



AUSTRALIAN
CHIROPRACTORS
ASSOCIATION

Research Summary and Strategic Research Opportunities

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ACA Tertiary Education and Research Committee

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PREAMBLE

ACA supports the *Australian Charter of Healthcare Rights of the Australian Commission on Safety and Quality in Health Care (ACSQHC)*, which describes the rights of patients and other people using the Australian health system (*ACA Position Statement on Patient Care, Clinical and Professional Chiropractic Education* June 2016). These rights are essential to make sure that, wherever and whenever care is provided, it is of high quality and is safe. The Charter recognises that people receiving care and people providing care all have important parts to play in achieving healthcare rights. The Charter allows patients, consumers, families, carers and services providing health care to share an understanding of the rights of people receiving health care. This helps everyone to work together towards a safe and high-quality health system. A genuine partnership between patients, consumers and providers is important so that everyone achieves the best possible outcomes. Chiropractic clinical practice, education and training should embrace the value of using best-available evidence, clinical experience and shared decision-making while providing patient-centred care.

The purpose of the *Research Summary and Strategic Research Opportunities 2016 (RSSRO)* document is to provide a review of the research evidence as it stands and to identify areas of opportunity to best inform future research. This will also inform the practitioner of what the current literature supports for public claims of effectiveness. It is also intended to be an aid in translating research into practice for the researcher and clinician. This must necessarily involve a combination of the informed consent process, due appreciation of the evidence in providing care, clinical experience of the practitioner, patient needs and preferences, and alternatives to management proposed which may include other health professionals or no intervention at all.

The informed consent process is fundamental to conveying options for care appropriately. Quality care involves a patient-centred approach, including a discussion on levels of evidence, risk, patient preferences and alternatives. This does not necessarily mean that highest-level evidence is required before the consideration of an intervention. If this were the case, many health interventions across all health professions would be challenged or excluded from coming to the potential aid of those who seek help.

Rather, where the level of evidence for a particular intervention is inconclusive but favourable (for instance), the practitioner would advise this as part of the consent process. The practitioner would also utilise clinical experience as well as patient expectations and preferences to assist joint decision-making. Where no other intervention exists with higher-level evidence of efficacy and/or the patient has a preference to proceed with appropriately obtained consent (including an understanding of relevant risks), then it may be quite appropriate to conduct a trial of care. This can occur in circumstances where the underlying mechanism of a therapeutic effect is widely documented and recognised as biologically plausible. Should the existing evidence suggest a moderate or strong negative effect of the proposed intervention or where a higher level of evidence supports efficacy of treatment available from a different healthcare provider, the patient should be advised and in general would suggest that alternative treatment options should be sought.

The ACA intends to review the available evidence on a regular basis and recognises the need for a focus on translating the best available evidence into practice for optimal patient outcomes.

ACA endorses the Chiropractic Board of Australia's *Code of Conduct for Chiropractors* to support chiropractors to deliver safe and effective health services within an ethical framework. All health practitioners have a duty to make the care of patients their first concern and to practise safely and effectively. Maintaining a high level of professional competence and conduct is essential for providing good care.

LIST OF ABBREVIATIONS

ADHD	Attention deficit/hyperactivity disorder
AHPRA	Australian Health Practitioner Regulation Agency
AIHW	Australian Institute of Health and Welfare
ARC	Australian Research Council
ACA	Australian Chiropractors Association
CAD	Cervical artery dissection
CBA	Chiropractic Board of Australia
CCEA	Council on Chiropractic Education Australasia
CCEI	Councils on Chiropractic Education International
CNS	Central nervous system
COPD	Chronic obstructive pulmonary disease
CPD	Continuing professional development
DALYs	Disability-adjusted life years
FLA	Formal learning activity
GBD	Global burden of disease
GPGs	Clinical practice guidelines
HVLA	High velocity, low amplitude
LBP	Low back pain
NHMRC	Health and Medical Research Council
NUCCA	Upper Cervical Chiropractic Association
PT	Physical therapy
RCT	Randomised controlled trials
ROM	Range of motion
RSSRO	Research Summary and Strategic Research Opportunities
SMT	Spinal manipulative therapy
TERC	Tertiary Education and Research Committee
TMJ	Temporomandibular joint dysfunction
YLDs	Years lived with disability

INTRODUCTION

The ACA recognises the need for ongoing robust, high-quality research that focuses on improving health outcomes by delivering evidence-informed diagnosis and management. To this end, the ACA aims to support excellence in health research by employing a number of initiatives. These will ultimately have a positive effect on improving patient outcomes, increasing the research literacy of its members, and contributing to health and wellbeing literature.

