The Chiropractic Report

www.chiropracticreport.com Editor: David Chapman-Smith LL.B. (Hons.) July 2006 Vol. 20 No. 4

Professional Notes

LBP – State-of-the-Art Management

The official word on state-of-the-art management of low-back pain (LBP), which will be widely read and quoted, has just been given in a review article titled *Diagnosis and Treatment of Low Back Pain* published in the June 17, 2006 issue of the *British Medical Journal.* This is by the prominent researchers Koes, van Tulder and Thomas.

This notes that over 1000 randomized controlled trials of all treatments for low-back pain and many new systematic reviews and clinical guidelines have now provided a "greatly improved" foundation for evidence-based management of LBP.

The article contains no great surprises – but chiropractic management fares very well (with spinal manipulation recommended for both acute and chronic LBP) and invasive procedures are hit hard (even for chronic LBP interventions listed as of unknown benefit and not recommended include facet joint, epidural, trigger-point, and sclerosant injections, and all surgery except surgi-

continued on page 4

Informed Consent

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

US Chiropractic Guidelines, 1993[1]

A. Introduction

IN THE MID-20TH CENTURY medical paternalism, summarized in the expressions "the physician knows best", governed the relationship between doctors and patients. Patients were seldom warned of risks of treatments.

When a patient sued for damages for injuries received during treatment the legal test for what was a material risk that should have been disclosed, was what "the reasonable doctor" would have done – not what "the reasonable patient" will expect to know. Expert evidence from fellow professionals defined patient rights and governed the court's decision.

That is all history. In the 1957 case of Salgo v Leland Stanford Jr., University Board of Trustees,[2] a California court coined the term "informed consent". In a malpractice case where the patient had suffered paralysis from translumbar aortography, a known risk of the surgery that had not been disclosed, the judge defined informed consent in this way:

"A physician violates his duty to his patient and subjects himself to liability if he withholds any facts which are necessary to form the basis of an intelligent consent by the patient to the proposed treatment. Likewise the physician may not minimize the known dangers of a procedure or operation in order to induce his patient's consent."

Courts in the US and internationally soon adopted the requirement of informed consent. Today, after two generations in which there has been a steadily increased recognition of patient rights and paternalism in health care is largely gone in the western world, there is a clear need for health professions to obtain informed consent – both as a matter of law and as a matter of ethics. That was recognized by the chiropractic profession in US national practice guidelines agreed at the Mercy Center Conference in 1992 and quoted above.

2. But what are the risks and other information that need to be disclosed by chiropractors to their patients? How should this be done to meet ethical, legal and risk management requirements? What is the reaction of patients? This article answers these questions and provides a sample consent form.

In countries such as Canada, the UK and the US, where most chiropractors routinely have consent forms completed by patients, the answers to these questions will be quite widely known. Associations and professional liability insurers have recommended consent forms and consent protocols. However, in some countries few chiropractors obtain written and signed evidence of informed consent, and all clinicians will benefit from a review of their obligations and their current approach to obtaining informed consent.

B. Ethics

3. All professional codes of ethics include duties of the professional to patients/clients, society, self, and the profession. Ethical reasons for informing the chiropractic patient of material risks of treatment include:

a) *Duty to patient.* The patient's interests

Main Article *continued from page 1*

are paramount, and in this era of greatly increased patient rights (e.g. rights to know, access to clinical records, confidentiality of health information) all chiropractors will be aware of an ethical duty to provide patients with appropriate information on risks and benefits of treatment proposed.

b) *Duty to profession.* In 2006 few things are as likely to bring your colleagues and the chiropractic profession to disrepute more than publicity surrounding the claim by a patient that he or she was seriously harmed by chiropractic treatment in a way that was never disclosed. Chiropractors have an ethical duty to their colleagues and the profession to take thorough and appropriate steps in the area of informed consent.

c) *Duty to self.* There are two aspects to this. The first is to maintain high standards of personal integrity in practice, "doing unto others as you would have them do unto you". The second, frankly, is to protect yourself in the unlikely but possible circumstance that a patient is seriously injured and disabled by your treatment.

