pertinent factors, including neck problems, circumstances and mechanism of injury, nature and time of onset of all symptoms, and self-assessment of health status.
Physical examination	Includes inspection, palpation, range of motion, neurologic examination, assessment of associated injuries, general health, and mental status; required details can be found on data form for all recommended visits (see form).
Plain radiographs	Include anteroposterior, lateral, and open-mouth views; all seven cervical vertebrae and the C7–T1 level should be included.
Reassurance	Patients should be reassured that most WAD are benign and self-limiting, and they should be encouraged to resume usual activities of life as soon as possible.
Prescribe activity	Interventions should focus on promoting activity. Range of motion exercises should be implemented. Techniques that promote mobility of the cervical spine can be used but should be applied by qualified personnel. Interventions that impede active mobilization of the neck are not indicated.
Return to usual activities	Patients should be advised to resume their activities of daily living (work, studying, leisure, social, etc.), as soon as possible (usually immediately for Grade I). It should be explained to patients that usual activities may be temporarily painful but not harmful in WAD.
Unresolved	Unable to resume usual activities. A patient who still has residual pain or limitation of range of motion but who is able to resume work and other usual activities is considered to have resolved WAD.
Specialized advice	Consultation with a health professional with in-depth formal training in managing WAD.
Reassessment	Includes history taking and physical examination as during initial visit and specialized advice as required.
Multidisciplinary team	Health professionals with in-depth formal training in musculoskeletal disorders, psychosocial assessment, and other specialties.

■ Clinical Guidelines

The Task Force would have preferred to make firm recommendations based on research findings of good quality in the literature. The virtual absence of such evidence made it necessary to develop these clinical guidelines from consensus and the knowledge of experts in many clinical fields who are members of the Task Force. It should be stressed that these are guidelines. We emphasize that the dates for early intervention and the dates for referrals to specialized consultants and to multidisciplinary teams are firm. These recommendations reflect the consensus of the Task Force that the prognosis of WAD can be altered by optimum management. In other specific matters, we stress the importance of the clinical judgment of the practitioner taking care of the patient and the importance of taking into account that each patient is an individual. Both clinical judgment and individuality of patients, nevertheless, should not be taken as excuses for a laissez-faire, highly variable approach to management. An important dictum in clinical practice, that common things are common and exceptions are uncommon, should be remembered.

This section, therefore, presents the Quebec Guidelines for Patient Care, shown as a flow chart (Figure 6). With it, the reader will find operational definitions that assist in the interpretation of the Guidelines (Table 18). We encourage and endorse its printing in a larger chart form that can serve as a useful and convenient reference for busy practitioners.

In Appendix I, we present the suggested data sheets for minimum information to be recorded at initial and follow-up visits. Form A (initial visit) and C (follow-up visit) can be completed by the patient, with or without assistance, or by the physician. It includes demographic and collision-related information, information on general health before the collision, postcollision symptoms, and a pain drawing. The pain drawing is used to describe presenting symptoms and can also be scored for research purposes according to the method of Margolis et al.[60] Form B (initial examination) and Form D (follow-up examination) record the physical examination, diagnostic tests, and diagnosis, including the Quebec classification and management plan.

■ Recommendations for Teaching

Through its work and scientific exchanges over the past few years, the Quebec Task Force on Whiplash-Associated Disorders has defined the skills and knowledge needed for optimal management of WAD patients. In our opinion, the primary interventionist must possess the qualities of a clinical anatomist. In addition to his or her basic knowledge of topographic anatomy, this clinician must have an in-depth knowledge of neuroanatomy and more particularly, of peripheral neuroanatomy. He or she must have basic knowledge of the autonomic nervous system and its influence on the locomotor system. He or she must be an excellent diagnostician. He or she must possess fundamental knowledge of rehabilitation of the musculoskeletal system, including psychosomatic medicine and the social aspects of chronic disorders of the musculoskeletal system. Also, he or she must possess the essential knowledge for the prescription of combined care, including principles, scope and value of activation and other interventions. Finally, he or she must acquire knowledge of the basic principles of clinical epidemiology.

Unfortunately, there are significant gaps in the teaching of these skills and knowledge in the training programs of all clinicians. Some specialists in various dis-

ciplines (medicine, physiotherapy, occupational therapy, biomechanics, and chiropractic) have acquired these fundamental skills through individual voluntary postgraduate training. Most formal specialty training, however, does not encompass all the necessary areas of knowledge and skills for management of musculoskeletal disorders. We must realize that most primary interventionists in the management of WAD have little chance of being effective, given the present university teaching curricula.

Conscious of the significant morbidity and socioeconomic costs of musculoskeletal ailments, and in particular WAD, we recommend that an international effort be made to integrate training in the skills essential to the proper management of WAD into the curriculum of those health care professionals involved in the diagnosis, treatment, and rehabilitation of WAD. There should be a considerable effort made to educate clinicians already involved in the management of WAD through postgraduate education programs.

Section 6. Research Priorities for Whiplash-Associated Disorders

Orientation

Considering the human toll and economic impact of WAD, relatively little is known about this common problem. Studies of neck injury in animal acceleration–deceleration models clearly document one end of a spectrum of tissue damage. Whether lesser trauma in humans can cause enough injury to explain the symptoms seen in WAD cannot be deduced. Although considerable work has been done on WAD, much of it is flawed, uninterpretable, or inadequate to form rational clinical or health care policy. Fundamental questions remain regarding the pathophysiology, diagnosis, treatment, clinical course, and prevention of this disorder. Based on a critical assessment of the published evidence, the Task Force has made a number of recommendations to fill what we perceive as critical gaps in knowledge. Central to these efforts are: 1) a proposed terminology that, coupled with measures of severity, will make future studies comparable and 2) attention to rigorous study design and execution in any new studies.

Future studies would benefit greatly from a standardized description of patients, their sources, physical findings, and symptoms of prognostic significance. Standardizing the assessment would ensure that critical baseline information is collected and that studies done in different locations can be compared with one another. Improved precision and standardization of findings would permit the evaluation of the clinical value of conventional radiography and newer, but considerably more expensive, imaging techniques that display soft tissues in previously unimaginable detail. These latter techniques such as MRI may ultimately provide an understanding of the pathoanatomy of WAD. In clinical practice, MRI may provide more sensitivity and information than we can interpret, unless studies are done with sufficient numbers of carefully characterized subjects spanning the spectrum of WAD. These tests, as well as electrophysiologic or neuropsychologic studies in WAD, must be evaluated in terms of their clinical value in improving prognostication and outcomes. With better clinical correlation, in this era of increasing technologic capacity, public expectations, and diminishing resources, the cost-effectiveness of these tests must also be evaluated. Paradoxically, new imaging techniques could also restore the history and physical examination to a central role in the initial evaluation of WAD patients and, in the absence of anatomic information, make the history and physical examination the gold standard for the evaluation of other diagnostic technology.

Improved clinical characterization of WAD would also contribute to true population-based studies of the spectrum of disease and its clinical course. This would allow comparisons in different settings, especially different disability claims systems, and help to understand the clinical and social determinants of prolonged symptomatology, disability, and health resource utilization.

The Task Force was disappointed, despite an exhaustive literature search, by the studies evaluating the common therapeutic interventions for WAD. These studies as a genre are flawed; few met even minimum methodologic standards for scientific rigor. Even in the studies that were well done, small sample sizes and the use of multiple therapeutic interventions in the same subjects made it difficult to deduce the benefits of individual treatments. The lack of crisp endpoints using standardized, valid, and reliable measures, particularly patient-centered ones, made it impossible to pool results or to do secondary analyses of effect sizes or of their clinical importance. The imprecise categorization of patients into prognostic strata and the confounding effect of different disability laws made generalizations impossible.

The philosophy of the Task Force in evaluating treatments was one of prudence in the absence of evidence. We required that any therapeutic intervention should do more good than harm and that health care should not medicalize a condition or reinforce disability behavior. Some therapeutic interventions such as analgesics, anti-inflammatory agents, and antispasmodics have not been evaluated specifically for WAD; their value for other musculoskeletal injuries might be generalized to WAD. The remaining group included essentially harmless but either ineffective or marginally effective interventions such as soft collars, special pillows, prescribed exercises, postural attention, and traction. Where there was an effect, it was small and of short duration. The other category consisted of interventions that were expensive because they were labor intensive or done by professionals and were either unproven or marginally beneficial. These included manipulation, mobilization, spray and stretch, steroid injections, and a host of physical approaches to administer heat or cold topically or to the deeper soft tissues.

