CHAPTER 13

Outcome Assessment

Chapter Outline

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I. OVERVIEW

Health care should be characterized by quality, effectiveness, and cost efficiency Health care should also be based on the fundamental values and wishes of the patient, provided those wishes do not conflict with basic legal, ethical or professional obligations and standards of the provider. The future focus of health care services will be on normalizing biologic function and postponing the inevitable physical decline of the patient, maximizing the body's inherent recuperative and regenerative powers.

To ensure effectiveness and efficiency, multilevel outcome assessments of health care services are being regularly be instituted. Patients, practitioners, payers, state boards, health care institutions, government agencies, etc. are increasingly involved in gathering and evaluating assessment data, as well as recommending and implementing changes in health care delivery based on those and related findings. Outcomes management has evolved into a technology of patient experience designed to provide all interested parties with better insight into the consequences of health care choices on a patient's life.

Chiropractic emerged over one hundred years ago as a vitalistic and natural approach to health care. Throughout much chiropractic's history, doctors of chiropractic based their approach almost exclusively on rationalism and uncontrolled empiricism. As evidenced by the recent explosion in the number of controlled studies and publications, the chiropractic profession has recognized the need and importance of outcomes assessments to enhance the quality and effectiveness of chiropractic care as well as to evolve chiropractic standards of care.

The objective of chiropractic care is the detection, analysis, control, reduction and correction of the vertebral subluxation complex. The vertebral subluxation not only compromises the function of the spine but also interferes with the function of the nervous system and all related systems. Correction of vertebral subluxations contributes to health by restoring spinal function and eliminating interference to body physiology. Through vertebral subluxation correction, the body, therefore, has greater adaptive ability.

The intent of this chapter is to present those outcome measures which serve to assess the patient-chiropractor health care process. The patient-chiropractor relationship represents one segment of the entire framework of chiropractic outcomes assessment.

Outcomes assessment is a data-driven process which quantifies the quality and effectiveness of fulfilling the objective of the Chiropractor's practice. Those objectives include measuring the quantifiable changes resulting from vertebral subluxation and other malpositioned articulations and structures reduction. Outcome objectives also include data on the implications of vertebral subluxation and other malpositioned articulations and structures reduction on patient health status, i.e., change in regimen.

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 optimally comprehending 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 and physiological sciences. Discussion of all possible outcome assessments is beyond the scope of this chapter. General health assessment measures are very important and will 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 clinical and laboratory tests and the analytical findings themselves 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 analyzing a patient’s condition and those used for assessing the outcome of care. The purpose of a chiropractic diagnosis is to categorize a patient’s condition so that the doctor can formulate an appropriate chiropractic care plan. Different findings usually imply different programs of care. In contrast, the purpose of an outcome assessment is to measure a change in patient status as a result of care.

The same outcome assessment may be used to measure the effect of different care approaches for any number of findings (for example, a general health questionnaire). Also, a clinical impression or description may not change even though the health status of the patient may improve under care. On the other hand, if the goal of care is to eliminate the identified disorder (i.e., "cure" the patient), then the appropriate analytical 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 details with evaluative 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 improvement
- **$** Uncover problems related to care such as noncompliance
- **$** Document improvement to the patient, doctor, and third parties
- **$** Suggest modifications of the goals of care if necessary
- **$** 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 care 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. 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 Assessment

- **$** Vertebral Position Assessed Radiographically
- **$** Abnormal Segmental Motion/Lack of Joint End-play
- **$** Abnormal Segmental Motion Assessed Radiography
- **$** Soft Tissue Compliance and Tenderness
- **$** Asymmetric or Hypertonic Muscle Contraction
- **$** Pain, facet syndrome, trigger points, etc.

III. LITERATURE REVIEW

Studies of patients seeking chiropractic care suggest that painful conditions of the spine and extremities are the leading symptoms presented (Nyiendo, 1989, Phillips, in press). However, chiropractic adjustive care have been shown to have value for patients with a variety of ailments. Spinal adjustment results 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 care 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.

The peer-reviewed literature in recent years has attracted papers dealing with case reports, theoretical models, and controlled studies related to non-musculoskeletal disorders.

