Cervical spine manipulation, a procedure with a rare but potentially disastrous adverse reaction: Exploring the ethical dimensions

Acknowledgements:

Firstly I would like to thank the Health Research Council (HRC) and Auckland University of Technology for offering the opportunity to undertake the HRC Ethics of Health Research Summer Studentship (2010/2011). Secondly I want to express my earnest appreciation and thank both my supervisors Duncan Reid DHSc and Kate Diesfeld BS, JD for their positive, kind and constructive guidance during this research. Their contribution has informed all parts of this project and I have grown academically under their skilled supervision as well as thoroughly enjoying the process.

Abstract:

High-risk procedures with limited or unestablished evidence bases are common to all health disciplines and create an ethical dilemma for many practitioners. Cervical Spine Manipulation (CSM) is a procedure carried out across alternative, complementary and traditional health disciplines to treat neck pain. The technique carries the infrequent yet tragic risk of stroke or death. The evidence for the effectiveness of the technique is growing however it is unclear whether the technique is more beneficial than alternative treatments that do not involve the same risk. Screening guidelines implemented to minimise the risk have been found to be unreliable. Therefore this project will look at applying an ethical framework, which balances four key ethical principles, to the topic of CSM. The principles of beneficence (creating good), autonomy (freedom of intentional choice), non-maleficence (do no harm) and justice (fair and equal rights) will be applied to the issue. This project will be carried out with the intention to provide insight into the universal issue of high-risk, limited evidence based health procedures, as well as the particular issue of CSM. The project will explore the four-principle framework as a medium for deliberating on these types of challenging ethical dilemmas.

Rose Culy; ID 0771193
Year III Physiotherapy Undergraduate
School of Rehabilitation and Occupational Studies
Auckland University of Technology (AUT)

Supervisors:
Duncan Reid DHSc
Kate Diesfeld BS, JD
CONTENTS

1 INTRODUCTION ......................................................................................................................... 3

1.1 THE ISSUE: CSM, A HIGH-RISK PROCEDURE BASED ON AMBIVALENT EVIDENCE ...................... 3

2 NEW ZEALAND HEALTH CARE LEGAL FRAMEWORK .................................................................. 4

3 A FOUR PRINCIPLES ETHICAL APPROACH TO CERVICAL SPINAL MANIPULATION ....................... 5

4 THE PRINCIPLE OF AUTONOMY ............................................................................................... 5

4.1 ETHICAL DELIBERATION OF CSM GUIDED BY THE PRINCIPLE OF AUTONOMY ......................... 5

4.1.1 Autonomy requires communicating sufficient information ................................................. 5

4.1.2 Autonomy requires adequate understanding ...................................................................... 5

4.1.3 Autonomy requires that significant risks be disclosed ....................................................... 6

4.1.4 Autonomy requires respecting patients' expectation to receive a service .............................. 6

4.1.5 Autonomy requires communicating the degree of evidential support ................................. 6

5 THE PRINCIPLES OF BENEFICENCE AND NON-MALEFICENCE ............................................... 7

5.1 ETHICAL DELIBERATION OF CSM GUIDED BY THE PRINCIPLES OF NON-MALEFICENCE AND BENEFICENCE ............................................................................................................. 7

5.1.1 When paternalistic beneficence conflicts with autonomy .................................................. 7

5.1.2 Do the benefits outweigh the risks? .................................................................................. 8

5.1.3 Do the risks outweigh the benefits? .................................................................................. 8

5.1.4 Alternative treatments produce the same benefit as CSM without the risk ....................... 8

6 THE PRINCIPLE OF JUSTICE .................................................................................................... 9

6.1 ETHICAL DELIBERATION OF CSM GUIDED BY THE PRINCIPLE OF JUSTICE .............................. 9

6.1.1 Justice requires equal distribution of resources ............................................................... 9

6.1.2 Justice requires equal communication of knowledge ....................................................... 9

6.1.3 Justice means equal standards of care ............................................................................ 10

6.1.4 Justice requires equal protection for all ........................................................................... 10

6.1.5 Justice in New Zealand requires consideration of Maori ethical principles .................. 11

7 CRITIQUE OF THE FOUR PRINCIPLES APPROACH ................................................................ 11

7.1 OTHER WIDER CONSIDERATIONS INCLUDE ........................................................................ 12

7.1.1 Emotional values ............................................................................................................. 12

7.1.2 Harm to profession ......................................................................................................... 12

8 RECOMMENDATIONS FOR THE FUTURE .................................................................................. 12

9 CONCLUSION ............................................................................................................................ 13
1 Introduction

An ethical issue that presents across alternative, complementary and traditional areas of health is the use of procedures of high risk, with inconclusive, limited, or controversial, evidence bases. Cervical Spine Manipulation (CSM) is a clinical example of a high-risk intervention with an uncertain evidence base. A critical review of the literature on CSM will be employed to explore this issue. The Four Principles ethical framework will be applied to address this specific example while attending to the issue in a wider context. Additionally, the project will allow exploration and critique of the usefulness of the four principles, giving comparison with other approaches and recommendations for the future.

