What Constitutes Evidence for Best Practice?

John J. Triano, DC, PhD

Quality health care delivery enhances satisfaction and value for patients, caregivers and society.

Health care costs have begun to increase again. During the 1990’s, savings came primarily from reduction of reimbursements with some administrative efficiencies. In fact, the additional administrative oversight has continued to grow, increasing overhead costs for doctors and reduced the face-to-face time the can spend with patients and read the literature. The cost of additional bureaucracy now is a factor.

This has slowed the advancement of new knowledge through research, and increased distrust between patient and provider. It has fostered suspicion among all members of the health care infrastructure and a loss of faith in the idea of a durable and adequate social safety net for patients. Undertreatment, especially in the management of pain, is a serious problem. Some suggest that there is evidence of increasing chronicity and expense associated with under-treatment.

Prevalence of Back Pain

The American Pain Society and the World Health Organization have called attention to both under-treatment of pain and acceptable standards of care.

In 43% of households in the United States at least one member experiences chronic pain.

Of American patients with low back pain, 84% have medical insurance:
• 42% indemnity
• 20% Medicare and supplemental
• 6% Medicare only
Skeletal pain accounts for 48% of chronic pain conditions. This study reported the following prevalence of musculoskeletal pain:

- Back pain 35%
- Low back pain 23%
- Disc 9%
- Upper/mid back 4%
- Knee 5%
- Neck 4%
- Shoulder/arm 3%
- Ankle/foot 2%
- Joints 2%
- Bones 2%
- Hip 2%
- Chronic bursitis 1%

Those with LBP are less likely to be under care than other disorders³.
- 40% of interviewees in one study reported suffering constant pain while 60% were intermittent in their symptoms.
- The majority do not consider their current treatment adequate, according to Lazarus and Neumann (2001)³
- 76% have tried alternative therapies including chiropractic with results rated somewhat successful (50%), very successful (19%), and extremely successful (8%).

Pain effects on the quality of life have been documented:
- 19% say it affects their employment (6.2 hours per month per patient).
- Severe pain patients studied lost 8.2 hrs of work per month.
- Pain interferes with normal activities of daily living as well as preventive health efforts:
  - Exercise 46%
  - Sports 43%
  - Sleep 37%
  - Daily tasks 35%
  - Job performance 19%
  - Coping ability 18%
  - Socialization 18%
  - Personal hygiene 8%

Clearly, the social and economic impact of under-treated pain is a significant problem to patients and to society that often is ignored in deference to concerns on over-treatment.³

**Efforts to Improve Care Delivery**

A series of recommendations have been made in effort to address the adequacy of health care delivery. They include a plethora of guidelines development and pathways of care. For the most part, these efforts have failed to alter the course of frustration.

To a large extent, dissemination⁴ of and seminars⁵ on guidelines have had little impact⁵–⁷. Individual physicians often have failed to voluntarily implement various guidelines within their practices.
Many professional associations have shied from the controversy, leaving a void in professional leadership. Noncompliance with guidelines result in part from a conscious decision by the physician, as indicated by concerns for patient age and comorbid illness.

**Guidelines from Payers.** Third-party payers have often developed guidelines used proprietary data from multiple sources that was constructed from in-expert opinion using limited or outdated literature. Many of those guidelines, as they relate to chiropractic practice, are inconsistent with each other and promote wide variation in clinical practice. They also fail to meet standards of validation expected of data within the public domain.

These inconsistencies are often driven by disparities in the motives behind what is presented as “evidence” and in the implementation of the resulting judgments. Being “evidence-based” was never intended to be “evidence-enchained”. Indeed, the concepts of evidence-based practice and that of guideline development, while sharing some common interests, are inherently incompatible when there is attempt to directly overlay them to create a template for patient care. The use of guidelines by various stakeholders often has been to foster economic or political agendas and to manage system resources rather than to seek what is known and accepted as the best approach to care.

**New Chiropractic Evidence Database.** The Council on Chiropractic Guidelines and Practice Parameters (CCGPP) has been charged with the effort to develop a cataloguing and summarization of the evidence as it relates to chiropractic practice. The goal is to establish a more equitable and fairer basis for judgments of health care delivery specifically as it applies to the profession. After years of discussion and debate, the Commission of the CCGPP recommended in 2001 the establishment of a new approach, the development of an evidence database - available to all stakeholders. The evidence, common to all, and following broadly accepted methods of evaluation may minimize the experience of selective evidence being used to drive agendas that are not patient centered. Moreover, it is believed that such a database, to the extent used by practitioners to guide decision making and justify appropriate care, can reduce being enchained by care templates.