With a planned research agenda, we should have the resources to remedy the shortfalls in our knowledge of WAD.

There are several options for conducting research in this area depending on the research question, context, and feasibility. A variety of alternate designs may be used, for example, historical or prospective cohort studies, case-control studies, and case-cohort studies. The randomized controlled trial is the preferred design for evaluating interventions.

We have divided this agenda into two categories: a) problems of high priority requiring immediate attention and b) problems of importance to be undertaken in the longer term.

■ High Priority Questions—Research To Be Initiated in the Near Term

1) What is the prognostic significance of factors detectable and measurable at the outset of a collision in WAD? Which factors predict good outcomes, notably early return to full function and usual work? Which factors predict poor outcomes?

2) What is the performance, including validity and cost-effectiveness, of diagnostic approaches for WAD at inception? Approaches needing immediate assessment include:

- History taking
- Physical examination
- Plain radiography and other imaging techniques

3) What is the efficacy and cost-effectiveness of common therapeutic interventions for WAD? The interventions needing immediate assessment include:

- Prescribed rest
- Manipulation
- Specific physiotherapeutic and physical medicine treatment
  - Mobilization
  - Other exercises
  - Postural advice
  - Traction
  - Passive modalities and electrotherapies
  - Psychotherapeutic interventions

4) What is the effect in WAD of a clinical strategy encompassing early intervention and emphasizing activation, the promotion of mobility and assertive occupational rehabilitation?

5) What are the results of implementing the Quebec Patient Care Guidelines for WAD? An evaluative process should be incorporated into their implementation.

The problems deemed to be "urgent and essential" imply studies that can be completed in 5 years. At that time, a new Task Force should be established to monitor new evidence, the resulting changes, and to contemplate new opportunities.

■ Investigative Challenges of Importance To Be Undertaken in the Longer Term

In the longer term, research should be focused on the development and evaluation of:

- Demonstration models with different configurations of health professionals with contrasting arrangement of access, referral, and team function, accompanied by formal evaluation of their impact, particularly among WAD patients in a chronic phase.
- Demonstration models of alternate methods of reimbursement to health professionals and compensation for patients. The models should enable assessment of formulae linked to results rather than process and should include incentives for good outcomes, without penalizing patients who have intrinsic or unavoidable poor prognosis. All modalities should be eligible for evaluation including capitation and salaried reimbursement arrangements.
- Demonstration models of new curricular components oriented to WAD and related principles of the management of musculoskeletal conditions.

In the long term, research must evaluate the effectiveness of headrests, seatbelts, and other automotive engineering strategies in preventing WAD. In addition, research must address the pathophysiology of WAD, particularly with the goal of understanding the evolution of WAD.

■ Quality of Research

As noted in the "Orientation" section, research already done and published in the literature was found seriously deficient in terms of adherence to conventional standards of research in clinical studies, epidemiologic studies, and projects from other relevant disciplines. The most common deficiencies of published research reports on WAD found by the Task Force were:

- Lack of clarity in statement of study purpose, research question, or hypothesis.
- Inappropriate study design to test research questions or form conclusions.
- Lack of appropriate denominator.
- Lack of controls or suitable reference group for comparisons.
- Absent or unclear statement of inclusion–exclusion criteria.
- Sources of subjects that introduce intrinsic selection biases.
- Substantial losses to follow-up resulting in potential for biased estimate of outcome frequencies and determinants.
- Ascertainment of outcomes subject to investigator and patient reporting biases.
- Measurement methods whose reliability and validity are not established.
- Absent or unclear statement of interval between collision and study entry, or wide variability of interval.
- Inappropriate statistical analysis.
- Inadequate statistical power (small sample sizes).

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The Task Force stresses that future research must avoid these and other shortcomings. The scarce resources available should be protected by subjecting research protocols to the highest rigor of peer review, preferably with international panels of scientists.

Future Research

The tables in Appendix III include a comprehensive statement of specific research recommendations, many of which have not been delineated in the research agenda described in this section. The additional recommendations concern important questions. Their importance is subordinate to that of the unanswered questions that this agenda sets forth. The reader is referred to those tables.

Although all the unanswered questions are important to Quebec, it would be inappropriate that agencies in Quebec should be solely responsible for funding and support of the activities proposed. The same questions are relevant in other provinces of Canada and in other countries. We are encouraged that some research on risk factors, prognosis, and treatment is already underway in a collaborative way between investigators in Saskatchewan and Sweden; principals from both studies are part of this Task Force. This is a model for international and interdisciplinary research, which this Task Force endorses, to enhance the widespread relevance of the findings and the quality of the effort invested. We encourage all interested parties, including government funding agencies, insurance companies, universities, researchers, and health care professionals to share the responsibility of finding the solutions to this important health problem.

Section 7. Epilogue

Over 3-year period, the Quebec Task Force sought to demarcate the borders of the body of evidence on the risk, diagnosis, management, and prognosis of WAD. We found very little scientifically admissible data, as documented extensively in this scientific monograph and in the Official Report submitted to the sponsor, la Société d'assurance automobile du Québec. The void, unfortunately, about what is known in prevention, diagnosis, and rehabilitation is particularly noteworthy.

Nevertheless, we are confident that this scientific monograph is a major milestone in the struggle to improve our understanding of WAD and to improve the treatment of patients affected by this disorder. Despite the paucity of scientific evidence, we redefined and formally classified WAD. We established that most persons with WAD have a relatively benign disorder that resolves spontaneously in days or in a few weeks and requires very little treatment. The benefits of early return to usual activities of daily living and normal work after whiplash injury have been emphasized throughout this monograph. We have proposed formal but flexible plans to improve the clinical care and management of WAD. Also, we have identified research priorities addressed to the welfare of injured persons, to the needs of clinicians attempting optimum care, and to a better understanding of the pathogenesis and the evolution of WAD.

Ultimately, society must become better empowered to deal with the complex determinants of WAD and with the correction of its effects. The necessary multifaceted strategies required to address this problem are too daunting for any one clinical discipline, for any one sector of society, for any one state or province, and for any one agency to take on with any chance of making significant progress. The partners in future quests will be disparate and diverse. Without attempting to be exhaustive, we should create teams with imaginative combinations of primary care physicians, physiotherapists, chiropractors, physiatrists, orthopedists, occupational therapists, ergonomists, neurosurgeons, radiologists, psychologists, psychiatrists, rheumatologists, epidemiologists, biostatisticians, computer experts, health policy analysts, and engineers. At a different level, the resources and expertise of governments, research-funding agencies, insurance societies, patient associations, and professional associations must be marshaled in a cohesive manner. The heterogeneous and complementary groups must pursue better care, relevant research, and improved societal interventions simultaneously, and, in our view, urgently. Large gaps in our knowledge reinforce the need for better focused education, not only in disorders of the spine, but musculoskeletal disease in general.

The governmental no-fault SAAQ sponsored the scholarly effort now diffused through this monograph. Having honored the members and President of the Task Force through scrupulous respect for its scientific independence, the SAAQ now endorses the Official Report they have received. More importantly, they now join the Task Force members in recognizing the starting point for the next phase. The SAAQ and the government of Quebec will continue to be involved with important, meaningful inputs. For the challenges of WAD, the SAAQ has been a major catalyst; for the future it can be expected to stimulate and conduct developmental activities. Any progress will depend on a concerted international effort. We are optimistic that collaborative efforts will materialize and hopeful that the chief beneficiary will be the patient with WAD.

