

# Chiropractic quality assurance: standards and guidelines

Meridel I Gatterman, MA, DC, MEd\*

Thomas P Dobson, BSc, DC\*\*

Ron LeFevbre, DC†

*Chiropractic quality assurance involves development of both clinical guidelines and standards. Confusion generated by poor differentiation of guidelines from standards contributes to mistrust of the guideline development process. Guidelines are considered to be recommendations that allow for flexibility and individual patient differences. Standards are more binding and require a high level of supporting evidence. While guidelines serve as educational tools to improve the quality of practice, standards that outline minimum competency are used more as administrative tools on which to base policy. Barriers to development of clinical guidelines and standards include fear that they will create prescriptive “cookbook” practice, and the distrust that guidelines are developed primarily for cost containment. Clinicians also criticize guidelines developed by academics that don’t relate to practice, and those based on evidence that lacks clinical relevance. Conflicting guidelines perceived to be based on strong bias or conflict of interest are also suspect. To reduce barriers to acceptance and implementation, guidelines should be inclusive, patient-centered, and based on a variety of evidence and clinical experience.*

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**KEY WORDS:** chiropractic, quality assurance, guidelines, standards, evidence-based, patient-centered, informed consent.

*L’assurance de la qualité en chiropratique comporte l’élaboration de lignes de conduite cliniques et de normes. La confusion qui règne entre les deux quant à leur nature respective entretient la méfiance à l’égard du processus d’élaboration. Les lignes de conduite sont considérées comme des recommandations souples permettant l’individualisation des soins. Les normes, quant à elles, sont plus contraignantes et exigent des preuves très solides à l’appui. Les lignes de conduite servent d’outils de formation pour améliorer la qualité de la pratique, tandis que les normes qui définissent les compétences minimales sont davantage des outils administratifs sur lesquels repose une politique. Parmi les principaux obstacles à l’élaboration de lignes de conduite cliniques et de normes, mentionnons la crainte de se voir dicter une conduite thérapeutique et la méfiance selon laquelle les lignes de conduite visent avant tout à restreindre les coûts. Les cliniciens et cliniciennes critiquent aussi les lignes de conduite élaborées par les théoriciens et théoriciennes, qui n’ont pas de lien avec la pratique et celles qui manquent de pertinence clinique. Les lignes de conduite divergentes, qui semblent teintées d’une forte partialité ou résulter d’un conflit d’intérêts suscitent également la méfiance. Pour faciliter l’acceptation des lignes de conduite et leur mise en œuvre, il faudrait qu’elles soient inclusives, axées sur le patient, en plus de reposer sur un large éventail de preuves et sur l’expérience clinique.*

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**MOTS CLÉS :** chiropratique, assurance de la qualité, lignes de conduite, normes, fondé sur des preuves, axé sur le patient, consentement éclairé.

\* Process Consultant, OBCE Guidelines Revision Steering Committee.

\*\* Member, OBCE Guidelines Revision Steering Committee.

† Dean of Chiropractic and Clinical Science, Western States Chiropractic College.

Member, OBCE Nominal Panel.

Contact: Meridel I. Gatterman, 13735 NE Brazee Ct, Portland OR, 97230. Phone: 1 (503) 408-9213. E-mail: meridelg@teleport.com

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### Historical perspective

Chiropractic quality assurance was addressed in North America as early as 1985 by Vear with the publication of a paper entitled **Standards of Practice**.<sup>1</sup> By the late 1980's it became apparent to the major chiropractic associations in North America that guidelines and uniform standards for quality assurance would have to be developed as part of the process of validation of chiropractic practice. In 1987 the Consortium for Chiropractic Research and the California Chiropractic Association established a joint commission to research and to make recommendations on standards of care in chiropractic.<sup>2</sup> Prior to 1990 several states, including Ohio, Oregon and Washington, had begun development of guidelines for chiropractic practice at the state level.