The *ACA Research Summary and Strategic Research Opportunities 2016* (RSSRO) provides information to assist the ACA in a number of important areas. Primarily, the RSSRO document provides information to assist the ACA with funding decisions for research that are *specific, measurable, attainable, realistic and timely* (SMART).¹ To support this aim, the ACA Tertiary Education and Research Committee (TERC) have summarised the literature relating to the practice of chiropractic. The RSSRO is not intended to be an exhaustive review of the literature, but serves to provide an overview across key domains relevant to chiropractic care in Australia.

AIMS AND PURPOSE

The need for more high-quality chiropractic research has been described in several consensus documents internationally and across a number of research domains.²⁻⁵ Translational research has been identified by the Health and Medical Research Council's (NHMRC) 10-year strategic plan as one such area⁶, and is key to providing evidence-informed delivery of service. Translational research primarily aims to improve the quality of patient diagnosis and disease management. It has particular relevance to identified areas of health burden that place a high cost upon the personal health, finances and productivity of the Australian community. High-quality translational research is part of a unidirectional continuum, in which research findings are moved from the researcher's bench to the patient's bedside.⁷

This RSSRO document is a first attempt to present material to guide decision-making related to: (i) funding for specific research projects; (ii) supporting PhD candidature through scholarship or similar; (iii) providing chiropractic representation when engaging with healthcare policymakers, third-party payers, healthcare professionals and the media; (iv) assisting the ACA for the purpose of communicating with members; and (v) informing continuing professional development/formal learning activity (CPD/FLA) assessment criteria.

It is proposed that this document be reviewed and updated on a biennial basis.

SECTION 1

BACKGROUND: CHIROPRACTIC AND THE AUSTRALIAN HEALTHCARE SYSTEM

CHIROPRACTIC TRAINING AND EDUCATION

Australian chiropractic education involves undergraduate and/or masters-level university training over five years. The Council on Chiropractic Education Australasia (CCEA) is granted authority by the federal government to accredit the four chiropractic training programs in Australasia and programs in other countries which are accredited through affiliated chiropractic education councils under the auspices of the Councils on Chiropractic Education International (CCEI).

All applicants from accredited programs overseas must pass a CCEA examination before being registered to practise in Australia by Australian Health Practitioner Regulation Agency/Chiropractic Board of Australia (AHPRA/CBA). All accredited chiropractic programs include units in basic and clinical sciences. Also included are units in physical therapy, physical rehabilitation, radiology, nutrition, paediatrics, geriatrics, public health and evidence-based practice. As with other primary healthcare professions, chiropractic pre-professional training requires a significant proportion of the curricula to be clinical subjects related to evaluating and caring for patients. As part of professional training, final-year students must also complete a minimum of a one-year supervised clinical internship.

This prepares graduates with the diagnostic and management skills necessary to manage a range of health conditions within their scope of practice, and to deliver public health education within a biopsychosocial framework (e.g. healthy lifestyle management). Chiropractic education is integrative and supportive of collaboration with other healthcare professions when appropriate. Licensed chiropractors must complete continuing education (FLAs) each year in order to maintain registration and practice as a non-pharmacological, non-surgical spine care and musculoskeletal-allied healthcare professional.

CHIROPRACTIC CARE: IDENTITY

Recent studies offer valuable information on the beliefs and experiences of Australian chiropractors. In one study, practitioners reported the basis of their scope of practice to be: 94% musculoskeletal dysfunction, 88% musculoskeletal pain, 49% wellness-care (not defined) and 37% subluxation-based care (not defined), when the categories 'most of the time' and 'always' were combined.⁸

In another practitioner-based study, 60% of patient encounters were reported to be musculoskeletal and 40% were reported to be 'general' or 'unspecified'. The three regions most often diagnosed were back problems (46.1%), neck problems (11.4%), back problems with radiating pain (3.6%) and headaches (3%). Delivery of health-maintenance or preventative-care was reported for 4.2% of patient encounters.⁹

The majority of Australian chiropractors thus report their scope or practice and patient encounters to comprise of predominately of musculoskeletal complaints, primarily related to the spine, followed by issues related to general health and wellbeing.

