



**National
Chiropractic
Council**

**YOUR
INFORMED CONSENT
PACKET**

National Chiropractic Council

800-622-6869

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Implementing Informed Consent Process

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The best, most conscientious and responsible doctors of chiropractic, applying the highest standards and most established procedures and protocols, can still be named in a malpractice claim. This is a fact of professional life in a litigious society. One of the easiest strategies to protect yourself from a possible malpractice claim is the use of the Informed Consent Process. In fact, written informed consent is required by law in many states. If a malpractice claim is made and it is found that the informed consent form was not discussed and signed off on, you may be found liable even if your care was entirely professional. This type of exposure is very serious and entirely avoidable.

You can help better protect yourself from certain causes of action—the basis upon which a malpractice claim is made. In the absence of the informed consent process - should an adverse event occur - the lack of informed consent by itself can be a cause of action. You can help remove this cause of action by implementing informed consent, maintaining good documentation and improving your doctor/patient communication.

Here are a few key points to consider when implementing an Informed Consent in your office:

1. **All new and existing patients** should complete the Informed Consent. Advise all existing patients that you are simply updating their patient information. You may want to include additional information to be completed at the same time. Example: list medications, supplements etc., or any new medical history.
2. **Make this a standard part of your intake process.** You should include a written Informed Consent as a standard part of your intake paperwork. If your form is properly worded, you should only need to obtain this once from a patient. Some offices will have the consent as part of their electronic office management system. Others use traditional paper forms for the patient to sign. You should have the patient sign and date the Informed Consent. You should maintain the signed copy of the Informed Consent in the patient's file and should also provide the patient a copy of the consent document they signed.
3. **Obtain the Informed Consent before care is provided.** Be sure that you obtain a written Informed Consent before any care or evaluation / diagnosis is conducted. This applies across the board for ALL patients – new and existing, unless an appropriate consent has already been obtained. You are seeking an authorization from the patient to proceed with the necessary examination and treatment procedures. The consent should be revisited if your recommendations involve non-standard treatment modalities.
4. **Be open and informative with patients.** During the doctor/patient consultation, the Chiropractor should review the consent, ask if there are any questions and respond. The conversation should be in layman's terms and the patient should have the opportunity to ask questions and gain clarification. The patient records should be noted indicating the patient was provided with an informed consent, it was reviewed with the patient by the chiropractor and questions asked by the patient and how they

were responded to should be documented. Always be prepared with facts and research.

5. As a proactive practitioner, remember to approach each patient interaction as an opportunity to orient them to what they can expect from chiropractic care. This is especially true if they are first-time patients. While most patients will experience an immediate benefit from chiropractic care, not all patients will react in the same way. A frank discussion of possible temporary or short-term discomfort (possible soreness, etc.) helps patients keep things in better and more realistic perspective. This also serves to increase your credibility with the patient, as well as your defensibility should any unforeseen issue arise.
6. Such frank and open dialogue can only strengthen the doctor/patient relationship, address patient concerns in a direct and honest manner and enhance the positive nature of the chiropractic experience. Ultimately, if a patient voices serious concerns, don't be afraid to politely offer them the option of considering other care. Usually this will cause a patient to relax, but, if not, perhaps they weren't ready for care after all.
7. **Use a professionally drafted Informed Consent.** We have worked with experienced chiropractic attorneys and chiropractors to create the enclosed Informed Consent. This Informed Consent addresses many of the risks associated with some of the more common chiropractic treatment modalities. If you are using modalities with risks not addressed in this Informed Consent, you will want to customize your form to advise patients of those additional risks. For an informed consent to be legal it must detail potential benefits and risks of the procedure, as well as common alternatives to the procedure-including refusing care and the risks associated with that decision.
8. **Adapt the informed consent** to add or eliminate procedures consistent with your own personal practice.

Informed Consent to Care

You are the decision maker for your health care. Part of our role is to provide you with information to assist you in making informed choices. This process is often referred to as “informed consent” and involves your understanding and agreement regarding the care we recommend, the benefits and risks associated with the care, alternatives, and the potential effect on your health if you choose not to receive the care.

We may conduct some diagnostic or examination procedures, if indicated. Any examinations or tests conducted will be carefully performed, but may be uncomfortable.