**Developing Relevant Evidence.** Once such a body of evidence is established, it can be updated through addendum periodically. By constructing such a database, it is felt that users of the information may be able to focus on the two substantive elements of practice worth emphasis: 1) The health and response of the patient 2) The process of care that defines quality practice.

The goal is to develop evidence that is relevant to many stakeholders within healthcare. The database is intended to support the development of individual
recommendations as may be applicable under varying local circumstances and challenges. The underlying motivation and value of evidence-based practice is in the guidance of clinical decision making for individual patients considering the individual context. The elements of that context include 1) the complexity of their condition and circumstances, 2) the best available evidence on what has been shown to be effective for most cases, 3) the provider’s expertise and experience, and 4) the patient’s preferences and beliefs.

Regulatory or evidence-based policy making, on the other hand, has as its primary motivation the management and distribution of health care resources to the population as a whole. The distinctly different focus between the needs of the individual and those for the conservation of social resources commonly places the provider in real conflict while engaged in the doctor-patient intervention. A satisfactory ethical conclusion of that intervention is reliant upon the conduct of common good-faith effort and intent in the exercise of patient-centered duties by both the provider and the administrators of the health care system under which he/she practices. Failure of either party results in, at least, moral if not tangible harm to the primary stakeholder, the patient.

The Process of Evidence Base Development. The product of this effort will be the accumulation, evaluation, reporting and rating of evidence – organized by condition (e.g. subluxation, herniation, stenosis, colic etc.) with conclusions as to what level of support exists. It will begin with both the more common conditions and types of care and is designed to progress by iteration to less common and complementary alternatives. The potential value of such a work-effort can be significant. Not the least of which is a common database of information on a national level, reviewed by stakeholder representatives and available generally for members to apply in the context of their local needs.

The election to address the evidence and group it in terms of various conditions was a conscious decision of the Council. Its purpose is to harvest information and supply it in categories that meet the practical need for providers to effectively communicate with other stakeholders (patients, payers and policy makers). Policy-makers are the designated social arbiters determining access to and compensation for services. The rapid adoption, internationally, of the expectation for positive benefits from regulatory, evidence-based policy making is a reality. Membership at the table requires participation in developing, cataloguing and interpreting the evidence that is used. Moreover, participation garners the only productive means by which professional stakeholders can represent their expertise and successfully influence interpretation of the findings in a context of the patients for whom their services are beneficial.
Evidence-based Practice: Best Practices versus Guidelines:

There are two principal dimensions of quality of care for individual patients; access and effectiveness. Stated more simply, Campbell et al (2000) suggest that quality in health care is provided when two questions can be answered affirmatively, "Do users get the care they need, and is the care effective when they get it?".

Evidence-based medicine (EBM) is not new. It has its origins in the mid-19th century. Its current emphasis often is economically driven rather than patient centered. The objective of EBM is the conscientious, explicit and judicious use of current best evidence, from various sources including the literature, in making decisions about the care of individual patients.

As much as 85% of current health care practices remain scientifically invalid despite the claims of medicine to scientific supremacy.

Clearly a useful concept for a practitioner seeing patients one at a time, currently the applicability of evidence may be limited to populations or to single patients with multiple diseases. The medical literature, moreover, has recently been characterized as disorganized and biased with little accountability for ensuring that publications meet minimum standards for quality or clinical relevance by stakeholders who are experts in the care being delivered.

Alternatively, one can choose to restrict the evidence used for care delivery to that derived from randomized clinical trials and results of meta-analyses. While in principal these forms are the strongest type of clinical evidence available, there are practical limitations that act as powerful constraints on their ability to identify effective treatment. Lambert characterizes succinctly, the problems of trying to apply populational evidence to individual patients. Many clinicians, epidemiologists, medical sociologists and statisticians agree that evidenced derived from randomized controlled trials and other studies on the effects of treatment cannot be applied directly to the management of individual cases. Even in circumstances where there is a “fit” between the evidence and a particular case, based on the very nature of statistical analysis underpinning these papers, it can only apply to those who represent the average behavior. That leaves about half of the population whose response to that care can be expected to deviate from the norm increasingly as they move further from being a close “fit”.

The pre-eminence of the randomized clinical trial (RCT), generally a positive factor for population health questions when high quality RCTs exist, can be a significant negative factor guiding care decisions. The positive value of these sources is that high quality studies that demonstrate efficacy of methods of care represents strong evidence favoring the use under the conditions of the study.
Unquestionably, the concept of providing care that has been proven to work is sensible and morally correct\textsuperscript{58}. The problem is that the complexity of conducting a randomized trial and the methodology issues are not only daunting but often unrecognized by those who have never tried them. The RCT tool often measures, with respect to the individual patient, the wrong things or a sample of patients to whom the individual is not a good representative\textsuperscript{58}. The works of Barry\textsuperscript{58} and Lambert\textsuperscript{57} succinctly describes the various mismatches (Table 1) that may arise between results from an RCT and the contextual elements for an individual patient.