A current understanding of Evidence Based Healthcare (EBH) is critical. EBH should be employed through a willingness to change practice according to strongest evidence accompanied by integrated observation of clinical and patient circumstances (Bronfort, Haas, Evans, Leininger, & Triano, 2010; Sackett, 1998). Modern consumers of health care are knowledgeable and concerned about evidence-based justification for treatments. EBH is sometimes criticised, placing practitioners in an ethical quandary when literature provides an inconclusive, weak or contentious picture of efficacy.

My interest in ethical decision-making was prompted by the usefulness and confidence it gave me when making decisions as a student without much clinical experience. Decisions are rarely black and white and ambiguity can produce conflict. Ethical frameworks provide individuals with the capacity to justify and rationalise action and portray an effectively debated thought process in making that decision. My chosen university and career path is in physiotherapy and I found the issue of CSM highlights the difficulty of making decisions, when there is a controversial and insufficient evidence base. Analysing the issue through the lens of an ethical framework provides a guide for practicing the technique and gives insight into the usefulness of that framework.

1.1 The issue: Cervical Spine Manipulation, a high-risk procedure based on ambivalent evidence

Mechanical neck dysfunction is a prevalent and costly disorder (Cote, Cassidy, & Carroll, 1998; Côté, Cassidy, Carroll, & Kristman, 2004; Linton, 1998). Neck dysfunction can cause pain, cervicogenic headache, stiffness, limited function and decreased quality of life. One form of treatment for these conditions is CSM, which involves passive, high velocity and low amplitude (HVLA) movements to the neck (Di Fabio, 1999). CSM is used by complementary, alternative and traditional medicine practitioners including physiotherapists, chiropractors, osteopaths, medical practitioners (Di Fabio, 1999) and traditional healers such as Maori bone setters (Hudson, 2010). While the evidence for the effectiveness of this intervention is growing (Bronfort, Haas, Evans, & Bouter, 2004; Gross et al., 2004; Hurwitz, Aker, Adams, Meaker, & Shekelle, 1996) some authors comment that this evidence may not be enough to overcome the inherent dangers involved in CSM (Di Fabio, 1999; Refshauge et al., 2002a). The major area of concern in treating the cervical spine is the close
proximity of the vertebral artery (VA) to the joints of the cervical spine (see figure. 1.). Manual therapy techniques such as CSM and mobilisation can result in a small yet serious risk of injury to these arteries leading to stroke or even death (Ernst, 2010a). The incidence for these serious events ranges from 1/163,371 (Rivett & Roid, 1998) to less than 1 in 5,000,000 (Jaskowiak, 1980), see appendix A. These figures may not reflect the true incidence, due to under-reporting and lack of a causal link with such events (Kerry, Taylor, Mitchell, & McCarthy, 2008). Different types of mechanical “trauma” such as sporting activities, activities of daily living, trauma, a minor fall, sneezing, turning the head while backing a car, fair rides and CSM may implicate the VAs causing a cerebrovascular accident (CVA) (Di Fabio, 1999; Haideman, Kohibeck, & McGregor, 2002; Kawchuk et al., 2008). The primary mechanism of cerebrovascular insult, occurring post CSM, is vertebral artery dissection (VAD) (Ernst, 2007; Taylor & Kerry, 2010). VAD occurs due to a disruption or tear to the lining of the blood vessel (Taylor & Kerry, 2010) causing blood to divide the outer and inner layer of the arterial wall leading to thrombus and stenosis (M.J. Haynes, 2002). A widely documented risk factor for a serious adverse event or VAD is vertebral-basilar insufficiency (VBI), which is a transient or permanent reduction in blood supply to the hindbrain causing particular signs and symptoms (Taylor & Kerry, 2010), these include difficulty speaking, double vision, difficulty swallowing, dizziness, drop attacks, nausea, rapid alternating eye movements and numbness of the face, lips, and tongue. Guidelines have been implemented by the physiotherapy profession to help identify and screen for those at risk following a HVLA procedure (Rivett, Shirley, Magarey, & Refshauge, 2006). These guidelines incorporate relevant questions about risk, as well as physical tests of the structures in the neck. However these screening procedures and tests have been shown to be unreliable (Rivett, Thomas, & Bolton, 2005) and some authors have argued these tests should not be used at all, as they may even precipitate a stroke in certain circumstances (Gibbons & Tehan, 2006; Thiel & Rix, 2005).