Chiropractic care centrally involves what is known as a chiropractic adjustment. There may be additional supportive procedures or recommendations as well. When providing an adjustment, we use our hands or an instrument to reposition anatomical structures, such as vertebrae. Potential benefits of an adjustment include restoring normal joint motion, reducing swelling and inflammation in a joint, reducing pain in the joint, and improving neurological functioning and overall well-being.

It is important that you understand, as with all health care approaches, results are not guaranteed, and there is no promise to cure. As with all types of health care interventions, there are some risks to care, including, but not limited to: muscle spasms, aggravating and/or temporary increase in symptoms, lack of improvement of symptoms, burns and/or scarring from electrical stimulation and from hot or cold therapies, including, but not limited to, hot packs and ice, fractures (broken bones), disc injuries, strokes, dislocations, strains, and sprains. With respect to strokes, there is a rare but serious condition known as an arterial dissection that involves an abnormal change in the wall of an artery that may cause the development of a thrombus (clot) with the potential to lead to a stroke. This occurs in 3-4 of every 100,000 people, whether they are receiving health care or not. Patients who experience this condition often, but not always, present to their medical doctor or chiropractor with neck pain and headache. Unfortunately, a percentage of these patients will experience a stroke. As chiropractic can involve manually and/or mechanically adjusting the cervical spine, it has been reported that chiropractic care may be a risk for developing this type of stroke. The association with stroke is exceedingly rare and is estimated to be related in one in one million to one in two million cervical adjustments.

It is also important that you understand there are treatment options available for your condition other than chiropractic procedures. Likely, you have tried many of these approaches already. These options may include, but are not limited to: self-administered care, over-the-counter pain relievers, physical measures and rest, medical care with prescription drugs, physical therapy, bracing, injections, and surgery. Lastly, you have the right to a second opinion and to secure other opinions about your circumstances and health care as you see fit.

I have read, or have had read to me, the above consent. I appreciate that it is not possible to consider every possible complication to care. I have also had an opportunity to ask questions about its content, and by signing below, I agree with the current or future recommendation to receive chiropractic care as is deemed appropriate for my circumstance. I intend this consent to cover the entire course of care from all providers in this office for my present condition and for any future condition(s) for which I seek chiropractic care from this office.

Both parties agree that this agreement may be electronically signed, and that the electronic signatures appearing on this agreement are the same as handwritten signatures for the purposes of validity, enforceability, and admissibility.

Patient Name: _____ Signature: _____ Date: _____

Parent or Guardian: _____ Signature: _____ Date: _____

IN ADDITION PLEASE SIGN THE ARBITRATION AGREEMENT PROVIDED



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Manual Spinal Care and a Relationship, If Any, to Cervical Arterial Dissection

Over the past several decades the question of a possible relationship between manual care of the cervical spine and the occurrence of cervical artery dissection, most notably, vertebral artery dissection has been discussed in case reports and case series in the scientific literature. The vast majority of these case reports and case series pre-date the latest understanding of cervical arterial dissection. In addition these case reports and case series also pre-date the more reliable and sophisticated study formats such as case-control studies and case-crossover studies.

These more recent and higher powered research efforts have shifted the thinking about this phenomenon in important ways. The “old” perspective and the “new” perspective are as follows:

“Old” view:

1. Patient presents for chiropractic care often with neck pain and/or headache, a cervical spine adjustment is administered in response to the patient presentation and findings
2. Patient develops signs and symptoms of an arterial dissection and progresses on to develop symptoms and direct evidence of a stroke
3. Conclusion: The chiropractic care caused the dissection which in turn caused the stroke

“New” view:

1. Patient presents for chiropractic care often with neck pain and/or headache, a cervical spine adjustment is administered in response to the patient presentation and findings
2. Patient develops signs and symptoms of an arterial dissection and progresses on to develop symptoms and direct evidence of a stroke
3. Presenting neck pain and/or headache are appreciated as signs of a dissection in progress
4. Conclusion: The patient was in the process of dissection when they presented for care to the chiropractor

The “New” view is supported by population studies involving over 100 million person/years that demonstrate no greater likelihood of a person presenting for health care to their primary medical provider or their chiropractor with neck pain and/or headache developing a stroke. Therefore the issue is the patient’s circumstance not what was done to the patient.

You quite reasonably might ask, "If this is the case why are we continuing to hear about this situation being related to chiropractic care?"