Gillman and Bergstrand published a case report involving an elderly male with traumatic vision loss. Optometric and ophthalmologic examination revealed that no conventional treatment was appropriate. The lost vision returned following chiropractic care. The authors stated, Behaviorial optometrists have often been interested in the work of chiropractors and the resulting vision changes. Schutte, Tesse and Jamison did a retrospective review of 12 children with ecophoria, and concluded that such patients may respond to cervical spine adjustments.

Changjiang et al reported on 114 cases of patients with cervical spondylosis who had an associated visual disorders. Visual improvement was not noted following manipulative treatment in 83% of these cases. Furthermore, of the 54 cases followed up for a minimum of six months, 95% showed a stable therapeutic effect. Cases of blind eyes regaining vision were included in the report. Gorman published a case report where a 62 year old male with a 1 week history of monocular visual defect experienced dramatic visual improvement after a week of spinal manipulation Gorman stated, Spinal manipulation can affect the function of the optic nerve in some patients presumably by increasing vascular perfusion.

Pikalov and Kharin compared the results of spinal manipulative therapy with traditional medical care in patients with endoscopically confirmed ulcer disease. Both groups received the same dietary regimen. Weekly endoscopic exams were performed. The group receiving spine care experienced pain relief earlier than the medical group. Clinical remission was observed an average of 10 days earlier in the SMT group than the medical group.

Kokjohn et al studied the effect of spinal manipulationon pain and prostoglandin levels in women with primary dysmenorrhea. 45 subjects were included in the study. 24 were assigned to the experimental group, and 21 to the control group. The controls received a sham manipulation. The authors found that immediately after treatment, the perception of pain and the level of menstrual distress were significantly reduced. It was suggested that further studies be performed over a longer time frame.

A prospective, uncontrolled study of 316 infants with infantile colic showed a satisfactory result in 94% of cases receiving chiropractic care. The results occurred within 2 weeks. Other authors have offered case reports of results obtained in patients with colic.

In 1997 landmark research was published validating the role of the chiropractic adjustment in the care of children with otitis media. This historic study of chiropractic adjustive care on children with this condition employed tympanography as an objectifying measure and studied 332 subjects. The results of this study indicate a strong correlation between the chiropractic adjustment and the resolution of this very common condition (Fallon, 1997).

There is evidence that adjustment stimulates certain metabolic activity within some types of white blood cells (Brennan, 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 post-treatment blood pressure for subjects adjusted in the thoracic spine employing an Activator adjusting instrument (Yates, 1988).}

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 care 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.

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. 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 care methods.

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.

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 care 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 intervention 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 patho-physiology 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 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 care by spinal adjustment or 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 dysfunctions. 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 care.

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 Oswesyry 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. Pain upon palpation and motion tests directed by the doctor of chiropractic are important indicators of joint malfunction and malposition. Such tests are unique to chiropractic practice and are used not only to determine the articular misalignment but to determine techniques and need for adjustive procedures. In the assessment of a chiropractic case these assume an important analytical role. Low-back and neck pain probably represent about two thirds of all chiropractic patient concerns (Nyiendo 1989).

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 10cm 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. Plain 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 care on a five point scale of signs and symptoms judged by the doctor. Glover et al. (1974) used a scale of pain relief from 1-100%. 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 affect 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 care, 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 doctor's clinical finding. 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 may include 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 dysfunction that can be effectively addressed by a variety of manual and rehabilitative procedures. Commonly, these include chiropractic adjustments. 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 (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 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 measure 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 Meal (1986) used neck pain and cervical mobility. Howe (1983) assessed measures of cervical mobility and improvement in pain and stiffness. Lopex (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.

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 pectoralis 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.

Instrumental 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 handheld 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.

Two studies indicate that adjustments/manual procedures may increase cervical lordosis (measured radiographically) (Leach, 1983; Owens, 1990).

Subluxation Assessment: The "vertebral subluxation" has been referred to as an event in which a vertebra has moved outside of its normal juxtaposition with the vertebra above or below. The normal architecture of the intervertebral foramina, which are formed by two interlocking arches above and below, is altered by this aberrant position and could cause impingement on the spinal nerve. If impingement occurred, this would interfere with the conduction of impulses innately generated within the brain and subsequently passing through neural tissue with the result that tissues supplied by the affected nerves could suffer some form of functional insult.

The term chiropractic was named by a minister, Dr. Samuel Weed and means "done by hand." Interpretations of this definition vary with the state laws governing chiropractic and correlates with the chiropractic scope of practice and school of thought. The chiropractic paradigm statement referenced in the Forward represents the clearest, most concise consensus statement regarding chiropractic's self-definition and has relevance in the discussion of every aspect of the guidelines process including outcomes assessment.