2 New Zealand healthcare legal framework

Contemporary attitudes toward health care in New Zealand have encouraged an interesting transition to a consumer-focused environment, which is reflected in the law (Haswell, 1996; Sladden, 2001). In New Zealand a range of legislation safeguards public health and promotes the quality of health services (Paterson, 2007). The Health Practitioners Competence Assurance Act (HPCAA) (2003) ensures health providers are competent to practice their professions. Under the HPCAA (2003) CSM is a restricted activity to regulated health professionals of which the intervention falls under their scope of practice (these are physiotherapists, chiropractors, osteopaths and doctors specialising in manipulative manual medicine). The Health and Disability Commissioner Act (HDCA) (1994) promotes and protects the rights of those receiving a health or disability service (Sladden, 2001) through the Code of Health and Disability Services Consumer’s Rights (CHDSCR) (HDC, 1996). The Code provides a comprehensible, accessible set of consumer rights and associated provider responsibilities (Sladden, 2001). A range of breaches of the rights four through seven, involving standard of care and Informed consent, are portrayed across case law reports involving CSM (HDC, 1998, 2002, 2003, 2004, 2008a, 2008b). This suggests that these rights are central when concerning CSM and more generally, any interventions of high risk and uncertain evidence bases.
3 A Four Principles approach to Cervical Spinal Manipulation

Principlism is an ethical framework, which balances four principles significant in health care, autonomy, non-maleficence, beneficence and justice (Beauchamp & Childress, 2009). The Four Principles approach can be a practically applied framework, which provides a thorough reflection on a situation (Pierce & Randels, 2010 79). A principle is a general guide or rule for conduct, with scope for interpretation between individuals (Pierce & Randels, 2010). When conflict arises between principles, the practitioner must weigh and balance them against each other (Beauchamp & Childress, 2009). The principles have no positional order to resolve conflict and the relative strength of the principles arises from particular case contexts (Pierce & Randels, 2010). This analysis will consider whether the four principles approach offers a beneficial ethical framework for making CSM decisions.

4 The principle of autonomy

Autonomy is liberty from controlling influences and the ability of deliberate action (Beauchamp & Childress, 2009). This concept is fundamental to Western medical ethics and the professional patient-practitioner relationship (Pierce & Randels, 2010). Although respecting a person’s right to choose is central to autonomy, the principle also requires a positive obligation to provide sufficient information to enable adequate understanding and empower autonomous choice (Pierce & Randels, 2010). Informed consent is intricately linked with this principle and within health care.

4.1 Ethical deliberation of CSM guided by the principle of autonomy

4.1.1 Autonomy requires communicating sufficient information

Autonomy is relevant to CSM delivery and is a central feature under rights five through seven of the CHDSCR (1996). Autonomy is initially created by communicating sufficient information that a reasonable person in that person’s circumstance would expect, as outlined within right six of the CHDSCR (1996). Next the principle of autonomy guides respect for the patient’s informed choice (1996). According to the CHDSCR (1996), relevant information a reasonable patient may want to receive includes: risks (particularly those considered material); options; benefits; side effects; prices; times; recommendations; and screening guidelines. Respecting autonomy in a discussion regarding CSM involves a discussion of all the information. For example, discussing side effects may need to include: CSM may have a minor adverse reaction of pain, stiffness or headache but this should not last long and often the pain will get worse before it gets better (Cagnie, Vinck, Beernaert, & Cambier, 2004; Ernsl, 2004; Hurwitz, Morgenstern, Vassilaki, & Chiang, 2004; Rubinstein et al., 2007)

4.1.2 Autonomy requires adequate understanding

Right five of the CHDSCR (1996), states a health consumer has the right to effective communication that enables understanding. A conscientious approach should be taken regarding communication, as the way in which information is provided can significantly impact informed choice and may compromise autonomy. For example in a case analysis of CSM by Haswell (1996) the therapist and observing therapist disagreed on the appropriate amount of disclosure. The degree of disclosure is seen as being a primary issue when considering CSM, as too much information may be confusing
and too little information may compromise autonomy. Another example may be whether a relative risk example helps a patient gain perspective or whether it manipulates the facts and compromises autonomy? Common medical interventions are claimed to have a much more frequent risk such as Non Steroidal Anti-Inflammatory Drugs (NSAIDs) or neck surgery (Dabbs & Lauretti, 1995; Jull, Margery, Niere, & Elvey, 2002). However comparing prolonged medication use to a single or limited number of CSM may be futile (Refshauge et al., 2002b; Rubinstein, 2008; Stevinson & Ernst, 2002). Drugs and medical devices are subject to post market surveillance (Stevinson & Ernst, 2002) where conversely the safety profile of CSM is not formally surveyed (Gouveia et al., 2007). A recent risk analysis showed the use of NSAIDs does not increase risk of death and using a surgery comparison may be a drastic "realistic" alternative to CSM (Refshauge et al., 2002a). When information is downscaled, manipulated or incomplete, autonomous choice may be limited.