CHIROPRACTIC CARE: PATIENT BELIEFS AND UTILISATION

Several recent studies provide valuable information from the health consumers who seek care from Australian chiropractors. One study reported that 68.7% of patients seek chiropractic services for reasons of musculoskeletal disorders and 21.2% for reasons of general health.¹⁰

In a second study, participants reported a high prevalence of back pain (71.1%), neck pain (55.6%) and headaches (45.5%).¹¹ A third study found the main reasons for chiropractic use to be back pain (65.7%), neck pain (20.7%) and headaches (9.3%), along with general health and wellbeing (32.3%).¹²

This literature suggests that the primary reason Australian health consumers seek chiropractic care is for spine-related musculoskeletal disorders, followed by reasons related to general health and wellbeing.

THE BURDEN OF DISEASE AND RELEVANCE TO CHIROPRACTIC

The Global Burden of Disease (GBD) study provides disability-adjusted life years (DALYs) for a range of acute and chronic conditions.¹³⁻¹⁵ Low back pain (LBP) is one of the most highly prevalent, disabling and costly health conditions.^{16,17} It is the most common problem among the working population within high-income countries.¹⁸ LBP was ranked as the greatest contributor to global disability, and the sixth-greatest in terms of overall burden (measured in DALYs).^{19,20}

Neck pain is a common condition (prevalence 5.3%) and is associated with substantial disability. Neck pain ranks as the fourth highest (in Australia) in terms of disability, and 21st in terms of overall burden.²¹ It is relevant to note that five of the top ten causes of disability are conditions within the chiropractic scope of practice (back pain, neck pain, other musculoskeletal conditions, migraine and chronic obstructive pulmonary disease).

Some conditions co-exist. For example, tension headache and migraine are often present together.²² Respectively, they are the second and third most common disorders worldwide with migraine ranking as the seventh-highest specific cause of disability globally.¹⁴ These common recurrent headache disorders place a considerable burden on the personal health, finances and work productivity of sufferers,²³⁻²⁵ with migraine further complicated by an association with cardiovascular and psychiatric co-morbidities.^{26,27} Cervicogenic headache is reported as the third most common recurrent headache with a prevalence of around 4% in adult populations.²⁸

The Australian Institute of Health and Welfare (AIHW) identifies arthritis and musculoskeletal conditions as the largest cause of disability in modern economies globally. Australian figures for this national health priority reveal that 6.3 million Australians (31%) suffer within this domain, and absorb 9.2% of total health expenditure (A\$4.6billion). Arthritis and musculoskeletal conditions rank only less than cardiovascular disease (10.9%) and diseases of the nervous system in cost to the healthcare purse.²⁹ **While the burden of low back pain is ranked sixth in the world, it is ranked first in Australasia.**^{14, 21, 30}

Research that reports trends in the prevalence and incidence of disease and injury, and the resulting years lived with disability (YLDs), provide information that is vital to the allocation of future healthcare research and resources. These data should inform health policy to ensure that the most burdensome health conditions receive appropriate attention. Appropriate contribution to research funding by the chiropractic profession will increase the research capacity and training of the profession so it can contribute in a more meaningful way and have a greater impact on these significant public health challenges. **Targeting appropriate research within these costly public health domains will assist the Australian chiropractic profession to become a leading primary healthcare provider.**

HEALTH PROMOTION OPPORTUNITY

The chiropractic profession has developed a core set of competencies across a range of health, wellness and disease prevention interventions.²²⁷ The CCEA also lists a number of elements of education and consequent competency for registration as a chiropractor. These include an understanding of the significance of the major risk factors for disease such as obesity, poor nutrition, alcohol abuse, drug abuse, stress, mental health disorders, smoking, exposure to harmful environmental factors and poor hygiene, the most common mental health disorders, and best practice treatment for these disorders. The council also expects chiropractors to recognise their role in overall public health practice within the Australian health system.³¹ This educational foundation provides the basis on which chiropractors can engage in health promotion of a wide range of behaviour- and lifestyle-related health issues that cause a significant burden on the Australian healthcare system. With appropriate further education, chiropractors are well placed to participate in health promotion concerning the prevention of chronic health issues.