First, arterial dissection and a related stroke are very important events and have the potential of causing long-term disability and death. If there is anything we can do to minimize this potential we must educate ourselves and be alert to how we can help avoid this problem. Second, this type of arterial dissection, and the stroke associated with it, represents a significant portion of strokes in persons from 25-40 years of age. These are not end-of-life events occurring in the final years of life, rather they are occurring in the prime of life and while all strokes deserve our attention, these even more so. Third, in the simple equation for the consumer is: this is a problem in the neck, we do something to the neck, if this follows something we did, we must have caused it. The fact that the situation is far more complex and nuanced is lost on much of the public. Fourth, this is a very rare occurrence and when it does occur it garners a good bit of attention.

We need to understand, appreciate and be aware of matters related to this clinical area at a higher level than any once else in health care. This allows us to be more suspicious of presenting symptoms with this condition in our minds, it allows us to provide current, accurate and evidence-based information to patients, other providers and the media when necessary.

Let's look at some of the facts and figures of the circumstances of arterial dissection related stroke as well as some of the most current literature on the subject:

Stroke in the U.S. Population: In General,

Washington Post, June **16, 2014** "Strokes, long on the decline in the elderly, are rising in the younger population"

Stroke in the U.S. Population: Specific to Chiropractic

Current Emergency Room (ER) protocols involve questioning all stroke and possible stroke patients about any chiropractic care they may have received. This will yield a distorted response as many, many people who have strokes have seen a chiropractor and there is absolutely no relationship between the events.

Best Available Data

750,000 strokes occur in the U.S. annually. Strokes arising from dissection of a vertebral artery occur at a rate of **1** per **133,000** population. If there are **315** million people in the U.S. we can expect **2,368** of these strokes to occur each year. This means we are not associated in anyone's mind with **747,632** of 750,000 strokes annually in the U.S. ($750,000 - 2,368 = 747,632$).

If **10%** of the U.S. population seeks chiropractic care annually then we could anticipate **237** of these strokes to cross the path of a chiropractor. If we estimate that there are 65,000 chiropractors practicing in the U.S. then **1** in **275** chiropractors may have this situation present in their offices.

It is estimated that one vertebral artery related stroke is associated with every 1-2 million cervical spinal adjustments. Persons who experience a vertebral artery dissection related stroke make a good recovery 75% of the time and the stroke is fatal 5% of the time. Therefore one fatality could be expected to be associated with every 20-40 million cervical spine adjustments.

Association versus Causation:

Many things in life are associated with one another; that does not mean there is a cause and effect relationship between them. For example, firemen are associated with house fires but firemen don't cause house fires. Similarly chiropractic care is associated with vertebral artery dissection related stroke, but, it has not been established that chiropractic cervical spine adjustments are causing vertebral artery related dissections and strokes.

“Risk of Vertebrobasilar Stroke and Chiropractic Care”, Cassidy et al. SPINE Volume 33, Number 45, pages: S176-S183

“Because the association between chiropractic care and VBA stroke is not greater than the association between PCP visits and VBA stroke there is no excess risk of VBA stroke from chiropractic care.”

“We have not ruled out neck manipulation as a potential cause of some VBA strokes. On the other hand it is unlikely to be a major cause of these rare events. Our results suggest that the association between chiropractic care and VBA stroke found in previous studies is likely explained by presenting symptoms attributable to vertebral artery dissection.”

Cassidy and associates compared the rate of vertebral artery related stroke among patients who had recently seen their primary medical provider and compared the rate of vertebral artery stroke among patients who recently saw a chiropractor. The discussion assumes the primary medical provider is not providing cervical spine adjustments and that the chiropractor is. In this situation there was no greater incidence of strokes among patients who had seen a chiropractor versus a primary medical provider. Therefore it was reasoned that there is nothing that the chiropractor is doing that increases the rate of occurrence of vertebral artery dissection related stroke. The table below compares patients of chiropractors versus primary medical care providers, compares them if they presented with neck pain or headache (symptoms of vertebral artery dissection) and compares them based on being above or below age 45. The odds of chiropractic care being associated with a vertebral artery stroke did not exceed the odds of a primary medical care visit being associated with such a stroke in five of the six data sets. In the 6th the difference was statistically insignificant. (The lower the number, the lower the odds)

Table 7. Odds Ratios and 95% Confidence Intervals (CI) and Accelerated and Bias Corrected Bootstrap 95% CI for Case-Control and Case Crossover Estimates of the Association Between the Total Number of Chiropractic (DC) and Primary Care Physician (PCP) Visits in the Month Prior to the Index Date