A problem for chiropractors is that their methods of treatment are so safe, with serious complications so rare, that those experiencing a patient with such complications are devastated. Strokes associated with chiropractic treatment, for example, are rare, but can happen following completely competent care – the best evidence is that they are usually random events in predisposed patients.[3] When and if you face the situation of a patient suffering a stroke, you will manage the experience far more easily if the patient was given previous knowledge of the risk by you and had documented his or her consent to your treatment.

C. Legal Issues

4. The legal doctrine of informed consent is now well known to, but frequently misunderstood by, members of the legal profession and health care professions. Exact requirements vary according to country and jurisdiction. Readers should therefore rely on legal advice where they practise. However general features of the doctrine and law in most jurisdictions are:

a) *Reasonable patient test.* A clinician is required to disclose all material facts that a "reasonable patient" would expect to know and consider relevant to a decision to accept or reject treatment. (It is true that some individual US states still have a "reasonable doctor" or "reasonable professional standard" test, but even there juries tend in practice to adopt a reasonable patient test when they make their decisions.[4])

b) *Disclosure of material risks.* Key items for disclosure include "material risks". These include known significant complications that are quite common or likely following treatment. Importantly, they also include very remote or unlikely complications that are serious – such as paralysis or death.

Current best evidence is that the risk of vertebral injury and stroke associated with cervical manipulation is about 1 in 1 million treatments – in other words an extremely remote risk.[5,6] As Terrett points out this amount to one case experienced by a group of 25 chiropractors practising for 40 years.[5] However, because the risk is a potentially serious one, it is a "material risk" which should be disclosed.

c) *Other material facts.* For the patient's consent to treatment to be informed, valid and effective, patients should also be aware of the benefits and risks of alternative treatments, and of having no treatment at all. These facts are particularly important for medical patients for whom invasive medical or surgical treatments are being considered – but who have not yet tried more conservative alternatives.

d) *Understanding and acceptance by patients.* It is not sufficient that material facts have been disclosed. They must have been understood and accepted by the patient. Whether or not this is so in any given case is a matter of fact to be decided by the court.

The plaintiff patient will likely allege that the risk of injury s(he) has suffered was not understood and accepted. This means that informed consent should be recorded in writing on a form that uses clear and easily understood language, and that makes specific reference to material risks.

e) *Negligence.* Where a court finds that there was no valid informed consent this amounts to a breach of a duty of care owed by the clinician to the patient – in legal language the wrong or tort of negligence. This helps to explain why providing the patient with adequate information for informed consent is an ethical obligation as well as a legal one – it is all about a duty or standard of care owed to patients.

The Chiropractic Report is an international review of professional and research issues published six times annually. You are welcome to use extracts from this Report. Kindly acknowledge the source. Subscribers may photocopy the Report or order additional copies (.80 cents each – minimum of 20 copies plus shipping) for personal, non-commercial use in association with their practices. However, neither the complete Report nor the majority or whole of the leading article may be reproduced in any other form without written permission.
Subscription: for rates and order form, see page 8.
For information or orders visit
www.chiropracticreport.com
or telephone 416.484.9601, fax 416.484.9665
email: TCR@chiropracticreport.com

Changes of mailing instructions should be sent to The Chiropractic Report, 203–1246 Yonge Street, Toronto, Ontario, Canada M4T 1W5, telephone 416.484.9601, fax 416.484.9665.
Printed by Harmony Printing Limited, 416.232.1472.

ISBN 0836-144

5. These legal principles may be well illustrated from Canadian law, where they have been applied in appellate cases involving both medical and chiropractic care. In summary:

a) The "reasonable doctor" test was fully replaced by the "reasonable patient" test in Canada in 1980 by the Supreme Court (the highest appeal court) in Reibl v Hughes.[7] The plaintiff patient, who had sought care for severe headaches, suffered a stroke, paralysis and impotency after neurosurgery to remove an occlusion in the left internal carotid artery. Stroke was a known risk, but was not disclosed to the patient.