SECTION 2 RESEARCH: CONTEXT AND SUMMARY

CONTEXT

In order to inform healthcare decision making, it is imperative that high-quality peer-reviewed research relevant to the clinical question or research hypothesis are utilised. An overview of the research domains relevant to chiropractic care (and health care in general) is outlined in the table below. This is not an exhaustive list but serves to highlight the utility of each domain.

RESEARCH DOMAINS RELEVANT TO CHIROPRACTIC WITH EXAMPLE STUDY DESIGNS

Research domain <i>(with example of study designs)</i>	Applicable to <i>(for example)</i>
Basic science research <i>e.g. Lab-based research</i>	<ul style="list-style-type: none">• Testing hypotheses related to proposed mechanism of action (e.g. the spinal adjustment)• Supporting future funding applications (e.g. to test hypothesis in a clinical setting)• Inferences are dependent upon quality rating of evidence• Results cannot be applied in the clinical domain (i.e. patient outcomes)

<p>Clinical research <i>e.g. Randomised controlled trials, diagnostic test accuracy studies, systematic reviews</i></p>	<ul style="list-style-type: none"> • Randomised controlled trials (RCT): Determining the effect of an intervention or diagnostic test in a specific patient population (harms may also be tracked as part of the study) • Systematic review (SR): Testing that can generally be applied to a broader population, with greater confidence in the study effect • Cannot (generally) be used to discover the mechanism of the dysfunction or the intervention
<p>Translational (clinical) research <i>e.g. Clinical decision rules, clinical practice guidelines</i></p>	<ul style="list-style-type: none"> • Clinical decision research: Determining the effectiveness of a clinical decision applied to a clinical population • Guideline research: Evidence based recommendations for how to manage conditions, imaging use, etc.
<p>Population health research <i>e.g. Large cross-sectional studies, prospective cohort studies</i></p>	<ul style="list-style-type: none"> • Measuring the cost effectiveness of chiropractic care • Studying harms related to chiropractic care • Measuring the utilisation of chiropractic services in the population

Basic science research, in some instances, may elucidate mechanisms that are important to manual therapy and therefore future clinical research. As such, basic science research cannot answer questions relating to who, when or how to manage specific clinical conditions, and is insufficient evidence as a basis for guiding frontline clinical care. The chiropractic profession lacks a body of basic science research that has scientifically investigated the validity of some chiropractic theories. While basic science research often does not lead to direct changes in clinical practice, there is need for basic science research to rigorously test chiropractic theories about health and disease. The findings from such studies may evidence the need for future clinical research or the need to abandon some theories and related clinical practices.

There is a substantial body of clinical research relating to conditions within the chiropractor's scope of practice. An excellent and accessible summary is Clar et al (2014) 'Clinical effectiveness of manual therapy for the management of musculoskeletal and non-musculoskeletal conditions: systematic review and update of the UK evidence report'³², which is an update of the original review by Bronfort et al. 'Effectiveness of manual therapies: the UK evidence report' (2010).³³

BASIC SCIENCE RESEARCH

The following section represents a distilled summary of the evidence regarding basic science (lab-based) research that is relevant to chiropractic. Each topic area briefly covers **what is known** (i.e. what is supported by robust evidence); **evidence gaps** (what is not yet supported by robust evidence) and where possible, **research opportunities**, given the identified research gaps. Comment on **translation of evidence** into practice is given where appropriate. This is not an exhaustive review of the literature, and is only intended to provide representative studies that are relevant to the chiropractic profession.

INTERVERTEBRAL DISC DEGENERATION

What is known	Recent studies into the mechanisms of disc degeneration ^{34, 35} and nerve growth ³⁶ demonstrate that these changes may play a role in discogenic pain. The majority of disc degeneration is reported to be genetically determined, ³⁵ with more limited evidence that disc degeneration is effected by abnormal physical loading. ³⁷
Evidence gaps	It is unclear under which conditions, if at all, chiropractic care can influence the rate of disc degeneration, beyond that of natural history alone.
Research opportunities	Large-scale prospective longitudinal study designs are required to answer such questions. ³⁸
Evidence translation	Basic science research of this type cannot directly inform clinical practice.