Exposures	All Cases		Age <45 yr		Age ≥45 yr	
	Odds Ratio (95% CI)	Bootstrap 95% CI	Odds Ratio (95% CI)	Bootstrap 95% CI	Odds Ratio (95% CI)	Bootstrap 95% CI
Case control estimates						
Any DC visit	1.14 (1.02–1.27)	1.00–1.27	1.58 (1.19–2.10)	1.19–2.19	1.01 (0.86–1.17)	0.83–1.18
Any PCP visit	1.77 (1.31–1.93)	1.61–1.94	2.12 (1.58–2.84)	1.53–3.01	1.73 (1.17–1.90)	1.58–1.91
Headache or cervical DC visit	1.13 (0.8–1.30)	0.96–1.31	1.57 (1.17–2.11)	1.08–2.18	0.95 (0.77–1.18)	0.67–1.20
Headache or cervical PCP visit	6.33 (4.27–9.37)	4.38–9.18	10.00 (3.26–30.63)	*	5.87 (2.85–8.95)	4.04–9.04
Case crossover estimates						
Any DC visit	1.10 (0.99–1.22)	0.97–1.24	1.37 (1.10–1.70)	1.04–1.91	0.96 (0.84–1.14)	0.80–1.15
Any PCP visit	1.49 (1.36–1.63)	1.34–1.66	1.34 (1.05–1.70)	0.94–1.87	1.52 (1.18–1.67)	1.36–1.68
Headache or cervical DC visit	1.18 (1.12–1.37)	0.99–1.45	2.80 (1.13–5.48)	*	1.01 (0.43–1.22)	0.74–1.29
Headache or cervical PCP visit	3.99 (2.88–5.53)	2.74–5.80	10.64 (3.45–32.78)	3.53–43.56	3.53 (2.51–4.98)	2.35–5.25

*Unable to compute due to small numbers.

“Etiology of Cervical Artery Dissection: The writing is in the wall”, Schievink, Neurology 2011;76;1452

“...it is not the intimal layer but rather the media and adventitia that are primarily affected in cervical artery dissection...(these findings) confirm the existence of an underlying systemic arteriopathy in patients with spontaneous cervical artery dissection and they suggest that the outer layers are primarily involved in the causation of the intramural hematoma...”

This article details the likelihood of an underlying abnormality in the histology of the arterial wall (arteriopathy) that greatly predisposes persons to dissection in their arteries, including the vertebral artery.

“Vertebral artery strains during high speed low amplitude, cervical spinal manipulation”, Herzog, Journal of Electromyography and Kinesiology;22:12 740-746

“Vertebral artery strains obtained during SMT are significantly smaller than those obtained during diagnostic and range-of-motion testing, and are much smaller than failure strains. We conclude from this work that cervical SMT performed by trained clinicians does not appear to place undue strain on the VA, and thus does not seem to be a factor in vertebrobasilar artery injuries.”

Herzog et al. have compared the strains created on a vertebral artery during a diversified cervical spine adjustment. They compared this to the strains found when doing a routine cervical range of motion study and they compared both with the level of strain needed to injure a healthy vertebral artery.

The level of strain needed for the artery to fail was nine times greater than the forces created during the spinal adjustment. The cervical range of motion study was found to create more strain than the cervical spine adjustment but again well less than the forces required for arterial failure.

“Chiropractic and stroke: association or causation?” Tuchin, Int J Clin Pract, September 2013, 67, 9, 825-833

Conclusion: There is lack of compelling evidence that SMT is causally associated with stroke. Physical triggers, including SMT, can serve as plausible final link between the underlying disease and stroke (for instance, in case of arterial dissection with existing connective tissue weakness). It appears few of Hill's criteria for causality appear connected with VAD and chiropractic.

“There may be some links or association with SMT and VAD in untrained practitioners, but this has not been established with chiropractors. The quality of evidence suggesting causation between chiropractic and VAD is mostly weak. Therefore, causality between chiropractic and vascular accidents has not been determined. It is possible that healthcare practitioners are not taking a thorough history to determine the cause of the VAD after SMT. Healthcare practitioners are probably missing many clinical facts, because they now only record the patient having SMT.”