The effects and importance of the vertebral subluxation can be divided into three major categories:

A. Immediate local effects which may include irritation, inflammation, and degeneration at the vertebral level.

B. Mechanical effects which include aberrations in motion, posture and overall mechanical function of the spine.

C. Physiologic effects which especially include disturbances in the nervous and circulatory systems.

As a result of the numerous structural and functional studies, these general effects of the vertebral subluxation have been focused into five categories:

1. Spinal Kinesiopathology which generally refers to the abnormal position and motion of the vertebra involved in the subluxation.

   Outcomes assessment parameters would include palpation analyses, X-ray analyses, computed tomography and MRI imaging, postural aberrations, goniometric assessment, videofluroscopic analyses, range of motion assessment, leg length check analyses.

2. Neuropathophysiology refers to abnormal nervous system function which is the most significant component of the vertebral subluxation.

   Assessment criteria would include somatic pain, paresthesia, hyperesthesia, hypesthesia through case history and questionnaire determination, somatic motor assessment through muscle analyses and complete neurologic assessment of the neuraxis as well as complete afferent and efferent assessment. In addition, MRI and CT Scans provide evidence of nerve structural damage which correlates with the neuropathophysiologic component. Visceromotor determinations via heat sensitive devices, thermography and thermometry. Additional research and quality assurance studies are needed in this area. Further research on the piezoelectric and pyroelectric effects of bone and corresponding effects on nerve function also need further study.

3. Myopathology refers to the abnormal changes in muscle function due to the vertebral subluxation.

   Outcomes assessment criteria include, palpation, dynamometer testing, surface EMG (electro-myograph) determinations, neuropressure algometry and pain sensitivity, range of motion determination, paraspinal tissue compliance, gain symmetry, Cybex testing.

4. Histopathology represents the abnormal changes to soft tissues involved in the vertebral subluxation.

   Assessment protocols primarily include the determination of disc and ligament-integrity by means of X-ray and other imaging methods.

5. Pathophysiology refers to the generalized abnormal changes generated in the spine and body as a consequence of the vertebral subluxation.

   Spinal pathophysiology is assessed primarily through radiographic, and other imaging determinations of bone degeneration. Pathophysiology peripheral to the spine remains the subject of scientific investigation. Continued research into the involvement of the nervous system in modulating immune function will represent significant outcome measure in the future.

Succinctly, the foundation of chiropractic rests on the premise that structural distortion causes interference to normal nerve transmission and results in the symptoms and tissue changes of disease. The basic chiropractic analysis consists of manual palpation of the bony elements of the spine, manual assessment of the motion of the spine and individual vertebra, and palpation of the numerous muscles which attach and control spine and vertebral motion. Additional analytic tools for the field chiropractor would include X-ray, devices to assess spinal and vertebral motion and posture, as well as instruments used to assess muscle function and skin temperature. Additional research will generate techniques and devices which can effectively assess physiologic dysfunction resulting from the vertebral subluxation.

Assessment of vertebral subluxations from this analysis, necessitates a choice of adjusting

techniques by the chiropractor to safely and effectively eliminate the vertebral subluxation. A discussion of the various chiropractic adjusting techniques and their effectiveness is outside the scope of this document. However, outcomes assessment for the chiropractor will depend on the specific analysis used to determine the presence of the vertebral subluxation as well as the exact adjustment methodology utilized in correcting the subluxation.

Exactness in chiropractic analysis, vertebral subluxation determination, and chiropractic adjustment protocol are essential components to practitioner based outcomes assessment. Schafer (1984) has noted that "it is this exactness of differentiation and specificity of correction that has been stressed by the chiropractic profession and has distinguished it from other health sciences that also use manipulation, mechanical therapy, physical therapy, or similar procedures."

The most exact criteria, indicative of vertebral subluxations, utilized by the field chiropractor focus on structural alterations in the spine. Therefore, the most measurable and exact data for outcomes assessment of chiropractic adjustments stems from structural criteria. However, such structural or mechanical faults are not the major criteria constituting the vertebral subluxation. Aberrant physiology, most notably neurophysiology, signifies a critical negative effect of the vertebral subluxation on homeostasis. This altered physiology for which there is no underlying structural pathology has been termed by Whatmore and Kohi (1974) physiopathology.