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Name: _____ Record #: _____

Address: _____ Telephone: _____

WHIPLASH-ASSOCIATED DISORDERS

Minimum data/Follow-up visit (FORM C)

Completed by patient or with assistance
Check the appropriate box or write answers where applicable

1. Date of visit: Day____Month____Year____

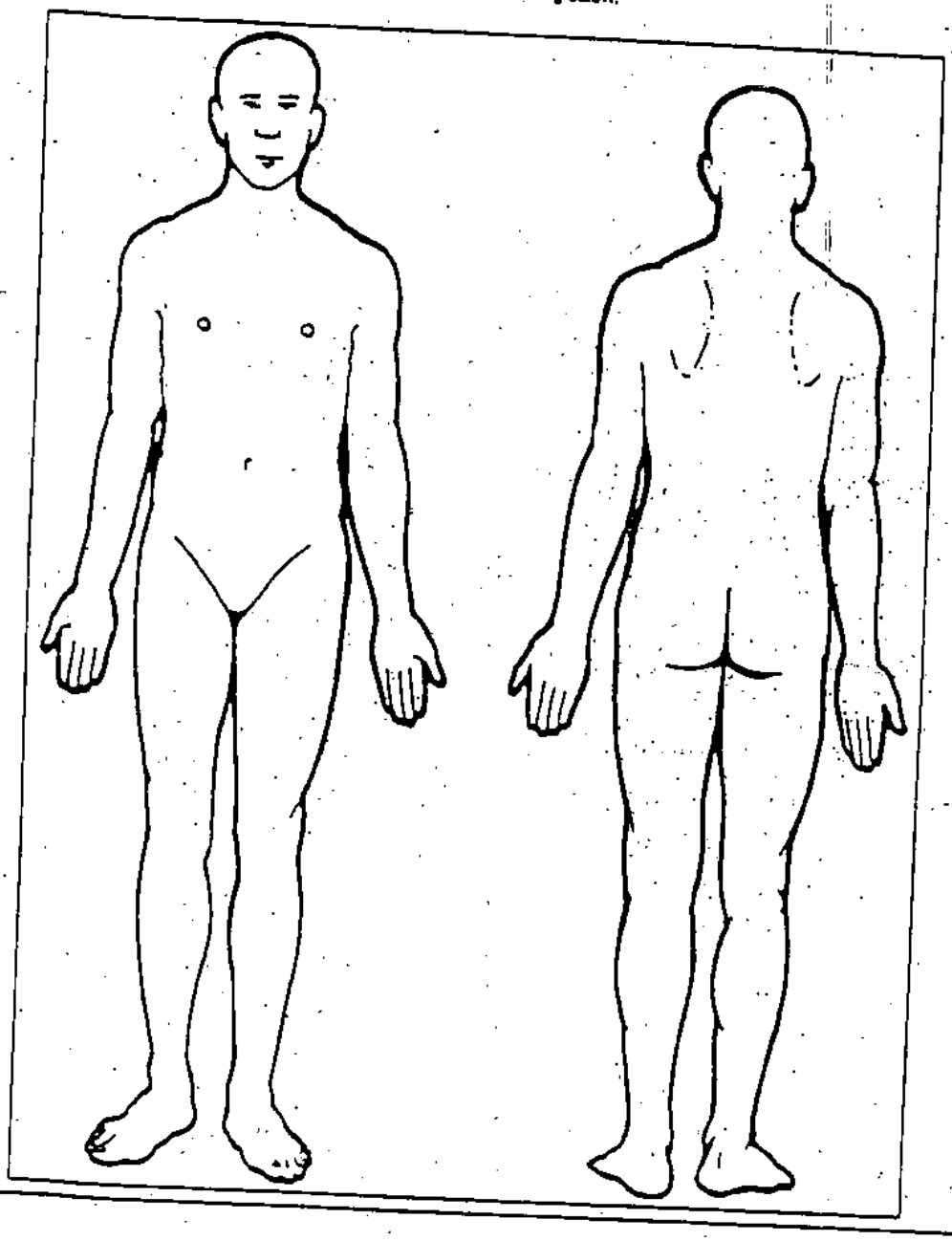
A. POSTCOLLISION INFORMATION

2. Have you felt the following symptoms since your past visit? Please check the appropriate box(es).

Symptoms		Present		If you have the symptom now, how severe is it?			
		No	Yes	Mild	Moderate	Severe	Unbearable
Neck/shoulder pain		☐	☐	☐	☐	☐	☐
Reduced/painful neck movements		☐	☐	☐	☐	☐	☐
Headache		☐	☐	☐	☐	☐	☐
Reduced/painful jaw movement		☐	☐	☐	☐	☐	☐
Numbness, tingling, or pain in arm or hand	Right	☐	☐	☐	☐	☐	☐
	Left	☐	☐	☐	☐	☐	☐
Numbness, tingling, or pain in leg or foot	Right	☐	☐	☐	☐	☐	☐
	Left	☐	☐	☐	☐	☐	☐
Dizziness/unsteadiness		☐	☐	☐	☐	☐	☐
Nausea/vomiting		☐	☐	☐	☐	☐	☐
Difficulty swallowing		☐	☐	☐	☐	☐	☐
Ringing in the ears		☐	☐	☐	☐	☐	☐
Memory problems		☐	☐	☐	☐	☐	☐
Problems concentrating		☐	☐	☐	☐	☐	☐
Vision problems		☐	☐	☐	☐	☐	☐
Lower back pain		☐	☐	☐	☐	☐	☐

Name: _____ Record #: _____

8. PAIN DRAWING
Carefully shade or mark in the areas where you feel any pain on the drawing below.



C. FORM COMPLETED BY:
- ☐ Yourself
- ☐ Clinician
- ☐ Other, specify _____

Name: _____ Record #: _____

WHIPLASH-ASSOCIATED DISORDERS

Minimum data/Initial visit (FORM 0)

To be completed by the clinician

A. SPINE EXAMINATION

1. Date of examination: Day____Month____Year____

2. Pain/limitation in cervical spine

	No	Pain	Limitation
Flexion	☐	☐	☐
Extension	☐	☐	☐
Right rotation	☐	☐	☐
Left rotation	☐	☐	☐
Right lateral flexion	☐	☐	☐
Left lateral flexion	☐	☐	☐

3. Palpatory tenderness
- ☐ No
- ☐ Yes

If yes:	Left	Midline	Right
Cervical spine	☐	☐	☐
Thoracic spine	☐	☐	☐

Other, specify _____

B. NEUROLOGIC EXAMINATION

4. ☐ Normal or ...

	Sensory deficit		Motor weakness		Decreased deep tendon reflexes	
	Right	Left	Right	Left	Right	Left
☐	☐	☐	☐	☐	☐	☐
C6	☐	☐	☐	☐	☐	☐
C7	☐	☐	☐	☐	☐	☐
C8	☐	☐	☐	☐	☐	☐
Other, specify	_____	_____	_____	_____	_____	_____

C. DIAGNOSTIC TESTS

5. Plain radiographs (cervical spine)
- ☐ Normal
- ☐ Degenerative changes
  specify levels _____
- ☐ Fracture/dislocation/subluxation
  specify levels _____
- ☐ Not indicated

6. Other specialized tests, specify:
_____
_____

D. DIAGNOSIS

7. Whiplash-associated disorder
Grade ☐ I ☐ II ☐ III ☐ IV

8. Other injuries, specify: _____
_____

9. Other important medical conditions, specify: _____
_____

E. MANAGEMENT PLAN

10. Reassurance
- ☐ Yes
- ☐ Not applicable

11. Activation
- ☐ Return to usual activities ASAP.
- ☐ Delayed return to usual activities.
  specify days: _____

12. Other treatments
- ☐ Medications, specify: _____
_____
- ☐ Exercises, specify: _____
_____
- ☐ Mobilization/manipulation, specify _____
_____
- ☐ Other, specify: _____
_____

