EDITORIAL

WHAT CONSTITUTES EVIDENCE FOR BEST PRACTICE?

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ABSTRACT

The guiding principles, methods, and common factors that serve as the foundation for the Commission of the Council on Chiropractic Guidelines and Practice Parameters best practices initiative are discussed in the context of the chiropractic practice environment. (J Manipulative Physiol Ther 2008;31:637-643)

Key Indexing Terms: Practice Guideline; Delivery of Health Care; Health Care Quality, Access, and Evaluation; Outcome and Process Assessment (Health Care); Chiropractic

By now, it should be of no surprise that the system for delivery of health care services is broken. During the 1990s, cost savings came primarily from reduction of reimbursements with some administrative efficiencies. In fact, health care costs have begun to increase again. The additional administrative oversight has continued to grow, increasing overhead costs for doctors and reducing the face-to-face time they can spend with patients and read the literature. The total number of health administrators is now approximately 0.95:1 in ratio with the number of physicians practicing in the United States. The cost of additional bureaucracy itself is now 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. At the same time, there is little evidence that the outcomes of musculoskeletal care have improved significantly. Pain strongly influences a person’s quality of life (Table 1).

Beside routine activities of daily living, work attendance is reduced with 19%, reporting 6.2 hours lost per month per patient. Those with severe pain lose 8.2 hours of work per month. The American Pain Society and the World Health Organization have called attention to both undertreatment of pain and the need for acceptable standards of care.

Undertreatment is a serious problem with evidence of associated increasing chronicity and expense. In 43% of households in the United States, at least one member experiences chronic pain. Skeletal pain accounts for 48% of chronic pain conditions. Lazarus and Neumann reported the prevalence of involvement in different body regions (Table 2). Of patients with low back pain, 84% have medical insurance (42% indemnity, 20% Medicare and supplemental, 6% Medicare only) but are less likely to be under care than those with other disorders. Results from cross-sectional interviews of households (Fig 1) show significant dissatisfaction with the persistence of their pain and therefore react by using nontraditional care methods.

Overtreatment and inappropriate treatment are both legitimate concerns for health policy. Clearly, however, the social and economic impact of undertreated pain is a significant problem to patients and to society, which is often ignored in deference to concerns of overtreatment.

EFFORTS TO IMPROVE CARE DELIVERY

The Council on Chiropractic Guidelines and Practice Parameters (CCGPP) has been charged with the task of developing a catalogue and summarizing 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.

The CCGPP, originally formed through the Council of Chiropractic State Associations, is an independent organization consisting of the council proper and a research commission. The membership of the council is composed of representatives of Council of Chiropractic State Associations, the Association of Chiropractic Colleges, the Foundation for Chiropractic Education and Research, the National Institute of Chiropractic Research, the Federation of Chiropractic Licensing Boards, and the National Association of Chiropractic Attorneys and representatives from the chiropractic vendor and public sectors. The council sets policy and appoints the members of the commission. It is the commission that carries out the charge to CCGPP.

**Evidence-Based Practice: Best Practices vs Guidelines**

The principle dimensions of quality care are simply expressed rhetorically, “Do users get the care they need, and is the care effective when they get it?”

Guidelines and clinical pathways have failed to alter the course of care or the frustration of its constituents. Dissemination of and seminars on guidelines have had little impact on provider behavior. Guideline implementation through payers is often economically driven rather than being patient centered, and there is little effect on outcome. The chiropractic profession needs to establish and to adopt its own practice document to specifically represent what the profession does. Where internally developed documentation is absent, payers and policy makers will continue to substitute their own (www.ccgpp.com).

Being “evidence based” was never intended to be “evidence enchained.” Although sharing some common interests, evidence-based practice and guideline development are inherently incompatible when directly overlaid to create a template for patient care. The underlying motivation and value of evidence is in the guidance of clinical decision making for individual patients considering the individual context. The elements of that context include (1) case complexity, (2) the best available evidence, (3) the provider’s expertise and experience, and (4) the patient’s preferences and beliefs.