Expert medical evidence was that the risk was so low that it did not need to be disclosed according to normal professional standards of care. In the lower courts the reasonable doctor test was applied, the expert evidence was accepted, and the plaintiff lost. On appeal the Supreme Court profoundly disagreed saying:

continued on page 6

Figure 1

INFORMED CONSENT TO CHIROPRACTIC TREATMENT

Please read this consent form, discuss it with your clinician if you would like to, and then sign where indicated at the bottom. Clinicians who use spinal manual therapy techniques, such as for example joint adjustment or manipulation or mobilization, are required to inform patients that there are or may be some risks associated with such treatment. In particular:

a) While rare, some patients have experienced muscle and ligament sprains or strains, or rib fractures following spinal manual therapy.

b) There have been reported cases of injury to a vertebral artery following neck adjustment, manipulation and mobilization. Such vertebral artery injuries may on rare occasion cause stroke, which may result in serious neurological injury and/or physical impairment. This form of complication is an extremely rare event, occurring about 1 time per 1 million treatments.

c) There have been reported cases of disc injuries following spinal manual therapy, although no scientific study has ever demonstrated that such injuries are caused, or may be caused, by adjustment or manipulative techniques and such cases are also very rare.

Treatments provided at this clinic, including spinal adjustment, manipulation and/or mobilization, have been the subject of much research conducted over many years and have been demonstrated to be appropriate and effective treatments for many common forms of spinal pain, pain in the shoulders/arms/legs, headaches and other similar symptoms. Treatment provided at this clinic may also contribute to your overall well-being. The risk of injury or complication from manual treatment is substantially lower than the risk associated with many medications, other treatments and procedures frequently given as alternative treatments for the same forms of musculoskeletal pain and other associated syndromes.

Your clinician will evaluate your individual case, provide an explanation of care and a suggested treatment plan, or alternatively a referral for consultation and/or further evaluation if deemed necessary.

Acknowledgement: I acknowledge I have discussed, or have been given the opportunity to discuss, with my clinician the nature of chiropractic treatment in general and my treatment in particular as well as the contents of this consent.

Consent: I consent to the chiropractic treatment(s) offered or recommended to me by my clinician, including joint adjustment or manipulation or mobilization to the joints of my spine (neck and back), pelvis and extremities (shoulder, upper limbs and lower limbs). I intend this consent to apply to all my present and future treatments at this clinic.

Dated this _____ day of _____, 20____

_____ _____

Patient Signature (Legal Guardian) Signature of Guardian (when applicable)

Name:_____ Name:_____

(Please print name of patient) (Please print name of guardian)

Name:_____ _____

(Please print name of Witness/Translator) (Signature of Witness/Translator)

This is a sample form and is not intended as a final product. Each clinician should use informed consent forms that satisfy the requirements of his or her community, in addition to his or her unique practice standards. Ed.

Adapted from a sample in the Form and Sample Letter Book, Charles W. Theisler, DC.

LBP – State-of-the-Art Management

continued from page 1

cal discectomy in selected patients who have not responded to conservative management).

Points of note include:

• About 90% of patients with LBP have non-specific LBP.

• "Health professionals use a variety of diagnostic labels, for example "general practitioners may use *lumbago*, physiotherapists *hyperextension*, chiropractors or manual therapists *facet joint disorder*, and orthopedic surgeons *degenerative disc problems*" but no valid classification system exists."

• In practice and in the literature non-specific LBP is defined by duration – acute (less than 6 weeks), sub-acute (6weeks to 3 months) and chronic.

• Most acute patients recover from pain but most (73%) according to a recent UK medical study) have at least one reoccurrence within 12 months. Only 5% of patients develop chronic pain – but identifying them early is important.