Functional disorders and functional illness have their origin in such physiopathology "Signal transmission in a complex system of neurons and endocrine fluids and signaling factors within this physiologic system are considered basic factors in the etiology of functional disorders." Fries and Crapo (1981) emphasize that the similarity among chronic diseases is that they all represent gradual long term breakdown of the body's physiologic functions; a process that begins imperceptibly, long before the first symptoms arise. Outcomes of chiropractic care based on data collected from functional analyses represent less exact means of assessment for the field chiropractor.

Improved function, elimination of functional disorders, quality of life, etc., represent outcomes of chiropractic care best assessed by process external to the chiropractic care best assessed by process external to the chiropractor-patient relationship, e.g. government agencies, insurance companies, hospital studies, etc. An extensive collection of scientific studies supporting the functional disorders resulting from the vertebral subluxation have been reviewed elsewhere.

Least exact methods of outcome assessment of the chiropractor-patient relationship stem from pain and symptom determinations. Pain and symptoms are not necessary correlates to the vertebral subluxation. However, elimination of the vertebral subluxation and the improved spinal and general physiologic function that results, can generally reduce and eliminate patient pain and symptoms. Although pain and symptom relief represent the major patient rationale for seeking chiropractic care, an outcome objective of the chiropractor is patient compliance with a cooperative chiropractic health care program which is not necessarily pain and symptom related. Patient based assessment of chiropractic care utilizes questionnaires, satisfaction, pain ratings such as the Oswestry Pain Questionnaire, Dallas and McGill Questionnaires, visual-analog scales, and general health and performance status assessments by the COOP and SF-36 systems and traditional methods of measuring physical and physiological function.

A philosophical premise within chiropractic is the vitalistic principle which recognizes that an "innate intelligence" actively organizes and maintains all living things. Vitalism permeated ancient medical writings and was apparent in the works of Hippocrates who believed that a "vital spirit" was responsible for "life" and the "natural self-healing tendency of the body." The vitalistic principle was essentially replaced in the Twentieth Century by a chemical-mechanistic concept of life in which living things were viewed as machines whose capabilities were constrained to those functions permitted by this model. Vitalistic attributes such as autonomy and self-healing do not exist in this model. Becker (1990) believes that this paradigm has ruled the allopathic model, "limiting both the methods that could be used to bring about a cure and our perceptions of the ability of the human body to heal itself." The

mechanistic paradigm has failed in many ways to prevent disease as well as to cure patients. Dissatisfaction with the mechanistic concept has resulted in a vitalistic resurgence emphasizing proper nutrition, exercises, meditation as well as a "reaffirmation of the innate healing ability of living things."

The chiropractic profession has recognized the importance of a proper functioning spine to insure homeostasis within the nervous system, since it is through the nervous system that the innate self-healing capacity can be expressed. Proper function, rather than simply symptomatic relief, is the paradigm objective of the chiropractic standard of care. Questionnaires and surveys of patient function and quality of life, similar to SF-36 and COOP charts, represent the best means, currently available, for outcome assessment of the vitalistic component of chiropractic care. Both the COOP charts and the SF-36 address health concepts such as functional status, overall health and well-being, and quality of life. Health attributes relating to function include: physical, emotional, role and social functioning. Pain, overall physical and mental health, health changes, vitality and energy, etc., make up the overall health and well-being component. Quality of life perceptions, social support and health changes provide measures for a quality of life assessment. These documents can be tailored to individual practices but should have a standardized component for external agency data assessment and evaluation.

IV. RECOMMENDATIONS

A. Functional Outcome Assessments (By Questionnaire)

As a category, functional outcome assessments of everyday tasks are very suitable for evaluating care of dysfunctions of the spine, spinal nerves and related structures and tissues. Many questionnaires could be used; choice should depend upon the validity, reliability, responsiveness, and practicality demonstrated in the scientific literature.

13.1.1 **Rating**: Established
Evidence: Class I, II, III

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.

13.2.1 **Rating**: Established
Evidence: Class I, II, III

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.

13.2.2 **Rating**: Established
Evidence: Class I, II, III

C. Vitalistic Assessment

General Health/Quality of Life Assessment: Due to a lack of measures capable of assessing innate self-healing capacities, surveys and questionnaires, such as the SF-36 and

COOP charts, which do not focus on pain and symptomatology, may be used as acceptable, safe and valid measures of outcome of chiropractic care.