### Table 1: Problems of the RCT in formulating practice benchmarks (Adapted from Barry 2006 & Lambert 2006)

<p>| | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Measure only items that easily are feasible and ignore subtle and complex effects.</td>
</tr>
<tr>
<td>2</td>
<td>Ignore context and the skill of the provider of treatment</td>
</tr>
<tr>
<td>3</td>
<td>Minimally acknowledge the confounding effects of placebo healing properties</td>
</tr>
<tr>
<td>4</td>
<td>Ignores patient actions, preferences and beliefs, which may confound outcome.</td>
</tr>
<tr>
<td>5</td>
<td>Poorly performed RCTs are more misleading than well-performed cohort studies.</td>
</tr>
</tbody>
</table>

For meta-analysis, the primary limitations include: 1) selection criteria for inclusion of studies within the analysis that may be a biasing factor; 2) the absent of standardized analyses and systematic method to validate new analysis methods, and 3) the consistency and/or accuracy of investigator application of criteria during the analysis \textsuperscript{13}.

As a result, it is incumbent upon the consumers of medical literature to be capable of evaluating the various forms of evidence according to reasonable and widely accepted standards in the context of their applications.

**Applying Both Research Evidence and Clinical Expertise.** Sackett has described the practice of evidence-based health care eloquently:

\[
\text{“[EBM] means integrating individual clinical expertise with the best available external clinical evidence from systematic research. By individual clinical expertise we mean the proficiency and judgment that we individual clinicians acquire through clinical experience and clinical practice.}
\]

By best available external clinical evidence we mean clinically relevant research, often from the basic sciences of medicine, but especially from patient-centered clinical research into the accuracy and precision of
diagnostic tests (including the clinical examination), the power of prognostic markers, and the efficacy and safety of therapeutic, rehabilitative, and preventive regimens.

Good doctors use both individual clinical expertise and the best available external evidence, and neither alone is enough [emphasis added]. Without clinical expertise, practice risks becoming tyrannized by external evidence, for even excellent external evidence may be inapplicable to or inappropriate for an individual patient. Without current best external evidence, there are risks that clinical practice will become rapidly out of date, to the detriment of patients. 14.”

While similar in expression, Higgs and colleagues reiterate these ideas but amplify:

“What challenges do practitioners face in blending clinical reasoning with evidence-based practice? In this article, the authors argue against basing clinical practice on narrow definitions of evidence, relying solely on experimental findings or, even more exclusively, on randomized controlled trials. Instead of defining best practice narrowly by the strength of the current empirical evidence used to guide clinical decisions, it should be defined broadly by what is the best information to use to make decisions for a given patient in a particular setting. Credible and accountable clinical decisions rely on a number of forms of knowledge and evidence. This evidence includes findings from across the range of research methods, including experimental, interpretive, and action research. .... Professionals, particularly advanced and expert clinicians ... use clinical reasoning to guide their practice in the uncertainty of clinical practice contexts. This reasoning helps ... make judgments about the relevance of particular research and clinical evidence for a specific patient and setting 15

Best practices are those with the strongest evidence that their use in a specific patient circumstance have higher probability of providing better outcomes, the diagnosis or treatment of a single patient or clinical question, one patient at one time. They are the product of agreement on the preponderance of evidence that must then be judged by the individual provider and the patient 16 in the context of clinical expertise and the complexity of the individual case. As stated by Driever,

“Best practice is not a specific practice per se but rather a level of agreement about research-based knowledge and an integrative process of embedding this knowledge into the organization and delivery of health care. Best practice requires a level of agreement about evidence to be integrated into practice. Best practice, built on a

Stakeholder review draft. Not for distribution otherwise or attribution.
foundation of EvBP, can bridge the practice-research gap and provide a basis for researchers and clinicians to work together to translate research into meaningful practice 17.”

Rigid standards and guidelines – being evidence enchained - must be avoided to allow for individual considerations and scientific innovation 18. It bears the emphasis of repeating that the elements of patient context that should enter clinical decision making include 1) the complexity of their condition and circumstances, 2) the best available evidence on what has been shown to be effective for most cases, 3) the provider’s expertise and experience, and 4) the patient’s preferences and beliefs.

How do we determine and use Evidence?