• Imaging is being used less. One reason is that abnormalities found on imaging are equally prevalent in the general public without LBP, another reason is that many LBP patients have no such abnormalities. Indications for imaging include one or more 'red flags' – e.g. age under 20 or over 55, non-mechanical pain, thoracic pain, feeling unwell or weight loss, widespread neurological symptoms, structural spinal deformity.

• A summary of diagnostic and treatment guidelines, taken from 11 national clinical guidelines for acute LBP, is given and shown in Figure 1. It is noted that "strong evidence shows that bedrest and specific back exercises (strengthening, flexibility, stretching, flexion and extension exercises) are not effective" for acute LBP.

Useful websites given include that for the European Guidelines (www.backpaineurope.org) – visit this for detailed recommendations with respect to both acute and chronic LBP.

(Koes, BW, van Tulder MW, Thomas S (2006) *Diagnosis and Treatment of Low Back Pain*, Br Med J 332:1430-1434).

Figure 1

Summary of Recommendations of 11 National Clinical Guidelines for Acute Low Back Pain.

Diagnosis

• Diagnostic triage (non-specific low back pain, radicular syndrome, specific pathology)

• History taking and physical examination to exclude red flags

• Physical examination for neurological screening (including straight leg raising test)

• Consider psychological factors if there is no improvement

• X-rays not useful for non-specific low back pain

Treatment

• Reassure patients (favourable prognosis)

• Advise patients to stay active

• Prescribe medication if necessary (preferably at fixed time intervals):

  – Paracetamol

  – Non-steroidal anti-inflammatory drugs

  – Consider muscle relaxants or opioids

• Discourage bed rest

• Consider spinal manipulation for pain relief

• Do not advise back-specific exercises

WHO – Prince Charles Speaks Out for Holistic Care. On May 23, 2006 Prince Charles from the United Kingdom, provided the keynote address to the Annual Assembly of the World Health Organization in Geneva, attended by ministers of health and delegations from most of WHO's 192 member countries worldwide. Also present was a 15-member delegation from the World Federation of Chiropractic (WFC), a non-governmental organization in official relations with WHO.

In his speech, which may be found at the WFC website (www.wfc.org under Newsroom) and the WHO website (www.who.int), Prince Charles strongly advocated the greater integration of complementary and alternative medicine into health care systems. Reasons included adopting a more holistic approach to health, improving the quality of health care and respecting individual choice.

Prince Charles, who for the past 11 years has been Patron of a Foundation for Integrated Health in the UK, left the ministers of health with a challenge – that each country over the next five years develop its own integrated plan for future health care, integrating modern, traditional and complementary medicine.

Two things are significant beyond what was said. The first is that Prince Charles was chosen to be the keynote speaker by the WHO Director-General, specifically to speak about the importance of complementary health care. The second is that this event was one more example of WHO's new level of acceptance of what it sees as developed CAM disciplines such as chiropractic. All of this results from WHO's TRM/CAM Strategy 2002-2006, another aspect of which is the recent publication of the *WHO Guidelines on Basic Training and Safety in Chiropractic* (available at www.wfc.org under Newsroom).

Other Research Notes

Canada – Chiropractic Research Chairs and Degenerative Disc Disease. The Canadian Chiropractic Association (CCA), having watched the example of Denmark where the planned development of research capacity in the 1990s greatly advanced the status and well-being of the chiropractic profession within the mainstream Danish health care system, is progressing successfully with a long-range plan to establish a highly qualified chiropractic researcher in a Chiropractic Research Chair in a major university in each of Canada's nine provinces. The ultimate aim is tenured positions with government/public funding not only for these researchers and their research, but also for the several chiropractic PhD candidates that will work under each of them. During an initial five year term each university

Chair or position is jointly funded by the CCA and the government/university.