13.3.1 **Rating**: Strong Positive Recommendation
Evidence: Class: E, L

D. Patient Compliance Assessment

Chiropractic Health Care Assessment: Practitioner based assessment forms and surveys should be utilized which measure patient compliance with chiropractic designed programs for Level III care and which measure patient growth in understanding of the components of health and chiropractic.

13.4.1 **Rating**: Strong Positive Recommendation
Evidence: Class: E, L

E. 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.

13.5.1 **Rating**: Established
Evidence: Class I, II, III

F. 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.

13.6.1. **Rating**: Established
Evidence: Class I, II, III

Thermography: Thermographic exams of the trunk and extremities with infrared or liquid crystal may be valid as a chiropractic assessment tool. The procedures are generally safe. Thermograms should be interpreted by those trained in the procedure.

13.6.2 **Rating**: Established
Evidence: Class III

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.

13.6.3 **Rating**: Established
Evidence: Class I, II, III

Postural Evaluations: Certain postural parameters may be responsive to care, but validity, reliability and relevance issues still need to be addressed scientifically. Depending on the method, postural observations are practical and safe.

13.6.4 **Rating**: Established
Evidence: Class II, III

G. Subluxation Assessment

The subluxation assessment provides decision-making information for application of chiropractic care methods, primarily adjustments. 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 are of importance chiropractically. Responsiveness of vertebral position to adjustive care has been established in many cases. Observational studies have not ruled it out. Many practitioners accept measurement of vertebral position as routine and customary. This risk/benefit ratio of using radiographs for measuring vertebral position as an outcome assessment should be carefully considered.

13.7.1 **Rating**: Established
Evidence: Class II, III

Abnormal Segmental Motion/Lack of Joint End-play Assessed by Palpation: There are a few validity studies of joint palpation. There are studies suggesting that palpatory signs diminish with care, but the degree of responsiveness has been difficult to quantify. In skilled hands, palpation is safe and yields valuable information to the doctor of chiropractic.

13.7.2 **Rating**: Established
Evidence: Class II, III

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 care. Algometers, tissue compliance meters, and palpatory methods are practical and safe.

13.7.4 **Rating**: Established
Evidence: Class II, III

Asymmetric or Hypertonic Muscle Contraction: There is no question that surface EMG procedures measure some aspects of muscle activity. Surface methods are safe.

13.7.5 **Rating**: Established
Evidence: Class II, III

H. Principles of Application

Outcome assessments should only be performed and interpreted by appropriately trained and qualified individuals.

13.8.1 **Rating**: Necessary
Evidence: Class II, III

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.

13.8.2 **Rating**: Necessary
Evidence: Class II, III

Patient outcomes should be assessed at appropriate intervals during case management depending upon the nature of the condition and the patient's progress.

13.8.3 **Rating**: Discretionary
Evidence: Class II, III

Generic functional and health status outcome measurements are helpful for comparing outcomes across different patient populations and methods of care intervention. 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.

13.8.4 **Rating**: Recommended
Evidence: Class II, III

V. COMMENTS

Many of the rated measures used to assess the outcome of chiropractic patient care concentrate on the structural components of the vertebral subluxation and other malpositioned articulations and structures. However, chiropractors recognize the vital importance of a properly functioning spine and nervous system to promote the expression of an individual's self-healing capabilities.

Scientific literature has illuminated the significant relationship between spinal function and neurophysiology. Nerve interference impacts on total body function. The next century promises to provide valid and reliable measures for chiropractors to assess aberrations in nerve function resulting from the vertebral subluxation and other malpositioned articulations and structures. Vitalistic forces, which are best expressed through a nervous system free of interference, represent the most exciting future possibilities for outcome assessment.

The continued validation and evaluation of the efficacy of these techniques should be endorsed by the profession in order to provide the best possible methodologies for patient care.

Multilevel outcomes assessment methods will be necessary to insure quality control and effectiveness in future health care delivery systems, especially chiropractic care.

The significant values derived from any outcomes assessment lie within the processes for data evaluation and implementation of appropriate changes. An ever evolving increase in the quality, effectiveness, and cost efficiency of Chiropractic care must be realized from the outcomes assessment process.

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