One can choose to restrict the evidence used for care delivery to that derived from randomized clinical trials (RCTs) and results of meta-analyses. Although, 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 population evidence to individual patients. Many clinicians, epidemiologists, medical sociologists, and statisticians agree that evidence derived from randomized controlled trials and other studies on the effects of treatment cannot be applied directly to the management of individual cases. Those cases that are a “fit” to the evidence represent the mean behavior. That leaves approximately half of the population whose response to care can be expected to deviate from the norm increasingly as they move further from being a close “fit.” The RCT does not address this subpopulation’s needs and can misinform when inappropriately generalized. The RCT often measures, with respect to the individual patient, the wrong things or sample patients such that the individual is not a good representative. The works of Lambert and Barry succinctly describes the mismatch (Fig 2) that may arise when applying RCT results to patients seen one at a time.

Meta-analyses, similarly, should not be casually generalized. The primary limitations include (1) selection criteria for
inclusion of studies within the analysis that may be a biasing factor, (2) the absence of standardized analyses and systematic methods to validate new analysis methods, and (3) the consistency and/or accuracy of investigator application of criteria during the analysis.

It is worth reviewing the purpose of evidence-based medicine in the words of one of its founders, David Sackett:

“[Evidence-based medicine] 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, practice risks becoming rapidly out of date, to the detriment of patients.”

Whereas similar in expression, Higgs et al extend these ideas:

“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.”

Best practices are the product of agreement on the preponderance of evidence that must then be judged by the individual provider and the patient in the context of clinical expertise and the complexity of the individual case. As stated by Driever,

“Best practice, built on a foundation of EvVP, can bridge the practice-research gap and provide a basis for researchers and clinicians to work together to translate research into meaningful practice.”

Rigid standards and guidelines—being evidence en-chained—must be avoided to allow for individual considerations and scientific innovation. The character-istics of quality care are summarized by Brown (as reported by Driever). It is patient centered, scientifically based, outcomes based, refined through quality improvement and benchmarking, and individualized in the context of each patient.

CCGPP METHODS

The CCGPP process 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 that inform individual treatment approaches. When faced with a dispute fostered by regulatory interpretations, often of select literature, best practices can provide a basis for evaluating and developing the best response available.

Details of the methods designed to guide the CCGPP effort and the recruitment of team members can be found in the accompanying article on CCGPP methods. In brief, the practice of chiropractic was divided by anatomical region. Each region was assigned to a team that has set out to identify and review the literature relevant to guiding clinical judgment. Team leads met with the commission cochairs at the inception of the initiative. A structure for team decision making was defined. Process was divided into 2 categories: those defined by the council through the commission cochairs and those to be defined within the team following a priori methods designed to guide their work. The CCGPP process is iterative, recycling through the literature for each topic area on completion of the initial efforts.

COMMON ISSUES

There are a few overarching issues that apply to all clinical regions. They include benchmarking of care (eg, natural history and process-of-care evaluation, case complexity, and risk stratification), documentation, and technology assessment.

Benchmarking

Benchmarking care has been attempted in a number of ways. 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 as “stop care” points is that it ignores the individual case risk factors and complexity. Natural history is widely misunderstood. The early 1980s literature was misleading. Data now show a greater symptom intermittency and more extensive chronicity than previously understood. There are 3 basic outcomes
from treatment to compliant patients: timely improvement, no change in course, or deterioration. The factors determining case progression include (a) the administration of timely appropriate care, (b) the case complexity, and (c) confounding events outside the control of the provider, and sometimes, the patient. These cannot be assessed by simple benchmark numbers alone. They require a consideration of the documented care process. That is, the attending doctor’s clinical judgment and response in managing the progress in the case. 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 all stakeholders to achieve agreement and promotion of best practices in the process of care, improve patient outcomes, and minimize the administrative disruption of continuity of appropriate care.

**Natural History**

Press\textsuperscript{21} pointedly surveyed the difference between early and modern evidence on natural history for low back pain, which can be an illustrative context underlying management decisions. Each team has the charge to address the modern evidence, as available, for their topic area.

Early evidence suggests that 40% to 50% of back pain is improved in 1 week, 85% to 90% in 6 to 12 weeks.\textsuperscript{22} As much as 90% have been estimated to resolve without intervention. Although true in cross-sectional population studies, it provides an incomplete picture of longitudinal prognosis for the individual. Von Korff\textsuperscript{23} has shown that even for acute lower back pain, many patients have persistent pain if followed for 1 to 2 years. As much as 62% will have one or more relapses during 1-year follow-up of an index episode and 40% still with lower back pain at 6 months. Initial relapses tend to occur at 6- to 7-week intervals with a decreasing number of cases experiencing renewed pain each time. Although 95% of patients may have returned, functionally, to near preepisode function within 6 months, 31% continue to experience pain with those activities.\textsuperscript{24} In most recent work,\textsuperscript{25,26} worker’s compensation injury patients were tracked for a 1-year interval while recording symptom severity and work status. Although 50% experienced no work time loss within the first month after injury, 30% of them had work absence because of their injury at the end of 1 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 1 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% and 40%, not the typical 10% often quoted.