The characteristics of quality care are summarized by Brown (as reported by Driever 17). It is patient centered, scientifically based, outcomes based, refined through quality improvement and benchmarking and individualized in the context of each patient. The contents of efforts attempting to enhance quality of care by blending best-practices with clinical reasoning should include as many of the following features as are available within the state-of-art: a statement of purpose and scope, the method of development; the authors' and reviewers names and affiliations; an analysis of the specificity, sensitivity, and predictive power of mechanisms of illness or injury, symptoms, signs and tests; findings that point to a complicated, serious or emergent condition and factors of delayed recovery; diagnostic criteria; and analysis of the evidence underlying the common treatment elements or alternatives. Statistics on disability/illness duration and an outline for reassessment of those patients whose health concerns remain after a reasonable recovery period 17,19 along with a discussion of management after reassessment, including behavioral referral, further testing, and procedures, may be useful benchmark tools 4.

Each constituent of the health care infrastructure has its role in ensuring adequate care and quality to offset patient illness, dysfunction and suffering. The CCGPP effort to help identify best practices in chiropractic cannot and does not determine the bounds of clinical expertise or the elements of individual cases, nor can it replace them. It can, however, provide resources to understanding the available evidence to inform individual treatment approaches. When faced with a dispute fostered by regulatory interpretations, often of selected literature, it can provide a basis for evaluating and developing the best response available.

Each of the teams of chiropractic, method and technical experts has been recruited from nominations to the Council. Team leads met with the Commission co-chairs, at the inception of efforts to develop the database, and a structure guiding the efforts of each team were concluded. Under these guidelines, a structure for team decision making was defined. Process was divided into two
categories: those defined by the Council through the Commission co-chairs and those to be defined within the team following the ‘a priori’ guidelines.

The pre-defined categories separated the practice initially, into seven topic areas that are defined below. Each team was assembled with expertise relevant to their assigned area. Each team was guided to begin with the literature (e.g. the NBCE Job Analysis, etc) defining the most common disorders and diagnostic methods reported as being treated by Chiropractors. Initial evidence rating methods were also defined using standardized and validated instruments. Instruments available to assess individual RCTs (CONSORT), diagnostic studies (STARD), meta analyses (Sackett / QUOROM), epidemiological study (MOOSE), published guidelines (AGREE) and cost analyses (Sackett / Drummond). Following initial efforts, the team leads met by conference call and agreed to add additional tools for evaluating the evidence including broader types of evidence.

The CCGPP process is iterative, recycling through the literature for each topic area on completion of the initial efforts. In order for the process to be practical, each team was authorized, after initial survey of the literature, to determine the depth and breadth of the initial cataloguing, setting priorities based on both the evidence on most common disorders and the quality of information available. Further, if the team’s opinion was in agreement with existing guidelines after considering the quality of evidence, the team was empowered to adopt the evidence or to engage in detailed reanalysis using the rating instruments to form an independent conclusion.

Evidence from the indexed and peer-reviewed literature (e.g. Index Medicos, CINAHL, Mantis, Cochrane published guidelines etc) beginning with formal literature search criteria developed by each team were surveyed.

**Topic Areas**

CCGPP teams have been identified consisting of content experts from within the profession and involving consultants that are cross-trained or external to the profession in select areas. Each team will handle the review of literature organized into the areas in the listing that follows. Individual ICD codes (including subluxation) used in clinical practice and relevant to the region of discussion will be identified and cited in a summary to provide clarity as to what clinical problems the discussion of best practices applies.

**Draft Topics List:**

1) Introduction

2) Low back (including subluxation) and low back related extremity conditions
3) Cervical spine (including subluxation), headache, and neck related extremity conditions

4) Thoracic conditions (including scoliosis)

5) Upper Extremity disorders

6) Lower Extremity disorders

7) Soft Tissue disorders;

8) Other Nonmusculoskeletal disorders

9) Subluxation

Teams will rate the available evidence according to a standardized rating system (see below) and will conduct spot checks of the original literature evaluated by reviews or meta analyses for accuracy and consistency of interpretations as necessary. Teams will consist of a content expert acting as team captain, one member of the commission, and a minimum of three other members selected from nominees from members of the CCGPP and stakeholders. A separate team of experts on overlapping issues (e.g. physiological therapeutics and technology assessment) will serve as consultants for each of the other topic teams.

Team Development

CCGPP teams have been identified consisting of content experts from within the profession and involving consultants that are cross-trained or external to the profession in select areas. Member nominations have been solicited from the academic institutions and the constituents of the CCGPP. Participants fall into categories that span the gamut of chiropractic practice styles from practitioners in solo or group and multidisciplinary practices and chiropractic clinical scientists including those with cross-discipline training in public health, basic science and methodology and medicine. Where specific knowledge and skills are needed in defined areas or in areas topics straddling multiple topic areas, content expert consultants (e.g. epidemiology, methodology, statistics, radiology and imaging, physiological therapeutics etc.) have been identified who serve as resources to individual teams. Content expertise for all participants has been evaluated by the individual's professional experience, teaching, research and publications.
Developing Recommendations

The key stages in developing recommendations on best practices should include the following:

1. Methodological evaluation using the checklist tools (e.g. STARD, MOOSE, QURUM etc.)
2. Synthesis of evidence with development of evidence tables as necessary.
3. Considered judgment looking at the volume and quality of evidence, consistency, applicability and clinical impact.