The recent appointment of Jill Hayden, DC PhD to a Chiropractic Research Chair follows earlier appointments of Dr. Greg Kawchuk at the University of Alberta, Dr. Mark Erwin at the University of Toronto and Dr. Jean Sebastien Blouin at the University of British Columbia. Collectively these leading young researchers, who have had to win their positions on merit in a most competitive process, are not only producing important research, but are also re-shaping attitudes to chiropractic within the health sciences, health policy and health care communities in Canada.

As an example of this consider the work of Professor Mark Erwin, Division of Orthopaedic Surgery, Toronto Western Hospital and Faculty of Medicine, University of Toronto. Dr. Erwin is doing leading research internationally on the cause of degenerative disc disease (DDD), one of the most expensive and disabling conditions faced by contemporary health science which has no cure – available medical treatments merely work on symptoms. A paper recently published in *Spine*, illustrates the animal experiments he is performing with co-researcher Robert Inman, MD from the Arthritis Centre of Excellence, Toronto Western Hospital. In summary:

a) In theory, Erwin and Inman explain, an ideal intervention to halt or even prevent DDD would be to introduce some natural agent to stimulate and maintain good cellular conditions – "to stimulate the local chondrocyte population to maintain production of the extracellular matrix" and "to protect the matrix from the degradative action of catabolic enzymes."

b) They have started looking at this by using disc material from mongrel (non-chondrodystrophic) dogs. Mongrels are known, and were further shown by the study, to be much less susceptible to DDD than inbred (chondrodystrophic) breeds of dogs such as beagles and dachshunds. The latter have profound and early development of DDD "often within the first year". The feature that distinguishes the two types of dogs is that the mongrels or non-chondrodystrophic dogs "maintain their population of notochord cells in the disc nucleus" whereas the others do not.

c) Erwin hypothesized that notochord cells might produce soluble factors that activated chondrocytes in the disc to produce proteoglycan, thereby maintaining the structure and function of the disc nucleus both in its natural state and when subjected to degradative enzymatic treatment.

d) In this study a culture containing notochord cells from dog discs was used to stimulate chondrocytes from cattle (bovine caudal discs) to evaluate proteoglycan production and other effects. It was found that the biology of the bovine chondrocytes was "profoundly affected" by the culture with canine notochord cells, but not a similar culture without those cells. This was through activation of proteoglycan production. This supported the hypothesis mentioned above, and points a possible way to development of a cure for DDD in humans.

(Erwin WM, Inman RD (2006) *Notochord Cells Regulate Inter-*

continued on page 8

WFC's 9th Biennial Congress
ECU's 75th Anniversary Convention

Hosted by
Portuguese Chiropractors' Association

Incorporating
WFC's and FCER's International Conference on Chiropractic Research
AHC's Annual History Convention

Celebrating the Past, Present and Future of Chiropractic

Art: Technique workshops from many leading instructors

Science: Report of the Neck Pain Task Force (Haldeman, Cassidy, Carroll, Carragee) and much more.

Philosophy: Bruce Lipton, PhD (keynote), Gerard Clum, DC, and much more.

Dates: May 17-19, 2007

Venue: Tivoli Marinotel, Vilamoura, The Algarve, Portugal

All information: For program, research submissions, registration, accommodations, tours, all other information:

- Visit www.wfc.org/congress2007
- Contact: Linda Sicoli at the WFC at 416-484-9978, fax 416-484-9665 or lsicoli@wfc.org.

Outstanding academic and social program, spectacular beachside hotel, golf courses, restaurants, venue . . . don't miss this one.

"To allow expert medical evidence to determine what risks are material and, hence, should be disclosed and, correlatively, what risks are not material is to hand over to the medical profession the entire question of the scope of the duty of disclosure, including the question whether there has been a breach of that duty. . . . The issue under consideration is a different issue from that involved where the question is whether the doctor carried out his professional activities by applicable professional standards. *What is under consideration here is the patient's right to know what risks are involved in undergoing or foregoing certain surgery or other treatment* (emphasis added)."