**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 historic and diagnostic documentation. For example, patients with uncomplicated low back pain generally improve more quickly than a patient who also has radicular leg pain.\textsuperscript{26,27} Aging is associated with continued experience of spine pain.\textsuperscript{28} 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 were directed to assess the relevant factors for their topic area and provide an assessment of the level of evidence available to support or refute them.

Much emphasis has been given to psychosocial factors, tending to overshadow biomechanical or physical factors as risk for low back pain.\textsuperscript{29} Worker satisfaction and other

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psychologic aspects are a factor in managing spine disorders. Psychosocial factors are able to explain only 15% of the incidence and recurrence of back pain complaints. There are substantive interaction effects of biomechanical factors including interactions with psychosocial effects (Table 3). Together they can help identify factors of causation, recurrence, and delayed recovery. The following points, summarized by McGill and McGill et al., 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 10 years.
- Mechanical tissue damage is often unable to be determined by modern imaging and testing procedures but are apparent on dissection/surgery.

Caution is necessary in evaluating risk factors. Many patients with significant risk factors respond well and achieve significant clinical improvement. Patients with a significant number of risk factors warrant close observation and quick reaction if treatment response is below expectations.

**Process of Care**

Donabedian (as reported by Schiff and Rucker) has suggested that quality for therapeutically necessary care requires a triad of elements (structure ≥ process ≥ outcome). Although 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). Patients deserve good processes of care as well as favorable outcomes. Significant relationships between processes and outcomes exist. Effective process provides the best opportunity for good outcome given realistic expectations and appropriate treatment pathways. Realistic expectations are derived from adequate diagnosis, documentation of risk factors, and active tracking of the clinical course under care with benchmarks. Health care is but one determinant of health. Other factors have important effects on outcomes, such as nutrition, environment, lifestyle, and poverty. Process of care effectively translates, in the individual episode, to the manner in which the doctor responds to the constellation of factors unique to each case. It encourages a patient-centered practice, using experience in conjunction with evidence to create effective treatment strategies. Ashton et al. have shown that process management has substantial validity and greater interrater reliability in measuring the quality of care. For therapeutically necessary care, provider behavior is an important component in all performance measures. It bears reiteration that management of a care episode can have but 3 alternative outcomes. They are that the patient (a) progresses favorably and in reasonable similarity to relevant benchmarks, (b) is below expectation and the provider has interceded appropriately with diagnostic or therapeutic modifications, or (c) is outside the bounds expected by appropriate benchmarks and appropriate action has not been taken. Where due process has been followed, then provider decision making should not be questioned.

**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.

**If There Is No Evidence?**

As much as 85% of current health care practices remain scientifically unfounded despite the claims of western medicine to scientific supremacy. The CCGPP recognizes the humanitarian charge to doctors to alleviate patient condition, the social responsibility for managing resources responsibly, and the occasional ethical conflict that may arise between these 2 priorities in a given case. As a result, the CCGPP adopts the positions of Sackett and of Sox in recommendations for provider considerations when strong evidence is absent. The following steps are suggested for the care giver:

1. Review and summarize available studies.
2. Biologic thinking may help. Is the method physiologically plausible?
3. Be sure that current thinking is based on valid evidence. Trust differences in subgroup result only when the intervention works unambiguously in one and fails utterly in another.
4. Consider costs to the patient.
5. *Primum non nocere.* When in doubt, take special care to avoid actions that might cause harm, whether it is physical, emotional, or economic.
6. Talk to the patient. Explain the ambiguity in the evidence and the steps you propose. Consider their preferences and beliefs.
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.
REFERENCES

45. McGill SM, Grewer S, Blueth M, Preuss RP, Brown S, Russell C. Previous history of LBP with work loss is related to
49. Hammermeister KE, Shroyer AL, Sethi GK, Grover FL. Why it is important to demonstrate linkages between outcomes of care and processes and structures of care. Med Care 1995;33:OS5-OS16.