13. Referral to specialized advice, specify
_____
_____

F. REMARKS: _____
_____
_____

G. CLINICIAN IDENTIFICATION: _____

APPENDIX II
TREATMENT OF WHIPLASH-ASSOCIATED DISORDERS
SUMMARY OF ACCEPTED RANDOMIZED CONTROLLED TRIALS

Reference	Quebec Classification	Time Since MVC at Entry	Treatments	Analyzed (n)	Outcome Time	Outcome Measure	Outcome Results
McKinney[20]	I, II, (III?) Excluded cervical fracture, dislocation, previous degenerative disease, previous whiplash	≤ 72 hr after	a. Prescribed rest 10–14 days, analgesics, soft collar; advice to activate after 2 wk.	33	1 mo	Pain: VAS-10 (median) ROM: lateral flexion (mean degrees)	Median Pain Score 0 / 1 mo / 2 mo a. 5.80 / 4.97 / 3.00 b. 5.33 / 3.28* / 1.64* c. 5.3 / 3.37* / 1.82* Mean (SD) ROM 0 / 1 mo / 2 mo a. 44 (15) / 47 (19) / 55 (15) b. 48 (19) / 63 (20)* / 64 (13)* c. 47 (21) / 54 (20)* / 64 (13)* *Group b, c vs. a: $P < 0.01$.
			b. Physical therapy 3/wk × 6 wk: Maitland mobilization in combination with individually determined modalities, including heat/cold applications, traction, diathermy, hydrotherapy, analgesics, and soft collar PRN. Advice on home exercise, posture, minimize reliance on soft collars.	71	2 mo		
			c. Program of home exercises: instruction (verbal and written) re: relaxation methods, posture; advice to minimize reliance on analgesics and soft collar.	66			
McKinney[21]	"		a. " b. " c. "	28 51 48	2 yr	Self-reported symptoms	Number Asymptomatic (%) a. 14 (54) b. 30 (54) c. 37 (73)* *c vs. a, b: $P = 0.02$.
Mealy[22]	I, II, (III?) Excluded cervical fractures.	"Acute"	a. Ice first 24 hr, analgesics PRN, Maitland mobilization, heat, daily cervical exercises.	31	4 wk 8 wk	Pain: VAS-10 ROM: total mobility score	Pain Mean (SD) 0 / 4 wk / 8 wk a. 5.7 (2.4) / 2.9 (3.2)* / 1.7 (2.4)* b. 6.4 (2.3) / 5.1 (2.6)* / 3.8 (3.2)* ROM Score Mean (SD) 0 / 4 wk / 8 wk a. 18.8 (8.7) / 29.0 (11.4) / 34.1 (8.4)* b. 25 (11.8) / 27.6 (11.5) / 28.6 (8.8)* *Group a vs. b: $P < 0.05$.
			b. Analgesics PRN, soft collar, prescribed rest 2 wk, gradual activation afterward.	30			
Brodin[23]	Not applicable. Neck pain without signs of nerve root compression; with reduced ROM.	Symptoms duration 8–6 + yr (mechanism of injury not reported).	a. Analgesia 3 wk, wait for treatment.	23	3 wk 4 wk	Pain: VAS-10 ROM increase >30°	Pain n (%) Slight/ None / Moderate / Increased a. 5 (22)* / 13 (56) / 5 (22) b. 2 (12)* / 13 (77) / 2 (12) c. 11 (44)* / 11 (48) / 3 (4) 3 wk ROM increase >30° n (%) a. 7 (30) b. 6 (35) c. 16 (64)† *Group c vs. a, b: $P < 0.05$. †Group c vs. a, b: $P < 0.10$.
			b. Analgesia 3 wk; "mack" therapy 3/wk × 3 wk; superficial massage, slight traction, electrical stimulation; 3 hr education.	17			
			c. As b. above, plus Stoddard manual mobilization 3/wk × 3 wk.	23			
Cassidy[24]	Neck pain excludes neurologic signs, 31% MVC.	Pain duration <1 wk to 6 mo	a. Single manipulation	52	Baseline, Immed. post-treatment.	Pain NRS-101 ROM: flexion-extension rotation, lateral flexion	Pain Mean (SD) a / b Baseline 20 (22) / 21 (20) Immediate 20 (21) / 21 (21) Change 17 (20) / 19 (15) ROM No differences between groups.
			b. Single manual mobilization (Bourdillon; & Day)	48			

APPENDIX II (Continued)

Zylbergold[33]	Not applicable. Neck pain, mixed diagnoses. 13% neck strain. Age <70 yr. Included radicular pain. Excluded previous neck surgery, RA, osteoporosis.	Not reported	a. Static traction, neck care, moist heat, program of neck exercises 2/wk × 6 wk b. Intermittent traction, neck care, moist heat, program of neck exercises 2/wk × 6 wk. c. Manual traction, neck care, moist heat, program of neck exercises 2/wk × 6 wk. d. Neck care, moist heat, program of neck exercises (control) 2/wk × 6 wk.	25 26 26 25	Baseline (Pre) Discharge (Post)	Pain: McGill present intensity. ROM (°): F. Flexion, Ext, R. Rot, L. Rot, R. Flex., L. Flex.	Pain Change Mean (SD) All Traction −1.27 (0.97) Control −0.88 (1.17) ROM Change Mean (SD) All Traction / Control F. Flex. 12.6 (15.9) / 10.6 (16.1)* Ext. 8.6 (11.2) / 13.6 (13.2) R. Rot. 10.4 (17.2) / 10.0 (18.7)* L. Rot. 18.3 (17.1) / 16.9 (16.7) R. Flex. 12.2 (9.7) / 10.2 (10.8) L. Flex. 11.8 (12.5) / 11.8 (11.6) * $P \leq 0.05$.
Foley-Nolan[31]	I, II, (III?) Excluded impaired reflexes indicative of cervical root lesion.	<72 hr	a. 8hr/day × 12 wk soft collar whh active PEMT; NSAIDS PRN; advice to mobilize neck hourly; addition of physiotherapy at 4 wk at patient request. b. 8hr/day × 12 wk soft collars with Sham PEMT (control); other treatment as in a.	20 20	Baseline, 2 wk, 4 wk, 12 wk	Pain: VAS-10 ROM: Total mobility score (0–4 range). Analgesic intake.	Pain (median) Baseline / 2 wk / 4 wk / 12 wk a. 8.3 / 4.6* / 2.5* / 1.5 b. 8.3 / 8.0 / 5.8 / 2.7 ROM (median) Baseline / 2 wk / 4 wk / 12 wk a. 7.5* / 3.0 / 1.0 / 0.5* b. 8.7 / 5.5 / 3.3 / 1.0 Daily Number Analgesics (median) Baseline / 2 wk / 4 wk / 12 wk a. 1.0 / 1.5* / 1.5* / 0* b. 1.0 / 0.0 / 1.0 / 1.5 *Group a vs. b: $P < 0.05$.
Byrn[11]	I, II, (III?)	4–6 yr	a. Subcutaneous sterile water trigger point injections × 3 mo as required. b. Subcutaneous sterile saline trigger point injections × 3 mo as required (control).	20 20	Baseline, Immediate, 1 mo, 3 mo, 6 mo	Pain: VAS-10 ROM: Sum score	Pain (mean) a / b Baseline 4.0 / 3.0 Change Immediate 0.8* / 2.0* 1 mo 2.1 / 3.4 3 mo 3.1* / 4.6* 6 mo 3.4* / 4.7* ROM (mean) a / b Baseline 288 / 291 Change Immediate +54* / +23 1 mo +36* / +1 3 mo +39* / +6 6 mo +22* / −11 *Group a vs. b: $P < 0.05$.
Barnsley[2]	Painful cervical zygapophysial joint pain after whiplash injury.	> 3 mo	a. Single intra-articular injection 1.0 ml bupivacaine (0.5%) (control). b. Single intra-articular injection 1.0 ml betamethasone (5.7 mg) (corticosteroids). Both groups: usual analgesics and physiotherapy.	20 21	Baseline, 1, 4, 6, 8, 10, 20 wk Baseline 2, 12 wk	Primary outcome: analgesic time to return to 50% of baseline pain. Other outcome: VAS McGill	Median time to return to 50% of baseline pain a. 2.5 days (control) b. 3 days* (corticosteroid) *NS, $P = 0.42$.
Haag[12]	Not applicable. Chronic neck pain. Mechanism not reported.	Pain duration > 1 yr	a. Magnetic necklace 24 hr/day × 3 wk. b. Nonmagnetic necklace 24 hr/day × 3 wk (control).	27 25	Baseline 3 wk	Pain: Intensity (0–4) Frequency (0–4)	Pain Intensity Mean (SD) Baseline / 3 wk a. 2.1 (0.8) / 1.7 (0.7) b. 2.3 (0.8) / 2.0 (0.6) Pain Frequency Mean (SD) Baseline / 3 wk a. 2.9 (0.8) / 2.5 (0.6) b. 2.8 (0.6) / 2.5 (0.7)

MVC = motor vehicle collision. VAS = visual analog scale. ROM = range of motion. PRN = pro re nata. SD = standard deviation. RA = rheumatoid arthritis. PEMT = pulsed electromagnetic therapy. NSAIDS = nonsteroidal anti-inflammatory agents.

Appendix III: Specific Clinical Recommendations

After reviewing a total of nearly 300 articles addressing risk, diagnosis, treatment, and prognosis of WAD, the Task Force accepted 62 studies. Although accepted, these studies, because of methodologic limitations, constituted at best, weak evidence to support recommendations regarding appropriate diagnosis and treatment, and prognostic factors. In the absence of strong scientific evidence, the recommendations for clinical practice that follow have largely been developed by the Task Force based on their clinical judgment and practice. They must be viewed as provisional, until the recommended research is completed. The research recommendations should have a high priority because they are critical to the establishment of evidence-based treatment recommendations.