4.1.3 Autonomy requires that significant risks be disclosed

Individuals may place differing significance on information provided. Case law demonstrates that one dimension of autonomy is informed consent. People can only assert their autonomy if they are aware of the risks. The Australian case of "Rogers v Whittaker" (1992) is relevant. According to Manning (2007) the case is highly relevant to the autonomy principle in New Zealand. In the case, a woman who consented to surgery on her blind eye was not told of the extremely rare risk that the operation might affect her good eye. Subsequently, the risk occurred, rendering the patient completely blind.

The court held the surgeon negligent in failing to inform his patient. The defence argued with reliance on the "Bolam Principle" that due to the rarity of the event it was standard for ophthalmic surgeons not to disclose the risk. Manning (2007) proposes the material risk in "Rogers v Whittaker" is relevant to the practice of CSM in that, although infrequent, permanent impairment or death following a stroke is a significant and tragic event and the risk should be disclosed as material. What may seem immaterial to practitioners due to infrequent occurrence, may be material, due to the significance or nature of the risk (in this case the significance given to retaining at least the vision she already had). New Zealand’s consumer orientated legislation highlights the patient’s right to know when there are "material" or "significant" risks involved with an intervention (HDC, 1996).

4.1.4 Autonomy requires respecting patients expectations to receive a service

A patient, who has previously had CSM and has the expectation of receiving that service, brings another element of discussion to autonomy. Because a patient has been previously informed of relevant information, it may not be necessary to provide all the information again. Protecting autonomy in this scenario may involve a quick review of the information and risks and checking the understanding of the patient. Therefore if clinically indicated, carrying out the treatment or referring on to a practitioner comfortable in providing CSM would respect autonomy.

4.1.5 Autonomy requires communicating the degree of evidential support

The degree to which the intervention is supported within the literature may be important, especially when discussing interventions with an element of high risk. Haldemman et al., (2002) states extensively differing current understandings and views of risk are unacceptable in the context of
informed patient decisions. It is difficult to inform patients when there is disagreement on the details, such as an accurate risk estimate and the efficacy of CSM (Haldeman et al., 2002). However, communicating up to date evidence and informing patients of the limitations of that evidence may still protect autonomy. Fully informing patients of the most up to date knowledge whilst clearly explaining the uncertainties within the literature allows for the patient's autonomous capacity to choose or refuse the service. Therefore to protect autonomy the discussion should include all the facts and it should be pointed out where evidence is lacking or unestablished and the degree to which this is so. For example, the estimated incidence of post CSM CVA is unknown and wide-ranging as portrayed in Appendix A. Further to this, several biases arise in determining a factual occurrence rate causing estimates to be misleading and inaccurate, these include: inadequate sample sizes (Haynes, 1994); short data collection periods; insufficient response rates; speculation of the frequency of applied CSM (Kerry et al., 2008); underreporting (Ernst, 2001; Kerry et al., 2008; Rivett et al., 2005); over-reporting; bias; and reliability in recalling past events in retrospective surveys (Kerry et al., 2008).

5 The principles of beneficence and non-maleficence

Beneficence is the positive obligation to contribute to the welfare of patients (Beauchamp & Childress, 2009). The principle involves role-related positive obligations of health professionals to provide specific duties of beneficence to their patients (Pierce & Randels, 2010). Non-maleficence is an obligation of health professionals to not inflict harm (Beauchamp & Childress, 2009). Non-maleficence is preceded and integrally linked with the Hippocratic Oath of medical tradition: “First, do no harm” (Beauchamp & Childress, 2009). Harm is generally considered as physical or mental injury (Pierce & Randels, 2010). The obligation not to impose a risk of harm on others is also understood under this principle (Pierce & Randels, 2010). According to Gillon (1994) it is important to understand the distinction and the correlation between the two principles. Therefore the following ethical analysis considers the role of risk and benefit probability to produce a "net benefit" (Gillon, 1994). These principles therefore will be used to debate a risk-benefit analysis to inform a professional decision to recommend CSM to any patient for whom the technique is clinically indicated. Nevertheless, what constitutes a "net benefit" for one patient may be a "net harm" for another (Gillon, 1994). Therefore the deliberation outlined under these principles needs to be considered in the context of the autonomous choice.

5.1 Ethical deliberation of CSM guided by the principles of non-maleficence and beneficence

5.1.1 When paternalistic beneficence conflicts with autonomy

Practitioners guided by benevolent paternalistic ethics may consider whether advising of the risk will cause unnecessary worry and jeopardise the patient not taking up the best treatment option (Haswell, 1996). This paternalistic view clearly conflicts with the principle of autonomy (Haswell, 1996). Some authors suggest that having more detail is better than not having enough and an uninformed patient may ultimately suffer more distress or anxiety (Haswell, 1996). Therefore although paternalistic values of beneficence may guide a practitioner along the path of what may be perceived as deception, clearly a patient's autonomous choice takes precedence.
5.1.2 Do the benefits outweigh the risks?