“They should enquire about other possible causes or circumstances for VAD. This may include minor neck trauma, a change in chronic neck pain or headache, recent infection or other predisposing lifestyle factors such as smoking, hyperlipidaemia, hypertension, and hyperhomocysteinaemia. Therefore, it is important that healthcare practitioners take a thorough clinical history to determine the cause of VAD. Systematic prospective studies are needed to assess the safety of cervical spine SMT with regards to cerebrovascular events. Such studies should also account for the education of the practitioner”.

“Changes in vertebral artery blood flow following various head positions and cervical spine manipulations”, JMPT 37(1) 22-31 Quesnele et al.

Findings: “The side to side differences between ipsilateral and contralateral Vertebral artery velocities was not significant for either velocities or flows throughout the conditions.”

Conclusion: “There were no significant changes in blood flow or velocity in the Vertebral arteries of health male adults after various head positions or cervical spine manipulation”

In a neutral head position physiologic measures of blood flow and velocity at the C1-C2 spinal level were obtained using phase contrast MRI after three different head positions and after an upper cervical manipulation. Thirty (30) flow encoded phase contrast images were collected over the cardiac cycle. Differences in flow and velocity were repeatedly analyzed. These analyses did not reveal any meaningful changes in blood flow or velocity that would predispose a patient to injury to the vertebral arteries or that would create an environment more likely to generate a thrombotic event.

Signs and Symptoms to be Alert To

1. Patients with a personal or family history of collagen disorders such as Marfan's Disease, Ehler-Danlos Syndrome etc.
2. Patients who present describing a headache or neck pain as the “most unusual pain in their head (or neck) that they ever had”

3. Patients with any of the 5 Ds (dizziness, diplopia, drop attacks, dysarthria, dysphagia), the 3 Ns (nausea, numbness, nystagmus) or an A (ataxia) [Patients often present for chiropractic care with numbness or dizziness, these are not necessarily contraindications but may be when other neurological symptoms are present]
4. Patients that demonstrate a worsening of any of the 5Ds, the 3 Ns or the A after an adjustment
5. Patients that develop new symptoms, particularly related to Cranial Nerve dysfunction, sensory disturbances or motor function, following an adjustment.

Time is of the essence for a patient experiencing an arterial dissection and/or stroke. It is urgent that you seek emergency medical services for a patient who complicates as noted above.

Every person involved in health care, regardless of the discipline or clinical approach, wants each patient to be healthier and happier as a result of the care provided to them. We, like all other providers need to be attentive to the presentation of our patients and to consider those circumstances that call for caution in providing care, withholding care or referring that patient for additional evaluation and consultation before delivering care. Because there are so few adverse effects of chiropractic care and because we are not called upon to deal routinely with the complications of care other disciplines it is easier to be less attuned to areas of concern—this is something we must not allow ourselves to do.

The steps to keep everything in focus are not difficult. They are routine in health care and deserve our attention. We suggest you consider the following “Top-Ten” procedures:

1. Complete a pertinent history at the time the patient presents for care. The history should reflect the patient presentation as well as your clinical judgment.
2. Complete a pertinent physical examination, don't see the patient as low back pain or headaches, but see them as a whole. Check their vital signs and provide an examination that correlates with the patient presentation and concerns developed from the history and other elements of the physical examination.
3. Seek additional studies to rule out any contraindications to chiropractic care and a more thorough understanding of the structure of the spine or areas to which care is being provided.
4. Don't hesitate to refer a patient to another chiropractor or other provider type if you are concerned about the presentation of the patient or any of your examination findings
5. Develop a care plan for each patient, provide them with a complete explanation of the care you propose to provide, do all you can to make certain they understand your recommendations
6. Provide the patient with an “informed consent to care”. Ideally this should include what you are proposing to do, why you feel it is needed, alternative to your care recommendations and the impact of them doing nothing in response to their circumstances. Document the informed consent in writing, preferably signed by the patient after providing them with an opportunity to ask you any questions about the plan.

7. Document your care, what you did-what was adjusted, how it was adjusted etc., the response to your care, feedback of the patient and any change in circumstances. Always relate their care back to their presenting circumstances and the findings you developed in your evaluation of the patient. If a patient complicates for any reason be as thorough as possible in documenting the events before, during and following the complication.
8. Re-evaluate the patient whenever there has been a change in their circumstances or after a given interval of time or number of adjustments.
9. Maintain and store your records appropriately, remember the demands of HIPAA!
10. Provide the kind of care to each patient that you would like to see your mother, father, brother, sister, husband, wife or child receive.