In 1990 the Canadian Chiropractic Association undertook the task of establishing guidelines for chiropractic practice in Canada.<sup>3</sup> With the publication of Vear's book *Chiropractic Standards of Practice and Quality of Care* in 1992,<sup>4</sup> standards for chiropractic practice were again addressed. Subsequently national guidelines were published in both Canada<sup>3</sup> and the United States.<sup>2</sup> Clinical Guidelines for Chiropractic Practice in Canada (the Glenierin Conference proceedings)<sup>3</sup> were sponsored at the national level by the Canadian Chiropractic Association with representation from the regulatory bodies of each province. In the United States, Guidelines for Chiropractic Quality Assurance and Practice Parameters (the Mercy Conference proceedings)<sup>2</sup> were developed, followed directly by the Wyndham conference guidelines<sup>5</sup> published by a group of "straight" (subluxation-based) chiropractors dissatisfied with the Mercy proceedings.

More recently in the United States, guidelines continue to be put forth, both nationally, by the Council on Chiropractic Practice (CCP),<sup>6</sup> and the International Chiropractic Association (ICA),<sup>7</sup> and at the state level<sup>8</sup> (Florida). To date all of these guidelines have been subject to the same criticism. Their heavy reliance on consensus opinion, and the lack of a systematic review of the best available supporting evidence<sup>9</sup> allows them to be dismissed when applying traditional guidelines for guideline development.<sup>10,11</sup>

### Differentiating Guidelines from Standards

While many use guidelines and standards interchangeably, the Institute of Medicine<sup>10</sup> in the United States makes a clear distinction between the two.

**Guidelines** are defined as:

**Systematically developed statements to assist practitioner and patient decisions about appropriate health care for specific clinical circumstances.**

**Standards of quality (Standards of Care)** are defined as:

**Authoritative statements of minimum levels of acceptable performance or results, excellent levels of performance or results, or the range of acceptable levels of performance or results ...**

Most standards fall into the first category above, and indicate minimal levels of acceptable performance, where they are used to refer to minimal competency. Guidelines for clinical practice while they may be intended to suggest preferable approaches to particular problems, are intended to be flexible, not necessarily indicating the only acceptable approach. They should be distinguished from standards of care that are more inflexible and rarely violated.<sup>12</sup> Standards, because of the expectation that they will be adhered to, must be supported by strong evidence that makes them ethically as well as legally defensible. Guidelines should serve as educational tools providing recommendations and practice tips designed to aid the practitioner in decision making related to patient care. When followed, guidelines can lead to the best practice and minimize unwarranted practice variation. Standards, on the other hand, provide administrative tools on which to base policy and to develop peer review criteria.

Both guidelines and standards form the basis of quality assurance and should be patient centered,<sup>13,14</sup> developed in the best interest of the patient. They should be established by collation and interpretation of scientifically valid research derived from extensive review of published literature. When data are not available that will withstand objective scrutiny, recommendations may be made by a consensus of experts based on the best available evidence including clinical experience, but this procedure is best restricted to guidelines and not used to define standards.

### Patient centered, evidence-based guidelines and standards

Patient centered care puts the patient first, before cost cutting by managed care, doctor's egos, or financial gain. Patient centered practice evaluates the individual patient's clinical state, predicament, and preferences, and applies

the most efficacious interventions to maximize the quality and quantity of life for that person.<sup>15</sup> Chiropractic practice has traditionally been patient centered with anthropological and sociological studies providing evidence and seed material for a patient centered paradigm.<sup>16–18</sup> Much of this data is qualitative research based on observation rather than quantitative research that provides evidence for a reductionistic approach to treatment of the patient's specific condition. Qualitative research supports consideration of the total patient through a more holistic patient centered practice.<sup>19</sup>

Writing on the future of chiropractic from the patient's perspective, an attorney advises chiropractors to **promote your patient-centered, service-oriented, participatory, individualized approach to caring for patients.**<sup>20</sup>

She notes that patients:

**... want a practitioner who takes the time to care for each person, listening to concerns and providing human touch. Paying attention to the patient as an individual and readily addressing his or her clinical condition are areas where chiropractors excel and gain high marks for patient satisfaction.**<sup>20</sup>

A patient-centered approach offers a challenge and an opportunity to provide guidelines that demonstrate that the lowest risk and highest outcome therapies can frequently be tried first.<sup>21</sup> Patient-centered practice is a desirable ideal and health care professionals should make an effort to preserve this ideal.<sup>22</sup>