Rubinstein (2008) states that the benefit of CSM to patients suffering mechanical neck dysfunction outweighs the relatively rare risk which may be considered negligible. The literature suggests that although inconclusive, the evidence of the efficacy of the technique is heading in a favourable direction (Bronfort et al., 2010; Bronfort et al., 2004; Gross et al., 2004; Leaver et al., 2010; Rubinstein et al., 2007). There is further strong evidence that a “multimodal approach” (incorporating CSM) is the most efficacious way to treat mechanical neck dysfunction (Jull, Trott, et al., 2002). Another important ethical consideration is a lack of, or limit in, evidence does not necessarily mean that a treatment is not beneficial (Lawrence & Ernst, 2004). Even a lack of plausible effect does not rule out the potential use of an intervention. This is seen in the example of the symptom modifier for osteoarthritis, the supplement, glucosamine sulphate, and the recent conclusion that its effect on pain was beneficial, although equal to that of a placebo (Rozendaal et al., 2008). To decide to withhold benefit is also in a sense to harm (Harris, 2001). Chestnut (2004) proposes that until data is available the ethical, scientific and logical analysis based on current understanding of risk factors, must consider VAD a rare, unpredictable event associated with, however not ‘caused’ by, CSM. The risk of serious adverse events of CSM is relatively less frequent compared to other medical treatments for neck pain such as, NSAIDs or neck surgery, (Jull, Margery, et al., 2002; Rubinstein, 2008). The growing support for the place of CSM in treating neck dysfunction, combined with an opinion that the risk of CVA is so infrequent the risk should be considered negligible, supports the debate that the benefits outweigh the risks.

5.1.3 Do the risks outweigh the benefits?

Others conclude that due to the catastrophic potential consequences such as stroke or death, the risk of CSM outweighs the potential benefits (Di Fabio, 1999; Rafshauge et al., 2002a). Even though there are reservations to assuming a causal relationship, it is generally accepted and many factors validate this relationship (Ernst, 2010b; Miley, Wellik, Wingerchuk, & Demaerschalk, 2008). There is an uncertainty in the literature as to the incidence of the rare yet catastrophic adverse sequel to CSM (refer appendix A) and current evidence does not entirely support the efficacy of screening protocol (Thiel & Rix, 2005). Therefore there is an inadequate ability to minimise the risk of harm (Ernst, 1996). Even though infrequent, the risk of permanent impairment or death, is serious enough to ultimately outweigh the inconclusive potential benefits of treatment and the treatment should be restricted or discontinued completely (Di Fabio, 1999; Rafshauge et al., 2002a).

5.1.4 Alternative treatments produce the same benefit as CSM without the risk

Not all practitioners who treat mechanical neck dysfunction choose to use CSM, which means there are alternative effective methods for treating neck dysfunction (Rafshauge et al., 2002a). Manipulation to the cervical spine has been shown to be both superior (Hurwitz et al., 1996) and equal (Gross et al., 2010) to other treatments, such as mobilisation. As a result it should be debated whether the benefit of treatments with serious risk and differing conclusions of efficacy within a current evidence base, are superior to the use of an alternatively effective treatment without the risk (Ernst, 1996).
Alternative treatments include doing nothing, as often mechanical neck dysfunction is self-limiting. However, this seems unacceptable for a professional whose job is to provide treatment and unsatisfying for the patient who is in pain. Mobilisation is also currently suggested to provide a similar benefit to manipulation (Leaver et al., 2010). However, when weighing this option, it is also important to consider that there has been documented similar serious adverse events with this intervention (Kanakamedala, 2002). Exercise provides an effective alternative and does not have the same inherent risks, although it is more effective combined with manual therapy (Jull, Trott, et al., 2002). HVLA to the thoracic spine is also another option in successfully treating mechanical neck dysfunction and is gaining increasing attention in the literature (Krauss, Creighton, & Podlewska-Ely, 2008). To conclude, it is possible to provide a treatment that is going to give similar results and eliminate the rare yet potential risk when using CSM.

6 The principle of justice

Justice is an entitlement to fairness and equality (Beauchamp & Childress, 2009). Fairness and equality requires consistency (Pierce & Randels, 2010). Gillon (1994) outlines key categories of justice. Equitable distribution of resources comes under distributive justice. Respect for people’s rights is suitably named rights-based justice. In New Zealand a health consumer has the right to fully informed decisions and appropriate standards of health care (HDC, 1996). Providers of health care also have a duty to cooperate amongst themselves to guarantee continuity and quality of services to consumers (HDC, 1996).