The Supreme Court therefore adopted a reasonable patient test, on that test decided that a remote but known risk of paralysis was a material risk that a reasonable person would expect to have been told of, and awarded the case and damages to the patient.

b) Four years later in 1984 that case was followed in the chiropractic case of Mason v Forgie.[8] The plaintiff, who was suffering from neck pain, had experienced a stroke after a cervical adjustment from the defendant chiropractor. He claimed negligence in the manner of treatment and failure to inform him of the risk of stroke. No consent form disclosing the risk of stroke had been signed. The court found there was no negligence in the delivery of treatment itself, but that the chiropractor was liable for failure to disclose the risk of stroke.

On appeal the Court of Appeal agreed. On the question of material risk it accepted this summary of the law in Reibl and Hughes:

"A risk which is a mere possibility ordinarily does not have to be disclosed, but if its occurrence may result in serious consequences, such as paralysis or even death, then it should be treated as a material risk and should be disclosed."

At the original trial a number of professional expert witnesses called on behalf of the chiropractor questioned the need to disclose such a remote risk. The court accepted that the risk was very remote but, because the possible consequences included paralysis, it was by definition a material risk regardless of what the professional standard and evidence might be.

c) By the 1990s, as the emphasis on patient rights grew even stronger, the case law was codified into legislation. Section 5(2) of the Consent to Treatment Act in Ontario, enacted in 1992, provides:

"A consent is informed if, before giving it,

(a) the person received the information about the treatment, alternative courses of action, the material effects, risks and side effects in each case and the consequences of not having the treatment that a reasonable person in the same circumstances would require in order to make a decision; and

(b) the health practitioner responded to the person's requests for other information about the treatment, alternative courses of action, material effects, risks and the side effects, and consequences of not having the treatment."

D. The Consent Form.

5. In most jurisdictions it is today accepted that a written, signed and witnessed consent form is necessary to satisfy the ethical and legal requirements of informed consent. A sample form appears as Figure 1 (page 3). With respect to this:

a) The form represents a starting point only. Readers should use a form that satisfies the requirements of their communities.

b) There are varying approaches to how long and detailed a consent form should be. Some advocate a lengthy document detailing all treatments and risks.[9] A disadvantage of that is that it may confuse, and subsequently be held to have confused, the patient. Some advocate a brief form focusing on vertebral artery injury and stroke. That may fail to cover other unlikely but material risks.

The sample, adapted from an excellent precedent drafted by Dr. Charles Theisler of Ohio, is of mid-length. Another approach, recommended to members by the British Chiropractic Association, is to combine two documents – an information pamphlet that the patient can read and retain, then a brief consent form acknowledging that the patient had read and understood the pamphlet.

c) Note that the sample form, at the beginning, makes it clear to patients that they have the option of discussing the contents of the consent with the clinician before signing. (See more on this under Process below).

d) Note the specific and clear reference to stroke and serious neurological injury. This is necessary and lies at the heart of the concept of informed consent. If there was only the more obscure reference to "vertebral artery injury" it is likely that a court would find no valid consent in a subsequent dispute. The first question the defendant will be asked under cross-examination is "why did you not choose to mention the risk of stroke on the consent form?" The patient will be believed when, in evidence, he or she denies knowing what "injury to the vertebral artery" means and explains that no form would have been signed or consent given if the words "stroke" had been used.

e) A common fear for those considering use of such a clear consent form for the first time is that patients will be upset and discouraged from proceeding with chiropractic care. Experience proves that fear to be wrong – and just another example of over-reaction to issues of risk and harm by chiropractors because their practice is so inherently safe and they have so little experience of patient harm. Most patients are well-accustomed to signing many consent forms, and see the disclosure of risk as a sign of professionalism and responsibility.