Rating Evidence:

The process of scientific investigation has been widely accepted as the best means to minimize the likelihood of fooling oneself. The quality of evidence arising from investigations can be rated based on the degree to which each report meets the broadly accepted tests of internal and external validity based on the care and attention to detail demonstrated by investigators in their work. Over the past 3 decades, the methods of systematic evaluation of evidence have evolved and are in broad use. The following evidence ratings have been adopted by the Commission of CCGPP as a basis for evaluating evidence based on the current American College of Physicians, Pier – Physician’s Information and Education Resource. The PIER language has been modified as appropriate to address relevant diagnostic studies as noted below.

Some disagreement exists on the hierarchy of less rigorous evidence, particularly over the role of case studies versus expert opinion. How this topic is handled is based on an assessment of the effort versus benefit of including case studies. In particular the following four considerations (Table 2)

Table 2: Case study considerations

<table>
<thead>
<tr>
<th>Factor</th>
<th>Deciding feature</th>
</tr>
</thead>
<tbody>
<tr>
<td>Scientific role</td>
<td>Acknowledging interesting/unusual case findings and hypothesis generation.</td>
</tr>
<tr>
<td>Credibility</td>
<td>Not credible as a basis for policy making.</td>
</tr>
<tr>
<td>Public position</td>
<td>The profession has repeatedly acknowledged the misleading nature of case studies when taken from the context of their scientific role and offered as evidence of harm, independent</td>
</tr>
<tr>
<td>Stakeholder review draft. Not for distribution otherwise or attribution.</td>
<td></td>
</tr>
<tr>
<td>---</td>
<td></td>
</tr>
<tr>
<td><strong>Feasibility</strong></td>
<td>The plethora of single case reports where observations have not been followed by appropriate hypothesis testing, for some topic areas, is beyond feasible or useful application in the context of evidence cataloguing.</td>
</tr>
</tbody>
</table>

Formal consensus process to develop expert recommendations, as opposed to single practitioners expressing opinion, has been acknowledged as authoritative when better evidence is not available. Examples directly related to chiropractic care include the RAND Corporation (See Index Medicus for specific references) consensus process using panels of experts.

Based on consensus meeting of the team leads, a decision was made to exclude individual case studies. However, case series of 2 or more cases were authorized for use.

**Evidence Rating**

All methods of rating the evidence are a relative judgement, following prospective criteria, regarding how well the individual report met methodological standards and rigor. Whether levels of evidence are categorized by letter scores or numerical scores, a hierarchy is evident that addresses its relative methodological strength. One highly rated study has greater probability of providing correct guidance than do less well conducted studies. Similarly, a poorly conducted study higher in the evidence hierarchy (e.g. RCT) is less reliable than well conducted lesser quality studies (e.g. cohort studies). Consequently, ratings of evidence are not a judgment on the effectiveness of treatment itself. Indeed, strong evidence can be present for very effective treatment or for very ineffective treatment. Conversely, minimal or moderate evidence may be all that is available to underpin very useful treatment.

The listing below describes the criteria for determining the strength of the evidence underlying the various topic matters that the teams considered.

**Clinical Trials and Evidence on Treatment**

The method is supported/not supported by:

- **A** – 1) one good randomized controlled trial, 2) a meta analysis 3) the preponderance of evidence or 4) in a systematic review.

- **AB** – 1) one good randomized controlled trial 2) by cohort, case-control, observational studies or 3) case series.
B – 1) research data that are less compelling than a randomized controlled trial (e.g. cohort, case-control, or observational studies, or a case series)

BC – research data that are less compelling than a randomized controlled trial 1) e.g. cohort, case-control, or observational studies, or a case series and 1) on expert opinion or consensus, or 3) on historically, generally accepted standards of clinical practice not based on evidence.

C – 1) expert opinion or consensus, or 2) historically, [and widely?] accepted standards drawn from clinical practice rather than research evidence.

**Diagnostic Tests**

A – The method of evaluation / diagnosis is supported by at least one study or of systematic reviews of studies meeting standards for reporting diagnostic accuracy; validating cohort studies with good reference standards; validated clinical decision rules; and studies which measure post-test probabilities.

B – The method of evaluation / diagnosis is supported by exploratory cohort studies with good reference standards; instrumentation studies of reliability and validity.