The recommendations regarding diagnosis and treatment are presented in tabular summary. They are grouped by type of diagnostic method or treatment modality. In the left-most columns, the accepted evidence is summarized. For each statement in the table, a more detailed description in the text of the section titled "Consensus Findings" is given. In the middle columns, the recommendations for clinical practice can be found. The last column presents the recommendations for research. Because the accepted studies provided so little evidence to guide clinical practice, we emphasize the importance of the recommendations for research regarding the specific diagnostic and treatment modalities considered.

The tabular presentation of recommendations regarding prognosis follows the same form as those for diagnosis and treatment. Because the accepted studies provided such weak evidence regarding prognostic factors, recommendations for clinical management are also largely practice-based and indicate what information should be recorded at each visit. It should be emphasized here that the expectations of recovery under optimum management are based on the review of pathophysiology of soft-tissue healing. These expectations reflect the consensus of the Task Force that the prognosis of WAD, as developed in the accepted studies, can be altered by optimum management.

DIAGNOSIS OF WHIPLASH-ASSOCIATED DISORDERS: SUMMARY OF EVIDENCE AND RECOMMENDATIONS

DIAGNOSIS	EVIDENCE	RECOMMENDATIONS FOR CLINICAL PRACTICE*	RESEARCH RECOMMENDATIONS
History taking	• Twenty studies dealing with aspects of the patient history in diagnosis of WAD were reviewed. No accepted study dealt with the value of history taking for the positive diagnosis of WAD. • These recommendations are based on the consensus of the Task Force.	History taking is important during all visits for the treatment of WAD patients of all grades. The history should include information about date of birth, gender, occupation, number of dependents, marital status; prior history of neck problems, including previous whiplash; symptoms including pain, stiffness, numbness, weakness, and associated extracervical symptoms; localization, time of onset, and profile of onset should be recorded for all symptoms; circumstances of injury (sport, motor vehicle . . .); mechanism of injury. This minimal history should be recorded on a standard form (see Appendix I).	Studies assessing the validity and reliability of the pertinent history for the positive diagnosis of WAD are needed. The impact of the minimal data collection form should be evaluated.
Physical examination	• Eighteen studies dealing with aspects of physical examination of WAD patients were reviewed. No accepted study dealt with the value of physical examination for the positive diagnosis of WAD. • These recommendations are based on the consensus of the Task Force.	A focused physical examination is necessary during all patient visits. The physical examination should include at least inspection; palpation for tender points; assessment of range of motion in flexion–extension, rotation, and lateral flexion; neurologic examination to assess sensorimotor function and tendon reflexes of upper and lower limbs; assessment of associated injuries; assessment of general medical condition, as needed. Results of the minimal physical examination should be recorded on a standard form (see Appendix I).	Studies assessing the validity and reliability of physical examination in the diagnosis of WAD are needed. The impact of the minimal data collection form should be evaluated.
Plain radiographs	• Sixty-one studies dealing with plain radiographs in WAD patients were reviewed. No accepted study dealt with the value of plain radiographs for the positive diagnosis of WAD. • Plain radiographs are not useful for the diagnosis of WAD I, II, and III. Radiographs are needed to diagnose bony lesions of WAD IV. There is a suggestion in the literature that WAD patients with Grade I WAD and no other injury, with no midline cervical pain, with normal alertness and attention, and who are not obtunded by narcotics, alcohol, or other drugs may not need radiographs. The small sample size of these studies and the resulting uncertainty around estimates of false negative and positive rates made it impossible to make recommendations about plain radiographs on the basis of scientific data. • Recommendations regarding plain radiographs in diagnosis of WAD are based on the consensus of the Task Force.	All patients in Grade II and III who present with WAD should have baseline radiologic examination of the cervical spine. This examination should include anteroposterior, lateral, and open-mouth views. All seven cervical vertebral and the C7–T1 disc space should be well visualized. In patients with Grade II or III WAD, flexion–extension views may occasionally be indicated. Grade I patients who are conscious, show no evidence of alcohol-related impairment, are not obtunded by narcotics or other drugs, and who show no physical signs on examination require no plain radiographs on presentation.	Studies to determine optimal use of plain radiographs in patients with minimal symptomatology and after a whiplash are needed. These studies should compare history, physical examination, plain radiographs, and comprehensive assessment of the cervical spine in a cohort of sufficient size and composition to estimate sensitivity, specificity, and predictive values with precision. Studies of plain radiographs in WAD should include assessments of cost, benefits and cost-effectiveness, including adverse side-effects of radiographic exposure.

Specialized imaging technique	• One study dealing with tomograms, 18 studies of CT scan, 6 of MRI, 1 study of myelography, 1 study of discography, 3 studies of scintigraphy, and no studies of angiography were reviewed. • No accepted studies dealt with CT scans in WAD patients; one study dealt with MRI, but did not provide any evidence that this technique might be useful for the diagnosis of WAD. • Specialized imaging techniques are not useful for the positive diagnosis of WAD I to III. • Specialized imaging techniques might be necessary, in some instances, to make the positive diagnosis of Grade IV. • Therefore, these recommendations are based on Task Force consensus.	There is no role for special imaging techniques (tomography, CT scan, MRI, myelography, discography, scintigraphy, angiography, . . .) in Grade I and II WAD patients. Special imaging techniques might be used in selected Grade III patients based on the advice of an accredited medical or surgical specialist.	Studies of the validity and reliability of special imaging techniques for the diagnosis of WAD patients are needed. Studies of cost benefits and cost-effectiveness of special imaging techniques in patients with WAD are needed. Research on specialized imaging techniques should prioritize evaluation of MRI to assess soft tissues.
Special examinations	• We examined one study dealing with evoked potentials (SSEP). No accepted study dealt with evoked potential in WAD. • We examined four studies of selective nerve root blocks and two studies of EMG. There were no accepted studies of these examinations in WAD patients. • We examined 5 studies of neurobehavioral tests, 5 studies of EEG, 1 study of ENG, 2 studies of other special audiology or visual examinations. There were no accepted studies of any of these special examinations in patients with WAD. • Therefore, all recommendations regarding these special examinations are based on the consensus of the Task Force.	Indications for evoked potentials (SSEP) in Grade III patients should be based on the advice of an accredited medical or surgical specialist. Indications for selective nerve root blocks and of EMG in Grade II and III WAD patients should be based on the advice of an accredited medical or surgical specialist. Indications for all other special examinations in WAD patients should be based on the advice of an accredited medical or surgical specialist.	There is a need for adequate studies of validity, reliability, cost benefit, and cost-effectiveness of special examinations for the diagnosis of associated lesions in WAD patients. Because of the small numbers of patients with indications for such specialized examination, it is foreseen that these studies might be difficult to implement.

* These recommendations are consensus-based.
CT = computed tomography. MRI = magnetic resonance imaging. EMG = electromyography.