Evidence-based guideline development explicitly requires the best quality of supporting evidence available. It is important to ensure adequate discussion of the data (or its absence) when developing the recommendations in the guidelines.<sup>23</sup>

Guidelines that link recommendations to research are one tool for bringing evidence of effective practice to the attention of clinicians.<sup>24</sup> Evidence-based practice has been defined as:

**“the conscientious, explicit, and judicious use of the current best evidence in making decisions about the care of individual patients.”**<sup>15</sup>

Evidence-based practice means:

**“integrating individual clinical expertise with the best available external evidence from systematic research”.**<sup>15</sup>

Sackett<sup>15</sup> emphasizes that good doctors use both individual clinical expertise, and the best available external evidence, and neither alone is enough. Without clinical expertise, practice risks becoming tyrannized by evidence, because even excellent external evidence may be inapplicable or inappropriate for an individual patient. Without current best evidence, practice risks rapidly becoming out of date, also to the detriment of the patient.<sup>15</sup>

It must be emphasized that evidence-based practice is not “cookbook practice”. It is also recognized that the best available evidence is not just limited to evidence from randomized controlled trials but also involves the individual clinician's expertise along with the consensus of leading chiropractic clinicians and researchers based on varying degrees of patient centered clinical research. A thorough unbiased literature review for evidence-based guidelines is crucial to successful development of both standards and guidelines.

### **Barriers to development and implementation of Guidelines and Standards**

To increase credibility of both guidelines and standards, the process, the participants, and the scientific grounding of guidelines must be clear to intended users<sup>10</sup> with barriers to acceptance reduced to a minimum (Table 1). Guidelines should be specific, comprehensive, and flexible enough to be useful in the varied settings and circumstances of everyday practice<sup>10</sup> not something apart from the real world of patient care. Guideline language, logic and symbols should be easy to follow and unambiguous, so that movement from guideline statements to educational tools and review criteria is unimpeded<sup>10</sup> and barriers that hinder development and reduce compliance are minimized.

One of the major problems in guideline development is that clinicians fear that guidelines will become rigid standards used for reimbursement and legal purposes.<sup>25</sup> Guidelines developed as flexible recommendations in 1989 were later adopted as rules by the Oregon Board of Chiropractic Examiners<sup>26</sup> creating a legacy of mistrust of guidelines that persists today in this jurisdiction. A clear differentia-

**Table 1**  
**Barriers to Development and Implementation of Guidelines and Standards**

<b>Barriers</b>	<b>Course of Action</b>
<b>1</b> Clinicians fear all guidelines will become rigid standards with loss of control of decision making if guidelines are applied inflexibly by outside agencies (i.e. regulatory agencies, or managed care providers, or used inappropriately in litigation).	<b>1</b> Clearly differentiate between statements that are guidelines (recommendations), and those that are intended as rigid standards.
<b>2</b> Clinicians fear that guidelines well represent prescriptive “cookbook” practice.	<b>2</b> Make allowance in guidelines and standards for individual patient differences.
<b>3</b> Clinicians distrust guidelines and standards developed primarily for cost containment.	<b>3</b> Make guidelines and standards patient-centered.
<b>4</b> Clinicians criticize guidelines and standards that are developed by academics and don’t relate to practicing clinicians.	<b>4</b> Base guidelines and standards on a variety of evidence that considers the reality of clinical practice.
<b>5</b> Clinicians, patients and others are confused by conflicting guidelines.	<b>5</b> Make guidelines and standards inclusive, based on consensus of diverse groups that minimize self-interest.
<b>6</b> Clinicians criticize guidelines and standards based on strong evidence alone.	<b>6</b> Base guidelines and standards on individual clinical expertise integrated with clinically relevant patient-centered outcomes of care, and not just RCTs.
<b>7</b> Clinicians criticize guideline developers for a perceived bias and/or conflict of interest.	<b>7</b> Address potential bias and/or conflict of interest up front.