C - The method of evaluation / diagnosis is supported by non-consecutive studies without appropriate reference standards; case control studies.

D - The method of evaluation / diagnosis is supported by expert opinion or consensus; case reports or clinical science prevailing knowledge.

**Common Issues:**

There are a few over-arching issues that apply to all of the areas that are to be reviewed as described in the section on Topic Areas. They include benchmarking of care (natural history & process-of-care evaluation, case complexity & risk stratification), physiologic therapeutics, documentation and technology assessment.
Benchmarking

Benchmarking care has been attempted in a number of ways. Non-professional observers who are focused on economical constraints frequently use issues of frequency and duration of care as sole criteria. Contrasting the individual patient’s recovery rate to population data on natural or treatment history has also been used. The problem with isolated quantitative benchmarks using number of visits and duration of care is that it ignores the individual case risk factors and complexity. In addition to these pitfalls, the use of natural history is widely misunderstood as more recent understanding of the natural intermittency and more extensive chronicity than was reported in the 1980s and early 1990s has largely been ignored. It is a reasonable assertion that there are only three outcomes to treatment of compliant patients: alternatively the patient improves in a timely manner, there is no change or the patient condition deteriorates. The direction in which the case progresses is dependent upon whether the appropriate care has been administered, the complexity of the case, and the intervention of factors outside the control of the provider, and sometimes, the patient. These factors cannot be assessed with simple comparisons. Rather, they require an assessment of the documented process of care. That is, is the attending doctor responding to the circumstances with reasonable clinical efforts to intervene with appropriate diagnostics, altered treatment plans or referral. Where the process of care is reasonable, it is counterproductive for third party intercession to hinder, stop or alter care. It is the intent of the CCGPP to assist stakeholders in reaching agreement and promoting best practices in the process of care and to facilitate improved outcomes for patients by optimizing the chance of recovery and minimize the administrative interference that can result in disruption of continuity of appropriate care while encouraging provider due-diligence in pursuing appropriate care.

The “Real” Natural History

Press (World Spine III, 2003) pointedly surveyed the difference between early and modern evidence on the natural history, at least for low back pain. Each team will address the modern evidence as available for their topic area. Using LBP, the more common complaint observed in a chiropractic setting, as being illustrative, this section will discuss the implications of the current understanding of natural history, on the process of care.

Early evidence suggests that 40-50% of back pain is improved in one week, 85-90% in 6 – 12 weeks (Berquist-Ullman). As much as 90% have been estimated to resolve without intervention (Dixon). While true to the extent studied in early sample populations, it provides an incomplete picture of prognosis. Von Korff (1996)\textsuperscript{21} has shown that a significant amount of even acute LBP patients
have persistent pain if followed for 1 to 2 years. As much as 62% will have one or more relapses during one-year follow-up of an index episode and 40% still with LBP at 6 months (Phillips & Grant, 1991). Initial relapses tend to occur at 6 to 7 week intervals with a decreasing number of cases suffering renewed pain each time. While 95% of patients may have returned, functionally, to near pre-episode function within 6 months, 31% continue to suffer pain with those activities. In most recent work, worker’s compensation injury patients were tracked for a one-year interval while recording symptom severity and work status. While 50 percent experienced no work time loss within the first month after injury, 30 percent of them had work absence because of their injury at the end of one year. Moreover, of those who had work absence within the first month (12%) and had returned, an additional 19% had absence later in the year. Clearly, reports of return to work experience at one month that are in general use do not capture the chronic, episodic nature of back problems. Many patients who appear to have improved and returned to stable employment continue to experience subsequent injury-related symptoms and work absences. Thus, assuming the typical case mix attended by an individual practitioner, the presence of symptoms and impairment beyond 12 weeks may be as high as between 31% to 40%, not the typical 10% often quoted.

Moreover, recent evidence shows that there is a significant difference in the morbidity of neck and back pain for women, at least in the aging population (Hartvigsen J., Christensen, et al. 2004). Overall patients, as age progresses, the prevalence of low back pain is 15%, neck pain 11% and combined low back and neck pain 11%.

**Complexity and Risk Stratification**

Ideally, there should be no dispute over the complexity of a case if the attending physician has compiled adequate and appropriate historical and diagnostic documentation. In a simple example, it is well known that patients with uncomplicated low back pain generally improve more quickly than a patient who also has radicular leg pain. Medicare widely recognizes the complicity of comorbid disease in retarding expected treatment response in the management of subluxation. Prior history, comorbidity, traumatic causation, ergonomic and environmental conditions, age, fitness and psychosocial factors are among the constellation of factors that may influence patient recovery. Documentation of these factors and relevant comorbid diagnoses can help anticipate prolonged recovery and help focus resource use to those more in need. Teams will assess the relevant factors for their topic area and provide an assessment of the level of evidence available to support or refute them.