TREATMENT OF WHIPLASH-ASSOCIATED DISORDERS: SUMMARY OF EVIDENCE AND RECOMMENDATIONS

TREATMENT	EVIDENCE	RECOMMENDATIONS FOR CLINICAL PRACTICE		RESEARCH RECOMMENDATION
		Evidence-based	Consensus-based	
IMMOBILIZATION Collars	• No research was found addressing independent benefit of collars in WAD. • Soft collars in combination with prescribed rest and analgesics are associated with delayed recovery (Pain and ROM) in WAD presenting within 4 days of injury. • Soft collars do not restrict ROM in normal subjects.	There is weak cumulative evidence to restrict their use to short periods of time.	Collars should not be prescribed for Grade I WAD. If prescribed for Grade II or III, they should be restricted to no more than 72 hr.	RCTs are needed to assess the short-term benefits (efficacy + effectiveness) of cervical collars in WAD.
Prescribed rest	• No research was found concerning independent benefit of prescribed rest in WAD. • Prescribed rest for 10–14 days in combination with soft collars and analgesia in WAD was associated with delayed recovery.	There is weak cumulative evidence to restrict prescribed rest to short periods of time.	Rest should not be prescribed for WAD I. Rest > 4 days should not be prescribed for WAD II and III.	RCTs are needed to assess the short- and long-term benefits (efficacy and effectiveness) of prescribed rest in WAD.
Cervical pillows	• No research was found addressing the therapeutic effects of cervical pillows in WAD.		Cervical pillows are not required.	No research is recommended.
ACTIVATION Manipulation	• No research was found addressing the short- or long-term benefits of a complete course of manipulative therapy on WAD. • The immediate effect on pain and ROM of a single manipulation is similar to that of a single mobilization in neck pain of varying durations. There is insufficient evidence assessing the independent contribution of this technique.		A short-term regimen of manipulation can be used for WAD. This technique should be restricted to qualified personnel.	RCTs are essential to assess the short- and long-term benefits of a regimen of manipulative therapy in WAD.
Mobilization	• No research was found concerning the independent effect of mobilization on WAD. • Manual mobilization combined with other physiotherapeutic interventions in WAD presenting within 4 days of injury and in neck pain syndromes of indeterminate duration, was shown to have short-term benefit; long-term results are no better than those for combined collar, rest, and analgesics.	There is weak cumulative evidence to support their combined use in WAD.	A regimen of mobilization can be used for WAD.	RCTs are essential to assess the short- and long-term benefits of a regimen of mobilization therapy in WAD.
Exercise	• No research was found regarding independent benefit of exercise in WAD. • Prescription of home exercise combined with activation advice, was found to have short- and long-term benefit for WAD presenting within 4 days of injury.	There is insufficient evidence assessing the independent contribution of exercise.	ROM exercises should be implemented immediately, in combination if necessary with intermittent rest when pain is severe. Clinical judgment is crucial if symptoms are aggravated.	RCTs are needed to assess the short- and long-term benefits of exercise in WAD.
Postural advice	• No research was found concerning the independent therapeutic effect of postural alignment in WAD. • Advice on posture, combined with advice on activation for WAD presenting within 4 days of injury, has short- and long-term benefit; combined with physiotherapy soft collar and analgesics there was only short-term benefit.		Postural advice can be given in combination with activation in WAD.	RCTs are needed to assess the short- and long-term benefits of postural advice in WAD.
Spray and stretch	• No research was found concerning the independent therapeutic effect of spray and stretch in WAD.		Spray and stretch is not recommended.	The benefit of spray and stretch for any grade and duration of WAD should be established in RCTs.

Traction	• No research was found addressing independent effects of traction in WAD. • Traction in combination with other physiotherapeutic interventions was found to be of short-term benefit in WAD presenting within 4 days of injury, and in neck pain syndromes of indeterminate duration; there was an long-term (2-yr) benefit for WAD presenting within 4 days of injury. In a small RCT, there were no statistically significant differences between static, intermittent, and manual traction in combination with other physiotherapeutic interventions in neck pain syndromes of indeterminate duration.	There is weak evidence that traction is of short-term benefit.	A regimen of traction can be used in combination with other mobilizing interventions in WAD.	RCTs are required to assess the independent and combined benefits of traction in WAD.
PASSIVE MODALITIES/ELECTROTHERAPIES Heat, ice, massage, TENS, PEMT, electrical stimulation, ultrasound, laser, short-wave diathermy	There were virtually no accepted studies addressing the benefit of these modalities. • Two small RCTs in WAD Grade I + II presenting < 72 hr; and in neck pain not related to WAD, > 8 wk duration, suggest a benefit from PEMT compared with sham PEMT in pain control when combined with NSAIDs, activating advice and soft collar. • All modalities except laser were possible adjuncts to mobilizing interventions, which had short-term benefit equivalent to activation advice. • There were no accepted studies in which the benefit of laser was addressed.		Grade I: Although active PEMT in a soft collar was better than sham PEMT in a soft collar, PEMT is not recommended because it involves wearing a soft collar 8 hr/day for 12 wk. Grades II and III: The other professionally administered passive modalities/electrotherapies are optional adjuncts during the first 3 weeks to activating interventions with emphasis on return as soon as possible to usual activity.	Direct immediate research efforts in Grade II < 3 wk. Evaluate efficacy/effectiveness of passive modalities in symptom (pain) relief and improvement of function. Research should evaluate their independent effects, and additive effects of combined interventions. If efficacy shown for Grade II, proceed to evaluate effectiveness and cost-effectiveness for Grade III < 3 wk. If efficacy shown for Grade II or III < 3 wk. may proceed to evaluate the above beyond 3 wk.
SURGICAL TREATMENT	• No studies were accepted concerning the benefit of disc surgery, nerve block, or rhizolysis for any grade or duration in WAD.		There are no indications for surgical intervention in WAD Grades I and II. Surgery is to be restricted to the rare WAD Grade III with persistent arm pain that does not respond to conservative management or with rapidly progressing neurologic deficit.	An RCT for efficacy of surgery for nerve root entrapment secondary to WAD Grade III desirable. Considering the low occurrence of the clinical indications for surgery in WAD Grade III, a multicenter RCT desirable.
INJECTIONS Steroid injections	One accepted study showed no benefit of intra-articular steroid injection in WAD > 3 mo. • No accepted studies were found concerning the benefit of epidural or intrathecal steroid injections in WAD. No research was found concerning trigger point steroid injections in WAD.		Intra-articular steroid injection can not be recommended for WAD. Epidural steroid injections should not be used for Grade I or II WAD. Occasionally, Grade III WAD with unresolved radicular pain of > 1 mo might benefit from epidural steroid injections. There is no indication for steroid trigger point injection in the "acute" phase (< 3 wk). Because harmful side effects of repeated steroid use have been reported, steroid trigger point injections should not be used unless their benefit in WAD is shown in valid RCTs. Intrathecal steroid injections carry such risk of serious morbidity that they should be avoided in all Grades of WAD.	
Sterile water injections	One accepted RCT on WAD Grade II patients with neck and shoulder pain 4–6 yr after injury suggested a sustained small benefit of subcutaneous sterile water injection.		Sterile water subcutaneous trigger point injections can be used for WAD II where trigger points are present as an optional adjunct to activating interventions with emphasis on return to usual activities.	RCTs are needed to confirm the efficacy and effectiveness of sterile water injections.

PHARMACOLOGY	• No research was found regarding the benefit of narcotic analgesics or psychopharmacologics in WAD. No studies were accepted regarding the benefit of muscle relaxants in WAD. • Analgesics or NSAIDs in combination with other treatment modalities were found to be of short-term benefit in WAD Grades I and II presenting within 3 days of injury (see activation, passive modalities).	No medications should be prescribed for WAD Grade I. Non-narcotic analgesics and NSAIDs can be used to alleviate pain for the short-term in WAD Grades II and III. Their use should not be continued for more than 3 wk, and should be weighed against possible side effects. Narcotic analgesics should not be prescribed for Grade I and II WAD. Occasionally they may be prescribed for pain relief in acute severe Grade III, but only for a limited period of time. Although commonly prescribed, muscle relaxants should not generally be used in the acute phase of WAD. The psychopharmacologic drugs are not recommended for use on a general basis in WAD of any duration or Grade, but they may be used occasionally for symptoms such as insomnia or tension, as an adjunct to activating interventions in the acute phase (< 3 mo duration). For chronic pain in WAD (> 3 mo duration), the minor tranquilizers and antidepressants may be used.	RCTs are needed to assess the efficacy and effectiveness of pharmacologic interventions in WAD.
MISCELLANEOUS INTERVENTIONS (formally prescribed) Prescribed function, neck school, work alteration and relaxation techniques, acupuncture.	One accepted RCT was found for chronic neck pain (daily neck pain with or without radiation ≥ 6 mo). The study suggested that acupuncture and NSAIDs or analgesics were not better than sham TENS with NSAIDs or analgesics for relief of pain. No research was found concerning the other treatments.	Grade I: Prescribed function, i.e., immediate return to usual activity, is recommended. Neck school, work alteration, and relaxation techniques are not indicated for Grade I. Grade II and III: Prescribed function, i.e., return to usual activity, is encouraged as soon as possible. Neck school, temporary work alteration, relaxation techniques, and acupuncture are optional adjuncts for symptom duration > 3 wk.	First, direct research efforts to Grade II and III. The studies should evaluate duration of symptoms, function, and recurrence. Evaluate efficacy of acupuncture in WAD Grade II and III ≥ 3 wk. Evaluate efficacy of work alteration in WAD Grade II and III ≥ 3 wk. Evaluate efficacy of neck school in WAD Grade II and III ≥ 3 wk.
OTHER INTERVENTIONS (not formally prescribed) Magnetic necklace, relaxation techniques, topicals, herbals and homeopathic remedies, over the counter medication, reflexology, and others.	An accepted RCT indicated that the magnetic necklace is no better than placebo for neck pain of duration greater than 1 year. No other research was found concerning the effectiveness of the magnetic necklace. No research was found concerning any of the other interventions.	There is no reason for a practitioner to prescribe any of these treatments. The practitioner should recommend against the magnetic necklace.	