**Table 2**  
**Origins of Guidelines and Standards**

Most recommendations assume the form of guidelines that make allowances for individual patient differences, are patient-centered, flexible and based on variety of evidence sources	Some guidelines have a preponderance of strong evidence that can be applied universally or administratively. These guidelines can become standards.	Some guidelines have inherent moral and ethical components that compel them to be used as standards.	Where there are pre-existing legal precedents through statutes and case law, standards are defacto.
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tion between guidelines which serve as recommendations and standards on which rules can be based is imperative if there is to be trust in the guideline development process.

Similarly, clinicians fear that guidelines represent prescriptive “cookbook” practice.<sup>25</sup> There is a concern that guidelines will be applied authoritatively by regulatory agencies, or managed care organizations as a “one size fits all”. Allowance must be made for patient’s individuality, and variations in response to the same treatment. Variations in practice however, must be documentable and based on evidence of effectiveness not just based on patient or practitioner preference alone.

A third reason for distrust of guidelines is concern that guideline development and application is driven by cost containment without sufficient consideration for patient welfare. High health care costs send messages that health care practitioners should look beyond the welfare of the individual patient with concern for the commonweal. Those concerned about health care costs advocate for the commonweal, while practitioners tend to advocate decisions made primarily on the basis of individual patient’s needs and wants.<sup>25</sup> Guidelines developed with profit from health care in mind create suspicion that patient needs are not primary. Control of patient care by bureaucrats sitting with an algorithm is not in the best interest of patients.

Another cause of mistrust of guidelines by practitioners is lack of relevance of guidelines. Clinicians criticize guidelines that are developed by academics that don’t relate to practicing clinicians.<sup>25</sup> A Canadian study of chiropractors’ attitudes towards clinical practice guidelines found of all the chiropractic organizations that could be potentially involved in setting standards of care, the least level of support was for the chiropractic research community.<sup>27</sup> In the average practitioner’s world, the application of guidelines derived purely from clinical trials may be irrelevant given the nature of the organizational setting, the patient characteristics,<sup>25</sup> and the controlled application of the treatment intervention. This should not preclude an appreciation of evidence based on scientific studies nor is it justification for an anti-science attitude.

Conflicting guidelines make it impossible for clinicians to comply with each set of recommendations.<sup>24</sup> When it is perceived that a set of guidelines have had a negative impact on patients and practitioners, a conflicting set of guidelines may be developed.<sup>2,5-7</sup> This can result in “expert panels” polarized by conflicting views, developing

conflicting guidelines. When this occurs a means should be found to develop guidelines and standards that do not separate practitioners into opposing camps. It is not helpful for one group to label itself rationalists<sup>27</sup> while the other extreme calls themselves principled chiropractors.<sup>28</sup> Is the implication that opposing camps are either irrational or unprincipled? It is more helpful to seek a balanced panel that includes both a scientific perspective and practitioner experience. Guidelines should be representative and inclusive of major viewpoints. Inclusiveness and balance in panel composition can bring differing opinions to the table where true consensus can be achieved. A token representative with a differing perspective does not bring about meaningful agreement, nor does a panel composed of like minds that agree mean consensus when other views are not considered. The consensus process does not always mean that the majority rules but rather agreement is sought that is inclusive of differing viewpoints. Occasionally a minority position must be stated when a significant number cannot agree with the majority.

Limiting recommendations to areas where strong evidence exists reduces the scope of guidelines and limits their value to clinicians and policy makers who need to make decisions in the presence of imperfect knowledge.<sup>23</sup> The solution is to consider a mixture of evidence linked to consensus based recommendations. A systematic review of the literature of varying strengths that allows for consideration of conflicting data is essential. The identification and assessment of the literature should be undertaken by a team to avoid the selection bias possible with a single reviewer, and to further reduce bias the best evidence available at the time the guidelines are being written should be available to all panel members writing the seed document.