In general, the complexity of an individual case may be assessed by observation of its factors (See Table 3 for examples). Much emphasis has been
given to psychosocial factors, tending to overshadow biomechanical or physical factors as risk for low back pain. While the recognition of worker satisfaction and other psychological factors represent a contribution to the understanding of managing spine disorders, the intensity by which it has been invoked is misplaced. Psychosocial factors are able to explain only 15% of the problem associated with incidence and recurrence of back pain complaints. A dispassionate review of the literature shows substantial effect of biomechanical factors including interaction between physical and psychosocial effects. Together they identify factors of causation, recurrence and delayed recovery. The following points, summarized by McGill are relevant:

- Biomechanical risk factors are linked to both the incidence of first-time low back complaints, absenteeism and subsequent episodes.
- Psychosocial factors are more important to subsequent episodes of back pain.
- Tissue damage can initiate a chain of events resulting in pain and activity intolerance that may affect some patients for as long as ten years.
- Mechanical tissue damage is often unable to be determined by modern imaging and testing procedures but are apparent on dissection/surgery.

Table 3: Some confirmed risk factors for injury, absenteeism and subsequent episodes of spine pain.

<table>
<thead>
<tr>
<th>Category</th>
<th>Factor</th>
</tr>
</thead>
<tbody>
<tr>
<td>Personal</td>
<td>Age (older) 23,24,31</td>
</tr>
<tr>
<td></td>
<td>Gender (female) 23,24,25</td>
</tr>
<tr>
<td></td>
<td>Severity of symptoms 23,24,25</td>
</tr>
<tr>
<td></td>
<td>Leg pain &gt; back pain 25,26</td>
</tr>
<tr>
<td></td>
<td>Increased spine flexibility 32</td>
</tr>
<tr>
<td></td>
<td>Reduced muscle endurance 32,33</td>
</tr>
<tr>
<td></td>
<td>Prior recent injury (&lt; 6 months) including surgery 23,24,29,34</td>
</tr>
<tr>
<td></td>
<td>25,35,36,37,26,38</td>
</tr>
<tr>
<td></td>
<td>Prior surgery 37,38</td>
</tr>
<tr>
<td></td>
<td>Asymmetric atrophy of multifidus up to 5 years later 39,40</td>
</tr>
<tr>
<td></td>
<td>Abnormal joint motion with or without abnormal emg function of medial spine extensors 41</td>
</tr>
<tr>
<td></td>
<td>Poor body mechanics 34</td>
</tr>
<tr>
<td></td>
<td>Falling as mechanism of prior injury 29,42</td>
</tr>
<tr>
<td>Biomechanical</td>
<td>Prolonged static posture &gt; 20 degrees (odds ratio 5.9) 43</td>
</tr>
<tr>
<td></td>
<td>Poor spinal motor control 44</td>
</tr>
<tr>
<td></td>
<td>Vehicle operation &gt; 2 hours per day 45</td>
</tr>
<tr>
<td></td>
<td>Sustained (frequent / continuous) trunk load &gt; 20 lbs 45</td>
</tr>
<tr>
<td></td>
<td>Materials handling (Static work postures, frequent bending and</td>
</tr>
</tbody>
</table>
twisting, lifting demands, pushing, pulling and repetitive exertion) ²⁹.

<table>
<thead>
<tr>
<th>Psychosocial Condition</th>
<th>chronicity</th>
</tr>
</thead>
<tbody>
<tr>
<td>Employment history (&lt;5 years same employer)</td>
<td>²³,²⁴,²⁵</td>
</tr>
<tr>
<td>Employment satisfaction</td>
<td>²⁷</td>
</tr>
<tr>
<td>Lower wage employment</td>
<td>²⁵</td>
</tr>
<tr>
<td>Family / relationship stress</td>
<td>²⁷</td>
</tr>
<tr>
<td>Attorney retention</td>
<td></td>
</tr>
<tr>
<td>Expectations of recovery</td>
<td></td>
</tr>
</tbody>
</table>

Caution is necessary in considering risk factors. Practice experience shows that many patients with significant risk factors respond well to treatment and achieve significant improvement and return to function. Best practices are intended to guide treatment planning and provide the greatest likelihood of benefit for the majority of patients. Patients with a significant number of risk factors warrant close observation and quick reaction if treatment response is below expectations.