6.1 Ethical deliberation of CSM guided by the principle of justice

6.1.1 Justice requires equal distribution of resources

Equitable distribution of resources may mean providing the most time-beneficial/cost-effective treatment. Manual therapy may be comparatively more cost effective compared to active physical therapy sessions and general practitioner care (Hurnwitz et al., 2009). A multi-modal approach (for example CSM/manual therapy and exercise) may represent the option that provides the most effective benefit in the shortest time frame. Jull et al., (2002) found that although exercise and manual therapy were both effective when treating neck dysfunction, when combined a greater percentage of people improved. Therefore, an intervention involving CSM may cost less and mean more equality in terms of distribution of resources potentially helping more people in a shorter time frame. However, it is important to recognise that if CSM is not an option in the patient identified as high risk, then the financial considerations should not be a factor in the delivery of alternative interventions.

6.1.2 Justice requires equal communication of knowledge

Similar ethical standards are seen across those certified professions restricted to perform CSM and all carry an ethical and professional responsibility to fully inform their patients (NZGB, 2004; NZMA, 2008; OCNZ; PBNZ, 2006). Unfair and unequal dissemination of CSM knowledge to patients seems to interfere with the principle of justice. Differences in communication of knowledge between individual practitioners and further between professions may occur. Haswell (1996) documented the differing
ideas of two individual physiotherapists in what established informed consent. There is also an issue of equality between professions in the process of informed consent. Although other professions do advise their members as to what information should be relayed to consumers, after correspondence with chiropractic and osteopathic leaders, it was considered that only the physiotherapy profession in New Zealand has attempted to standardise what knowledge should be communicated in the form of a screening guideline, (Rivett et al., 2006) and a "take-home" sheet to inform patients, such as provided by the New Zealand Manipulative Physiotherapists Association. There are also significant differences in professional perspectives of the frequency of post CSM complications for example higher risk estimates of the frequency of CSM is often seen in non-manual therapist's surveys compared to manual therapists (Kerry et al., 2008; Murphy, Taylor, & Marshall, 2010). Therefore it would be fair to assume that differences exist between individuals and professions when informing patients.

6.1.3 Justice means protection of patients right to equal standards of care

The justice principle applied to CSM across professions requires equal standards of care. Right four of the Code (HDC, 1996) outlines a health consumer's right to an appropriate standard of care. In particular right four (5) describes a consumer's right to cooperation among providers to ensure quality and continuity of services. Currently, different practices of the procedure and screening guidelines across the different disciplines raise ethical concerns. Professions or individual practitioners following different screening procedures can generate marked differences in standards of care. An HDC case report portrayed differing practices of the chiropractic and physiotherapeutic profession and highlighted corresponding concerns of the Commissioner (HDC, 2008a). The concerns are further highlighted by the fact that only the physiotherapy profession has implemented a guideline. Current evidence however, negates the efficacy of implemented physical screening tests (Taylor & Kerry, 2010; Thiel & Rix, 2005; Thomas, Rivett, & Bolton, 2008). Justice would require an equal standard of care by all professions using the technique. Right four of the CHDSR addresses this issue by requiring appropriate standards of care, and that right applies to CSM. Therefore, one proposal that responds to the ethical principle is consistent training and quality assurance across the professions that use the technique.

6.1.4 Justice requires equal protection for all

Those professions who are either unregistered or for whom CSM does not fall under their scope of practice (such as traditional Maori healers and barbers) will not be registered as they will not have undergone sufficient formal training in the technique. Therefore there may be an increased risk of CVA when visiting an untrained therapist due firstly, to performing more CSM with less knowledge of dangers and screening/selection procedures and due secondly to not implementing safety-screening procedures. Trained manual practitioners may incur less risk of post CSM CVA due their knowledge of the risks involved in screening and selection procedures. Therefore it is advisable to monitor restricted activities under the HPCAA.

Undoubtedly there is disparity in the level of knowledge, skill and clinical judgment between new graduate and practising and experienced manipulative therapists, even though both groups are legally
entitled to use CSM (Refshauge et al., 2002a). Are we all trained effectively and equally to a sufficient level that we would be competent in providing a treatment with such a serious risk? Physiotherapists and other therapists do recognise the risk (Rivett et al., 2006). However Refshauge et al., (2002b) question whether the skill should be restricted to those who have undertaken postgraduate education. Another question prompted is how do professional manual therapists maintain their skill level and knowledge base to adequately protect equality of informed consent and standard of care?