PROGNOSIS OF WHIPLASH-ASSOCIATED DISORDERS: SUMMARY OF EVIDENCE AND RECOMMENDATIONS

INITIAL FINDINGS	EVIDENCE	RECOMMENDATIONS FOR CLINICAL PRACTICE*	RESEARCH RECOMMENDATIONS
Symptoms	• Three accepted studies provide information on symptoms that are useful for predicting recovery. These studies did not cover similar symptoms and outcome measures. • Similarly, only one accepted study provided useful information about signs of prognostic value. • Therefore, our recommendations are based on both evidence and the Task Force consensus.	• Data on symptoms and signs present at time of first visit should be recorded. These should include all symptoms and signs that are needed to classify patients into Grade I to IV (see table on diagnosis for a list of symptoms and signs). • These signs and symptoms should be recorded on a standard form (see form in Appendix I).	• There is a need for adequate studies of the prognostic value of symptoms, signs, radiologic findings, psychologic factors, and sociodemographic predictor in WAD patients. These studies should be based on exhaustive cohorts of patients, similar definitions of zero time predictors, outcome, and follow-up procedures. These studies should have a sample size sufficient to do subgroup analysis and modeling of interactions. These prognostic studies should examine both short- and long-term outcome of WAD.
Radiologic findings	• Although several accepted studies addressed radiologic findings, none of the results are definitive. • Our recommendations are based on both evidence and the Task Force consensus.	• Data on radiologic findings such as osteophytes and narrowing of the disc space should be recorded during the first visit.	
Sociodemographic factors	• Of the 11 studies accepted, 3 provided data on potential predictive factors. • Our recommendation is based on both evidence and the Task Force consensus.	• History taking should include basic sociodemographic information such as age, gender, number of dependent, marital status.	• Prognostic studies should result in the development of pain rating or disability rating tools specific to WAD. Validity and reliability of these tools should be assessed in adequate studies.

* These recommendations are consensus-based.

Chiropractic
Patient Management Guidelines

Recommended by the

Nevada Chiropractic Association

Contents

Introduction

These guidelines were developed specifically for the Nevada Chiropractic Association (NCA) utilizing the current state of peer reviewed research and clinical experience. They have been adopted as an official policy statement of NCA and its peer review committee to assist in the handling of patient management issues as of January 1, 1999.

These guidelines describe and reflect typical courses of patient management. They are not to be used as an inflexible protocol. It is expected that patients will require less or more care than average and practitioners will be allowed to provide supportive documentation to justify care if subject to review.

These guidelines are considered descriptive rather than prescriptive. Professional judgement is paramount in assessing patient need. The function of this document as a guide precludes its use for denial of care or to charge mismanagement of care.

These guidelines are intended to be advisory and informative, sharing clinical experience for the purpose of providing optimal care to chiropractic patients. It is expected that these guidelines will be reevaluated and modified as additional scientific and clinical information becomes available. The NCA understands that alternative practices may be desirable in the judgement of the practitioner to address the unique circumstances each patient presents. There is absolutely no requirement that Nevada Chiropractic Physicians adhere to these guidelines. It is not recommended that third party payers utilize these guidelines to evaluate care and services.

1. Disclaimer on Use of Extract

Disclaimer to be used when quoting an extract or part only of these proceedings:

"The following is an extract from the Nevada Chiropractic Association Patient Management Guidelines." The authors recommend against the use of extracts from this document because of the potential of reader misinterpretation which may occur when taken

out of context. It is recommended that you acquire a complete document."

2. Professional Title

In Nevada the professional titles in use for practitioners of Chiropractic include "Chiropractor", "Chiropractic Physician", and "Doctor of Chiropractic". To coordinate with the new name change of our board of examiners to the "Chiropractic Physicians Board of Nevada" we suggest the use of Chiropractic Physician. The NCA recognizes that post graduate chiropractic education leading to certification and/or diplomate designation is available. With the exception of the privilege to advertise a diplomate designation, no additional privileges are granted. Specifically, this applies to the fact that scope of practice privileges are identical for all Nevada Chiropractic Physicians.

3. Chiropractic case management versus manipulation

Chiropractic care is comprehensive management of a patient considering and, when necessary, advising modification. This includes but is not limited to lifestyle, exercise, diet, and nutritional supplements as well as precise chiropractic adjustment.

Comparisons of chiropractic case management to manipulation procedures performed by a non-chiropractor are not valid. Manipulation is defined elsewhere in this guide but a simple thrust to a bone is not a substitute for chiropractic.

Treatment Guidelines

1. Red Flags

- new patient treatment without documented initial examination
- frequent office visits treating different areas for same injury
- insufficient care for diagnosis
- treatment of new complaints without proper documentation

2. History

- Date and time of injury
- Mechanism of onset
- History of chief complaint (location, frequency, severity, duration)
- Review of symptoms
- Occupational history
- Past history/treatment

3. Examination

- Range of motion
- Palpatary findings
- Muscle strength
- Orthopedic findings
- Neurological findings
- Visual analog (pain chart).

4. Diagnostics

- regional A-P and lateral radiographs
- other x-rays necessary as indicated by history (ex. results of examination, pathology)
- after initial four to seven weeks, MRI, CT, etc. is considered if patient is nonresponsive, has signs of hard neurological deficit, or tests are otherwise indicated by history

5. Therapies

- indicated modalities in addition to chiropractic adjustment for the purpose of enhancing the adjustment

6. Complicating Factors

These may extend expected treatment times. Each patient is unique and these guidelines must be flexible enough to accommodate documented complicating factors.

- severity
- past episodes
- duration
- radicular symptoms
- age
- DJD
- organic disease
- delayed treatment
- deconditioning
- instability
- inappropriate previous treatment
- suboptimal patient compliance
- lifestyle factors
- nutritional factors

7. Referral Criteria

- referral to another chiropractic or medical provider should be made for a second opinion if a patient is not responsive to treatment after the first four weeks of care
- if the patient is not responding to conservative medical care, referral for chiropractic treatment should be considered
- immediate referral should be considered for signs of cauda equina syndrome, progressive neurological deficit, or concerns for other pathology.

8. Suggested length of therapy

Rehabilitation referenced in this chart relates to procedures performed in a chiropractic office setting. Supervised rehabilitation may be necessary in more complicated cases.

Body Part: Cervical, Thoracic, Lumbar Sprains/Strains (Acute)				
Diagnosis:	Mild	Moderate	Severe or Radiculopathy	*Physical Modalities*
Treatment Guidelines:	12 Weeks	16 Weeks	18 Weeks	Yes
Relief	3 tx/week 2 weeks	3 tx/week 4 weeks	3 - 5 tx/week 4 weeks	Yes
Therapeutic	3 tx/week 4 weeks	3 tx/week 6 weeks	2- 3 tx/week 8 weeks	Yes
Rehabilitative	1-3 tx/week 6 weeks	1-3 tx/week 6 weeks	1-3 tx/week 6 weeks	
Support Care	Episodic care for mild or moderate exacerbations, 2 - 6 visits per episode 1 - 2 tx/month for 6 months followed by reevaluation Severe aggravations/exacerbations or new injuries may require acute care per Chiropractic Treatment Guidelines			

In addition to these primary guidelines, the Nevada Chiropractic Association has adopted the CCP guidelines as a secondary source.

Modalities of Treatment

1. Duration of care

Duration of care is to be marked from the time management of patient care is initiated, not from the time and date of injury. Duration is affected by patient compliance, delays in seeking care, and complicating factors. See the *Chiropractic Treatment Guidelines* for recommended durations in typical cases.

2. Treatment modification

Suboptimal or poor response to a specific treatment wherein positive functional results are not produced should prompt the practitioner to modify or discontinue that treatment. Reevaluation of the diagnosis should be considered along with the possibility of a referral for a second opinion by an appropriately qualified doctor.