**Process of Care**

Donabedian ⁴⁶ has suggested that development of quality for therapeutically necessary care requires a triad of elements (structure => process => outcome). Past efforts to evaluate quality of care in individual cases by performing peer review. While peer review in complex cases may have a role, the consistency and reliability of opinions between reviewers has been shown to be poor (0.40) ⁴⁷. Patients deserve good processes of care as well as favorable outcomes. Significant relationships ⁴⁸ between processes and outcomes exist. Effective process provides the best opportunity for good outcome by ensuring that realistic expectations exist and appropriate treatment pathways have been attempted for patients whose response is lower than expected. Realistic expectations are derived from adequate diagnosis and documentation of risk factors and active comparison of the clinical course under care with benchmarks. Health care is only one determinant of health and other factors have important effects on health outcomes, such as nutrition, environment, lifestyle and poverty ⁴⁹. Process of care effectively translates, in the individual case, to the manner in which the doctor responds to the characteristics and constellation of factors unique to each case. How is the doctor reacting to patient process? How is he coordinating and organizing resources to address the problems? How has the patient been assessed? What avenues of treatment have been considered? What rationale has been used? Process of care illustrates an episode of care to assess appropriate resource use within a practice ⁵⁰. It encourages a patient centered practice, using provider experience in conjunction with evidence to create effective treatment strategies for reducing the cost per episode of care and optimizing quality while moving from managing costs to managing the care.
process\textsuperscript{50}. Ahton et al \textsuperscript{51} have shown that process management has substantial validity and greater inter-rater reliability in measuring the quality of care.

For therapeutically necessary care, provider behavior is an important component in all performance measures\textsuperscript{52}. Management of a care episode has only three alternative outcomes: a) the patient progresses favorably and in reasonable similarity to relevant benchmarks; b) the patient’s progress is below expected benchmarks and the provider has interceded with appropriate diagnostic or therapeutic modifications in response; or c) the result of patient’s care is outside the bounds expected by appropriate benchmarks and appropriate action has not been taken. Appropriate processes of care result in documentation of risk factors, setting realistic expectations and altering the course of treatment to accommodate. Where appropriate process is or has been followed, then provider decision-making should not be questioned\textsuperscript{53}.

\textbf{Physiologic Therapeutics}

Physiologic therapeutics and their application span the gamut of musculoskeletal complaints. As such, the review of evidence can become redundant across topic areas. The CCGPP process will provide a team of content experts who will serve as resource persons to the other teams in formulating comments regarding the evidence on the use of various modes for treatment of different regions and the specific disorders that affect them, as may be appropriate.

\textbf{Technology Assessment}

As review of common disorders and treatments progresses, it may be necessary to review new or existing technologies more prevalent in use within the chiropractic profession and for which there may be a lack of knowledge or evidence external to the profession. Each team will evaluate the relevance of technology to their topic areas. Where appropriate, technology assessment will be independently conducted following standard and widely recognized methodologies\textsuperscript{54}.

\textbf{Dissemination, Review and Revision}

It is widely recognized that evidence changes with time and the commitment of resources to study the effects of care. The CCGPP is working with other professional organizations, both inside and outside the profession, who are experienced in dissemination of guidelines / best practices to make the Commission database available to the broadest group of stakeholders. The potential of a broadly disseminated database on best practices that has strong professional input is to minimize the variation in the interpretation of the evidence and the means by which the evaluation of practice is conducted.
While the Commission of the CCGPP is actively pursuing its work on establishing the database, the Council is establishing the means of broad stakeholder review. By modularizing the process, the Commission believes it will be more efficient to periodically review and update the database as sufficient circumstances may dictate.

And, if there is no evidence?

The CCGPP recognizes both the humanitarian charge to doctors to alleviate patient suffering, the social responsibility for managing resources responsibly and the occasional ethical conflict that may arise between these two priorities in a given case. As a result, the CCGPP adopts the positions of Sackett and of Sox (in recommendations for provider considerations when guidance is absent).

1. Review and summarize available studies.
2. Biological thinking may help. Is it physiologically plausible?
3. Be sure that current thinking is based on valid evidence. Trust differences in subgroup results only when the intervention works unambiguously in one and fails utterly in another.
5. Primum No Nocere. "Many believe that this principle has particular force when applied to healthy persons. . . when we are in doubt we should take special care to avoid actions that might cause harm."
6. Talk to the patient
7. Plan for the usual, adapt for the unusual. Algorithms are applied to usual patients and modified for unusual patients. Patient care decisions should be made on an individual basis.

Reference List


Stakeholder review draft. Not for distribution otherwise or attribution.


34. Mcgill S.M., Grenier S, Preuss RP, and Brown S. Previous history of LBP with work loss is related to lingering effects in psychosocial, physiological, and biomechanical characteristics. In Press 2004.


48. Hammermeister KE, Shroyer AL, Sethi GK, and Grover FL. Why it is important to demonstrate linkages between outcomes of care and processes and structures of care. Med Care 1995;33:OS5-O16.