A guideline may be important in forming a conclusion about an infringement of the code or law and clinical practice guidelines and protocols are increasingly prominent in EBH (Manning, 2007). The chiropractic and osteopathic professions do not have published guidelines. The highest numbers of CVAs come from chiropractic CSM (Ernst, 2010a). Other manual therapy professions might consider the issue as the physiotherapy profession has done. The reliability of that guideline may also be brought to attention of an investigating body (Kerry et al., 2008). Having a regularly updated, consistent guideline across and within professions may help to provide protection for consumers’ right to an appropriate standard of care, consistent medico-legal protection for a practitioner as well as a tool for practitioners to maintain adequate skill and knowledge. Therefore it may be appropriate to now define a guideline, which protects both the patients’ right to informed consent and standard of care across the profession’s practicing the skill.

6.1.5 Justice in New Zealand requires consideration of Maori ethical principles

Te Tiriti o Waitangi (The Treaty of Waitangi) is the founding document between Maori iwi and the British Crown on behalf of the latter arrivals (Hera, 2011). The principles developed from Te Tiriti o Waitangi are pertinent to all law formed in New Zealand. In New Zealand there is an increased interest in traditional Maori healing (Ahuriri-Driscoll et al., 2008). Patients seeking alternative healthcare is a widespread theme in the western world challenging a traditional biomedical view on health. Traditional Maori healing involves a holistic system embodying spiritual as well as physical, emotional and mental aspects of health (Ahuriri-Driscoll et al., 2008). EBH is challenging for many alternative health professions including traditional Maori healers, as researching specific components of practice can be considered inappropriate on cultural philosophical grounds (Hudson, 2010). Focussing on the entire outcome of the care is one way to approach the issue (Hudson, 2010). Universal ethical frameworks such as the four principles approach may often fail to recognise cultural impact on the application of those principles (Hudson, 2004).

7 Critique of the four principles approach

Gillon (1994) and Beauchamp (2009) state that the Four Principles approach provides a comprehensive strategy for health dilemmas and are a productive and reasonable way to analyse ethical health issues. Campbell (2003) argues the Four Principles approach is useful as it offers simplicity, clarity and some universality. A counter argument is that categorising ideas under headings does not cover all aspects of ethical deliberation. Additional critique is a failure to involve emotional or personal concerns (Campbell, 2003). Also the framework has been criticised because it oversimplifies complex ethical dilemmas and the proponents’ claims may overstate the principles’ universality.
(Campbell, 2003). (Takala, 2001) suggests the principles can be interpreted in numerous ways and therefore does not provide a foundation for mutual understanding of global bioethics. Takala (2001) suggests that even if the principles are intelligible, they do not express a universally common ethical language. Thornton (2006) questions whether the step-by-step process is too procedural and missing good judgement. Campbell (2003) suggests that combining the four principles approach with virtue ethics (an ethical framework that guides right actions by aligning with what a virtuous character would do) provides the insight of emotion and context in ethical analysis, therefore offering more to ethical analysis than either on their own. Seedhouse (2009) offers a unique multimedia approach to ethical deliberation. Individuals can use an online system (www.values-exchange.com), written or diagrammatic approach to ethical deliberation. The online tool provides a reference system for viewing others' ethical deliberation, which could add to the debate surrounding these types of issues and in particular CSM. Considering wider ethical issues that could not be classified under the four principles supports this critique.

7.1 Other wider considerations may include

7.1.1 Emotional values

Considering the physical nature of the technique and the seriousness of the risk, emotional context may play a part in ethical decision-making. For example, either patient or practitioner may have a relative/friend who died from a stroke and the risk is significant to that individual above all reason or logic or respect for the four principles, or the technique may not ‘feel’ right or may be ‘scary’. These feelings and considerations although they do not come under the principles outlined above, respect for autonomy would overall indicate a respect for patients/practitioners right to make decisions.

7.1.2 Harm to profession

It is also important to consider that when a CVA occurs with CSM, harm occurs not only to the patient but would also have devastating effects on the therapist, community and profession. This harm to the profession may occur through a media frenzy surrounding the issue. Villanueva-Russell (2009) discusses the social context, and development of a moral panic surrounding the risk of CVA from CSM. There may be a loss of respect or tarnished reputation of a manipulative profession, which is widely seen to provide natural treatments without serious risks. There is a possibility for a public view of some manual professions as a deviant or wicked science (Villanueva-Russell, 2009).

8 Recommendations for the future

A guideline such as implemented by the physiotherapy profession, and developed by all those manual therapists entitled by law to practise the skill, could help to ensure equality of patients’ rights (both in standard of care and informed consent) and consistency between individual practitioners and between professions. A periodically updated, collaborative, screening guideline could help to ensure manual therapists maintain skill-levels according to current evidence. This ethical analysis supports further research to apply ethical frameworks to dilemmas we face every day in practice, in the face of limited evidence and potentially high or material risk, for example CSM. Alternative frameworks that
might add insight may be virtue ethics or David Seedhouse’s ethical online approach using the values exchange. Encouraging communication as well as research is the way forward in the ethical landscape of these particular issues and other similar issues.