Equally important is avoidance of conflict of interest on the part of guideline developers. Even a perceived conflict of interest can invalidate otherwise sound guidelines and standards and hinder compliance. It is important to identify any potential bias and/or conflict of interest to prevent this from becoming a barrier to acceptance of guidelines and standards.<sup>10</sup>

### **Methodological and developmental issues**

Methodological and procedural issues central to the development of guidelines and standards must be addressed if validity is to be achieved. Financial support and commit-

ted teams with a range of skills are both essential to completion of the project.<sup>23</sup> A steering committee that oversees the process must be representative of the stakeholders covered by the guidelines. A principal investigator with a project management group is necessary to undertake the day to day running of the project.<sup>23</sup> The project management group should include a process specialist in guideline methodology, and individuals trained in information retrieval and selection. Technical assistance may be helpful in rating the strength of the literature. Seed panels with heterogeneous representation and content experts are needed to develop recommendations for practice in the light of evidence, or in its absence, based on expert opinion. Seed panel leaders trained as facilitators, with expertise in consensus development are essential for facilitating consensus through a nominal process. To avoid selection and interpretation bias, evidence should be available to all seed panel members rather than reviewed by a single "expert". Seed statements can then be further scrutinized and agreed to by nominal and Delphi panels. Nominal panels meet face to face with agreement obtained through a facilitated consensus process. A Delphi panel does not meet and the process is conducted by mail with agreement typically involving several rounds before consensus is achieved. These panels should include external reviewers as well as a broad representation of the stakeholders.<sup>11</sup> Administrative assistance is required for such tasks as preparing papers, arranging meetings, and taking notes. All participants need to have two specific characteristics: interest in the project and a positive attitude towards guidelines<sup>23</sup> as well as the time to devote to a time consuming process.

### Development of a Standard

If we consider that standards define appropriate care based on well-founded scientific evidence that should be followed in all circumstances with no flexibility for the clinician, then standards must be clearly distinguished from guidelines. In this sense, standards of quality represent the highest level of clinical scrutiny that, in essence, represents core elements of clinical practice.<sup>26</sup> Standards may have a broad universal application with regional variations. An example of a universal standard that has regional variations is informed consent.

There is both an ethical and legal duty to inform patients of the risks and benefits<sup>29</sup> to any intervention, and in some jurisdictions alternatives.<sup>30</sup> The universal standard in

this case is that practitioners must obtain informed consent from all patients. Informed consent is a process in which risks and benefits must be disclosed, understood, and accepted by the patient. While the standard requires that practitioners obtain informed consent not all jurisdictions require written informed consent. Some may require a PARQ conference<sup>31</sup> where the doctor discusses with the patient, procedures, alternatives and risks and questions the patients whether they wish any further information. The PARQ<sup>32</sup> format requires a notation in the patient's chart that the doctor has had this discussion with the patient. In this manner informed consent must be documented but not necessarily through a signed consent form. Where the use of an actual consent form is required by law, this obligation should not be viewed in a negative light for the essence of informed consent is communication. The written or oral process of obtaining informed consent offers a positive educational opportunity for the chiropractor to explain the comparative safety of chiropractic procedures.<sup>14</sup> While a universal standard mandates informed consent, regional standards based on differing laws may require differing methods of obtaining consent. Where a jurisdiction does not specify how consent is obtained, options, in the form of guidelines may be presented. While the guidelines allow for flexibility, a standard based on legal and ethical grounds requires that informed consent must be obtained. Where the law specifies a signed consent form or a PARQ conference then a regional standard exists that must be adhered to. Standards may be developed through the courts,<sup>30,32</sup> government agencies,<sup>26</sup> or insurance companies<sup>33</sup>, but preferably by the profession.<sup>31</sup> In the case of informed consent the courts have mandated a standard that the profession has recognized as an ethical as well as a legal right of the patient.<sup>29</sup>

### Conclusion

Chiropractic quality assurance involves development of both guidelines and standards. Both should be patient centered and evidence based to be of maximum benefit to both patient and society. Guidelines are considered to be recommendations that allow for flexibility and individual patient differences. Standards are more binding and require a high level of supporting evidence. While guidelines serve as educational tools to improve the quality of practice, standards outline minimum competency and serve as administrative tools that form the bases of policy.

Panel composition, thoroughness of the search for published papers, and explicit definition of evidence are essential components of the guidelines development process.<sup>34</sup> Development and adoption of both guidelines and standards offers a challenge to all health care professionals interested in quality assurance in the patient's interest.

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