In Canada, as use of clear consent forms became common in the 1980s, most chiropractors experienced no adverse reaction from patients. At a recent seminar in South Africa the prominent Australian lecturer and clinician Dr. Alan Terrett, explained that he had had one patient decline care in 15 years use of consent forms explaining the risk of stroke in Australia.

f) The sample form is not signed in favor of a specific person but, as stated at the end, applies to "all my present and future treatment at this clinic." This covers treatment by associates and locums who provide ongoing future and similar chiropractic care at the clinic.

g) There is intentional reference to clinicians rather than chiropractors, and spinal manual therapy rather than just the adjustment, since known risks apply to the generic approach to care rather than solely chiropractic care – this is a spinal manual treatment issue, not a chiropractic issue.

h) Statements on risk rates and benefit are in accordance with current evidence.

E. Process of Obtaining Consent

6. It is most important to understand that obtaining a valid informed consent involves a process, not just signature of a form. Patients need to understand what they are reading and to be given an opportunity to ask questions – and you need to be able to demonstrate that if called upon to do so at a later date.

Some practitioners have patients read and sign the consent form in their presence, and then witness the patient's signature themselves after answering any questions the patient may have. More commonly the consent form is a part of the documentation completed by a new patient upon arrival at the office for the initial consultation and/or treatment. The sample form in Figure 1 is prepared on that basis. However, it should be noted:

a) The form expressly invites the patient to discuss the contents of the consent form with the clinician before completion if desired.

b) This offer should be verbally reinforced by the assistant who gives the form to the patient and witnesses the patient's signature.

c) During the consultation, and before treatment, it is important that the clinician should confirm with the patient that s(he) has *completed* and *understood* a consent form, and then ask for and answer any questions the patient may have. Importantly, note on the patient file that this was done.

d) All these steps should be taken on a routine basis with each new patient – so that evidence of such a routine can support the facts on any individual disputed case that may arise.

e) In the US, where health professionals are at particular risk of being sued by patients because of societal attitudes, many chiropractors adopt the risk management practice of formally recording the patient's status at the time of the informed consent process, together with any questions asked and information supplied. A sample form for that appears in Figure 2. Indeed, further than that, many medical doctors and their clinics and hospitals insist upon a videotaping of the consent process before invasive medical or surgical procedures so that later claims of incapacity or confusion by the patient can successfully be defended.

F. Frequently Asked Questions.

7. How often do I need to have a patient sign an informed consent form? If the consent form, like the sample given, applies to all manual therapy to the spine and extremities, then in most cases it only needs to be completed by a patient once – it applies to all present and future care. Chiropractors are in a different position than, for example, dentists and surgeons who need separate consents for different dental and surgical procedures that have differing risk rates.

There will be cases where it is necessary or wise to obtain a further signed consent. An example may be a patient previously treated for low-back or leg pain with lumbar adjustment only who consults you some weeks, months or years later with markedly different symptoms such as severe neck pain and/or headaches and/or vertigo for which you propose cervical adjustment. If in doubt, obtain a further signed consent. Additionally some practitioners choose to update all patient information annually, and have patients complete another consent at that time.

8. What about management approaches used in chiropractic practice other than manual treatment, such as electrotherapy, rehabilitative exercises, nutritional supplements, acupuncture

Figure 2
Patient Status at Time of Informed Consent Process

Based on my personal observations of the patient's medical history and direct conversation with the patient, I conclude that throughout the consent process the patient was:

- ☐ Of legal age
- ☐ Well-oriented
- ☐ Disoriented as to …….
- ☐ Coherent and lucid
- ☐ On prescription/OTC medication but unimpaired
- ☐ Proficient in understanding the English language
- ☐ Assisted in understanding by an interpreter. (Interpreter's name……)
- ☐ Resolute in denying the use of alcohol and/or recreational drugs prior to consent
- ☐ Unable to give legal consent
- ☐ Consent given through legal guardian

Name_____ Relationship_____

Patient's questions (if any) and information supplied are as follows:

_____
_____
_____
_____
_____
_____

Comments:

_____
_____
_____
_____
_____
_____

I certify that the above accurately describes the above named patient's status during the informed consent process on:

Date_____ Signature of Doctor_____

(Reprinted with permission by Charles W. Theisler, from his Form and Sample Letter Book).