9 Conclusion

The four principles provided an effective framework to discuss the pertinent issues in CSM. This ethical analysis also allows application to other treatments of high risk and uncertain evidence bases. Based on current evidence it is possible to ethically argue that either the benefit of CSM outweighs the harm and vice versa. However the principle of autonomy carries the strongest weight in this analysis as consumers have a right to choose for themselves what constitutes "net-benefit" or "net harm". Manual therapists are obliged to fully inform patients, including risks that may seem immaterial due to an infrequent occurrence however is considered material due to severity or nature. If evidence underpinning an intervention is incomplete, limited or controversial, this should be disclosed. The principle of justice highlights the importance of equal rights to informed consent and appropriate standards of care. This section highlights the need for an interdisciplinary guideline to inform this intervention. Categorising ideas under the four principles can miss wider ethical considerations. Therefore combining the four principles approach with other ethical frameworks (such as virtue ethics) may provide a more full discussion. Alternatively using an ethical tool (such as David Seedhouse’s online values exchange) may provide greater insight.
References


Campbell, A. V. (2003). The virtues (and vices) of the four principles. Journal of Medical Ethics, 29(5), 292-296. doi:10.1136/jme.29.5.292


Ernst, E. (1996). The ethics of complementary medicine. Journal of Medical Ethics, 22(4), 197-198. doi:10.1136/jme.22.4.197


HDC. (2002). Physiotherapist, Mr B. (Case 00HDC0313B). 1-18.

HDC. (2003). Osteopaths, Mr B and Mr C. (Case 02HDC11987). 1-11.

HDC. (2004). Osteopath Mr B (Case 03HDC09752).

HDC. (2004a). Chiropractor, Mr B. Case 07HDC20616.


Health Practitioners Competence Assurance Act 2003.

Hera, J. (2011). *Cultural competence and patient centred care*. In M. Council (Ed.), *Cole's Medical practice in New Zealand* (pp. 41-47)


### Appendix A: Table showing estimates of frequency of CVA occurring with CSM

<table>
<thead>
<tr>
<th>Case-control studies</th>
<th>Incidence Rate (CVA/CSM)</th>
<th>Profession</th>
<th>Type of study</th>
</tr>
</thead>
<tbody>
<tr>
<td>(Jaskovák, 1980)</td>
<td>&lt;1 in 5,000,000</td>
<td>Chiropractic</td>
<td>Case review</td>
</tr>
<tr>
<td>(Gutmann, 1981)</td>
<td>1 in 50,000</td>
<td>Medicine</td>
<td>Questionnaire survey</td>
</tr>
<tr>
<td>(Dvorák &amp; Oreli, 1985)</td>
<td>1/383,750</td>
<td>Medicine</td>
<td>Retrospective survey</td>
</tr>
<tr>
<td>(Terrett, 1987)</td>
<td>1/300,000–500,000</td>
<td>Chiropractic</td>
<td>Case review</td>
</tr>
<tr>
<td>(Michael, 1993)</td>
<td>&lt;1/75,500</td>
<td>Physiotherapy</td>
<td>Retrospective survey</td>
</tr>
<tr>
<td>(Carey, 1993)</td>
<td>1/3,846,153</td>
<td>Chiropractic</td>
<td>Case review</td>
</tr>
<tr>
<td>(M. J Haynes, 1994)</td>
<td>1/200,000</td>
<td>Chiropractic</td>
<td>Retrospective survey</td>
</tr>
<tr>
<td>(Lee, Carl, McCormick, &amp; Albers, 1995)</td>
<td>1/500, 000</td>
<td>Neurologists on chiropractic manipulation</td>
<td>Retrospective survey</td>
</tr>
<tr>
<td>(Kloogart, Leboeuf-Yde, &amp; Rasmussen, 1996)</td>
<td>1/300,000</td>
<td>Chiropractic</td>
<td>Retrospective survey</td>
</tr>
<tr>
<td>(Rivett &amp; Reid, 1998)</td>
<td>1/163,371</td>
<td>Physiotherapy</td>
<td>Case review</td>
</tr>
<tr>
<td>(Rothwell, Bondy, Williams, &amp; Bousser, 2001)</td>
<td>1.3/100,000 in persons &lt; 45 years</td>
<td>Chiropractic</td>
<td>Population based nested controlled study</td>
</tr>
<tr>
<td>(Haldeman, Carey, Townsend, &amp; Papadopoulos, 2001)</td>
<td>1/5,850,000</td>
<td>Chiropractic</td>
<td>Case review and survey questionnaire</td>
</tr>
<tr>
<td>(Magee et al., 2004)</td>
<td>0/50,000</td>
<td>Physiotherapy</td>
<td>Retrospective survey</td>
</tr>
</tbody>
</table>