3. Chiropractic adjustment

This is the primary therapeutic in-office intervention to address pain. As pain decreases, consistent care in addition to pain relief is provided to guide healing, rehabilitate, and return to pre-injury status or maximum chiropractic improvement. A variety of modalities and procedures per area are allowed with each chiropractic adjustment provided that enhanced patient response is expected.

The NCA recognizes that chiropractic care is efficacious for a variety of unwanted health conditions. We promote referral from non chiropractic practitioners for chiropractic adjustment when indicated and appropriate and when patients are unresponsive to their care. Lack of proper referral to a chiropractic physician may increase necessary duration of care due to lack of timeliness in initiating effective management by a chiropractic physician. In cases like this it is advisable for the chiropractic physician to duly note this fact.

4. Modalities

Modalities are accepted treatment procedures utilized to enhance the chiropractic adjustment and are acceptable for use at any time during management of care. Passive modalities include electrical stimulation, ultrasound, diathermy, hot packs, cold packs, heat, and light. They are most successful and efficacious as an adjunct to chiropractic adjustment, exercise, and patient education. It is appropriate and advisable to use the same therapy, such as electrical stimulation or ultrasound, on multiple areas during the same office call to increase the rate of patient response and decrease the need for additional office visits when attending to multiple injuries. For example, if a patient has multiple injuries from a single event such as to the cervical spine, a shoulder, and a knee, all of which can be reasonably expected to respond favorably to electric stimulation, it is advisable to treat all three areas on the same office visit rather than to schedule separate additional office visits for each area performing only one unit of therapy on each visit.

Modalities are performed three to five times per week in conjunction with the chiropractic adjustment.

5. Lifestyle modificotion and nutritional recommendations

It is considered proper and appropriate for chiropractic physicians managing care for unwanted health conditions to prescribe dietary changes and nutritional support. Management of non musculoskeletal conditions require the practitioner to consider the unique factors presented on an individual basis. No protocol exists which meticulously defines numbers of visits or amounts of nutritional supplements as guidelines.

6. Traction

Traction is an accepted therapy and is available in a variety of forms such as intermittent, intersegmental, manual, overhead cervical, and cervical extension.

7. Exercise

Therapeutic exercise is directed toward achieving strength, endurance, flexibility, and the reeducation of proper movement patterns. This includes improved or reestoblished proprioception, coordination, balance, and posture. It is advisable to individualize

recommended exercises to address functional deficits in accordance with unique patient needs.

8. Patient Education

It is advisable to educate chiropractic patients and orient them to the uniqueness of chiropractic methodology and care. Patient education is directed towards involving the patient as an active participant for a successful outcome.

9. Spinal Bracing

Orthopedic supports are acceptable in treatment of all spinal and joint disorders as indicated.

10. Supportive Care

Patients who have reached maximal improvement evidenced by plateaued response may still be candidates who experience residuals and instability. Management is recommended to retain the level of function attained, pre-empt or reduce frequency, duration and severity of exacerbations, and prevent regression of the patient's condition.

Patients not returning to pre-injury status should be scheduled for periodic supportive care if complete withdrawal is expected to result in degradation in the patient's condition.

11. Re-injury, aggravation, or acute exacerbation

Refer to the Guidelines. Documentation with new examination is recommended prior to treatment.

Appendix A - Definitions

Definitions from the Nevada Revised Statutes indicate the chapter and paragraph numbers in the statutes and are quoted directly.

Chiropractic defined (NRS 634.013).

Chiropractic is defined to be the science, art and practice of palpating and adjusting the articulations of the human body by hand, the use of physiotherapy, hygienic, nutritive and sanitary measures and all methods of diagnosis.

Derived from the Greek terms praktikos meaning "done by" and chiras meaning "hand", chiropractic is a branch of the healing arts that is concerned with human health. Doctors of chiropractic consider man as an integrated being, and give special attention to spinal mechanics, musculoskeletal, neurological, vascular, nutritional, and environmental relationships.

Subluxation complex defined (NRS 634.0175).

Subluxation complex means a biomechanical skeletal misalignment or dysfunction in a part of the body which results in aberrant nerve transmission and expression.

Subluxation is an alteration of the normal dynamics, anatomical or physiological relationships of contiguous articulations. This definition is different thon the traditional medical definition that defines subluxation as partial dislocation.

A subluxation complex is a complex phenomenon that has or may have biomechonical. pathophysiological, clinical, radiologic and other manifestations. Subluxation complexes are of clinical significance as they are affected by or evoke abnormal physiological responses in the neuromusculoskeletal structures and/or other body systems. Sprains and strains are only components of the overall subluxation complex.

Sprain

A joint injury in which some of the fibers of the supporting ligament are ruptured, but the continuity of the ligament remains intact. Due to poor blood supply, sprain injuries generally heal slower the strain injuries.

Strain

An overstretching or overexertion of some part of the musculature. Due to a rich blood supply, muscles generally heal quicker than ligaments.

Exacerbation

(relates to a previous quiescent unwanted health condition) A flare up or increase in symptoms of the original complaint associated with activities of daily living or normal work demands

Aggravation

(Relates to a new injury) A preexisting condition that has been worsened by a new injury.

Chiropractic adjustment defined (NRS 634.014).

Chiropractic adjustment means the application of a precisely controlled force applied by hand or mechonical device to a specific focal point of the anatomy for the sole purpose of creating a specific angular movement in skeletal articulations to eliminate or decrease interference with neural transmission and correct or attempt to correct subluxation complex.

Manipulation

Unskilled imitation by non chiropractors of the chiropractic adjustment. Manipulation of bony articulations and/or soft tissue is performed in a manner less specific than a deliberate chiropractic adjustment.

Modalities

Any physical agent applied to produce therapeutic changes in biologic tissue including but not limited to thermal, acoustic, light, mechanical, or electrical energy.

Therapeutic Procedure

A manner of effecting changes through the application of clinical skills, procedures and/or services that attempt to improve function. Therapeutic procedures include but are not limited to, education, massage, manual traction, myofascial release, chiropractic adjustment, and joint mobilization.

Passive care

Application of treatment/care modalities by the caregiver to a patient who "passively" receives care.

Active care

Modes of treatment/care requiring "active" involvement, participation and responsibility on the part of the patient.

Continued care post maximum improvement

This is an active treatment to subluxation complex which seeks to prevent unwanted health conditions, enhance quality of life, and promote health.

Supportive care

The necessary patient management directed toward a condition with instability.

Positive Potient Response

Defined primarily as functional and/or physiologic gains which can be objectively measured. Objective functional gains include, but are not limited to, positional tolerances, strength, endurance, range of motion, decreased muscle tension, and efficiency/velocity measures which can be quantified. Subjective reports of pain and function should be considered and given relative weight when the pain has anatomic and physiologic correlation. Anatomic correlation must be based on objective standardized findings. Outcome assessment forms and pain drawings are considered valid diagnostic procedures to objectively quantify potient pain to manitor potient progress.

NRS 634.019 Legislative declaration.

The practice of chiropractic is hereby declared to be a learned profession, affecting public safety and welfare and charged with the public interest, and therefore subject to protection and regulation by the state. (Added to NRS by 1997, 818)

NRS 634.140 Grounds for initiating disciplinary action.

The grounds for initiating disciplinary action pursuant to this chapter are:

a) Unprofessional conduct.

b) Conviction of:
   (i) A violation of any federal or state law regulating the possession, distribution or use of any controlled substance or any dangerous drug as defined in chapter 454 of NRS;
   (ii) A felony;
   (iii) A violation of any of the provisions of NRS 616D.200, 616D.220, 616D.240 or 616D.300 to 616D.440, inclusive; or
   (iv) Any offense involving moral turpitude.

c) Suspension or revocation of the license to practice chiropractic by any other jurisdiction.

d) Gross or repeated malpractice.

e) Referring, in violation of NRS 4398.425, a patient to a health facility, medical laboratory or commercial establishment in which the licensee has a financial interest.

NRS 634.220 Construction of chapter.

Nothing in this chapter shall be construed to permit a chiropractor to practice medicine, osteopathic medicine, dentistry, optometry or podiatry, or to administer or prescribe drugs.

NRS 634.225 Chiropractor prohibited from piercing or severing body tissue; exception. A chiropractor shall not pierce or sever any body tissue, except to draw blood for diagnostic purposes.