– should they and their risks be mentioned? The issue is whether or not these interventions or any other treatments being used pose a material risk to the patient. Many hold the view that they do not in the context of appropriately qualified chiropractic practice – and may even distract the patient's attention from the more clear material risks. Therefore there is no need to mention them. Again, however, this is a matter for a clinician's own professional judgement according to the standards of his or her community.

G. Conclusion

9. This Report is read in many countries with many different cultures and legal systems. In most western world countries, however, the public is well aware that all treatments carry some risk, that patients have a right to know about these risks, and that individuals must commonly sign consents with respect to health care – and indeed in many other areas such as school trips for children. Patients approve of being fairly informed of risk, and fears of the opposite must not stop health professionals including chiropractors, from fulfilling their duties in this area.

To conclude with an anecdote, Dr. Vern Welsh, a much admired senior chiropractor in Ontario, Canada, sat on the Ontario Chiropractic Association Board of Directors in the 1980s as the use of consent forms disclosing the risk of stroke was first widely introduced. He had the usual concern about how his patients would respond as he began to use such forms, and whether some new patients might refuse care.

One year later he reported that only three patients had expressed any concern, each was easily reassured, and no patient had refused treatment. To the many who thanked him for informing them of the possible risks of care, his habit was to reply "lie down on the table – there's more chance I'll die from the effort of giving you an adjustment than that you'll come to any harm".

The message? Clinicians must be conscientious about the process of informed consent but, because patients are generally more comfortable about it than you and because of the inherent worth and safety of chiropractic care compared with most other options, lighten up about the subject and "just do it." TCR

References

1 Haldeman S, Chapman-Smith D, Petersen DM, eds. (1993) *Guidelines for Chiropractic Quality Assurance and Practice Parameters: Proceedings of the Mercy Center Consensus Conference*. Gaithersburg, Maryland: Aspen Publishers.

2 Salgo v Leland Stanford Jr. University Board of Trustees, 317 P2d 170 (Cal 1957).

3 Haldeman S, Kohlbeck FJ, McGregor M (2001) *Unpredictability of Cerebrovascular Ischemia Associated with Cervical Spine Manipulation Therapy: A Review of Sixty-Four Cases After Cervical Spine Manipulation*, Spine 27(1):49-55.

4 Kutz J, Chapman-Smith DA, Morris CE (2006) *Risk Management for Low Back Syndromes*, Chapter 36 in *Low Back Syndromes: Integrated Clinical Management*, ed. Morris CE, McGraw Hill, New York.

5 Terrett AGJ (2001) *Current Concepts in Vertebrobasilar Complications Following Spinal Manipulation*, NCMIC Group Inc., West Des Moines, IA.

6 Haldeman S, Carey P et al. (2001) *Arterial Dissections Following Cervical Manipulation: The Chiropractic Experience*, CMAJ 165(7):905-906. This and other references justify arisk rate as little as 1 in 6 million treatments, but most experts currently adopt the more conservative estimate of 1 in 1 million.

7 Reibl v Hughes (1980) 2 SCR 880, 114 DLR(3d) 1, 14 CCLT 1, 33 NR 361.

8 Mason v Forgie (1984) 59 NBR (2d) 320; (1986) 30 DLR(4th) 548.

9 Campbell LK, Ladenheim CJ et al. (1993) *The Chiropractic Form and Sample Letter Book*, Health Services Publications, Fincastle, Virginia.

continued from page 5

vertebral Disc Chondrocyte Proteoglycan Production and Cell Proliferation, Spine, 31(10):1094-1099)

Dr. Erwin's ground-breaking work in such an important field, which is now progressing to human studies, has already produced international notice – next year he attends a meeting in Hong Kong limited to 25-30 of the world's top disc scientists – and is the focal point of a current plan to establish a world disc biology centre in Toronto.