RESTORATION OF NORMAL JOINT BIOMECHANICS

What is known	Research into the biomechanical effects of spinal manipulation have demonstrated changes to both facet joints ³⁹ and surrounding tissues. ^{39, 40} Animal model studies have helped to elucidate changes to spinal biomechanics using simulated manipulation. ^{41, 42} Other biomechanical research has examined forces applied to the spine during the high velocity, low amplitude (HVLA) adjustment. ⁴³
Evidence gaps	Lack of research regarding the efficacy of individual technique styles within the clinical setting limits any argument for biomechanical differences between HVLA styles or between HVLA and low velocity (mobilisation) interventions.
Research opportunities	This domain informs our biomechanical understanding of the adjustment and may be useful for hypotheses generating in later clinical effectiveness research.
Evidence translation	Basic science research of this type cannot directly inform clinical practice.

NEUROPHYSIOLOGICAL

Most of the findings reported in this section are taken from a recent summary of neurophysiological research presented at the 2015 WFC Conference by Dr Scott Haldeman.⁴⁴

SOMATOSENSORY REFLEXES

What is known	A large body of research investigating changes to the somatosensory system as a result of the spinal adjustment has been undertaken. ⁴⁵⁻⁵² These studies have demonstrated changes beyond the biomechanical effect of the adjustment and are useful to inform our understanding of neurological function.
Evidence gaps	From Haldeman: <i>'The fact is that these reflexes do exist and have been widely documented and described in some detail. However, almost all of the experimental research has had very short term response recordings without documentation that these reflexes are responsible for any pathology or have any beneficial impact on health.'</i> There is a lack of high-quality evidence to demonstrate worthwhile physiological changes in visceral organs via somato-autonomic reflexes as a result of HVLA spinal manipulative therapy (SMT). Only low-quality research has demonstrated brief response periods, so the clinical significance of these findings must be questioned.
Research opportunities	Ongoing research into the somatosensory effects of chiropractic manual therapy, including SMT, may provide a greater understanding of mechanisms of effect. ⁵³ However, to date research into somato-visceral or viscerosomatic reflexes has not yet demonstrated plausible biological mechanisms that would underpin clinically meaningful outcomes in high-quality large population clinical trials.
Evidence translation	Basic science research of this type cannot directly inform clinical practice.

LOCALISED NERVE PRESSURE

What is known	There is no evidence to show that a localised spinal lesion has any clinically significant direct impact on aberrant brain function.
Evidence gaps	From Haldeman: <i>'There is now ample evidence that nerves can be compressed at the spinal level by disc herniations and spinal stenosis but it is equally clear that nerve compression does not occur with minor deviations of vertebral position. There is also no evidence that nerve compression at the spinal level has any defined impact on visceral organ pathology.'</i>

Research opportunities	This area of research has not demonstrated plausible biological mechanisms that would underpin clinically meaningful outcomes important to the direct functioning of viscera or the central nervous system (CNS) or that SMT can have any positive impact on visceral or CNS disorders through these pathways. However, through helping to decrease pain, we may have positive secondary effects. These include enabling the patient to return to gainful employment, improve their mood and self-esteem, and take up exercise thereby reducing their cardiovascular risk, which may be achieved by chiropractors via effective treatment of pain and disability.
Evidence translation	Basic science research of this type cannot directly inform clinical practice.

CENTRAL SPINAL REFLEXES

What is known	Central spinal reflexes (H reflexes) have been reported to respond to forces applied to the spine. ⁵⁴
Evidence gaps	From Haldeman: <i>'The difficulty lies with the short latency of these responses and the lack of a body of research demonstrating that they are of any clinical significance.'</i> Future research in these areas will determine whether these observations in the laboratory are simply normal physiological responses or are clinically important.
Research opportunities	The exact clinical importance of this research remains unknown and this can risk further extrapolation if this research is not reported in a robust manner.
Evidence translation	Basic science research of this type cannot directly inform clinical practice.

SENSORIMOTOR FUNCTION

<i>What is known</i>	<p>Recent studies have demonstrated changes in sensorimotor disturbances (dizziness and poor postural stability) may occur in those with neck disorders. One hypothesis points to dysfunction in the cervical receptors in the neck altering afferent input via a number of mechanisms such as trauma, functional impairment of the receptors, changes in muscle spindle sensitivity and the effects of pain at many levels of the nervous system. This may result in poor integration and tuning for some aspects of sensorimotor control.^{55, 56} As a result, recommendations for clinical assessment and management of sensorimotor control disturbances in neck disorders has been proposed, including the use of manual therapies (including SMT) along with specific exercises combined with tailored sensorimotor control programs.⁵⁵ Limited evidence suggests that this approach may be appropriate to address altered cervical afferent input and secondary adaptive changes in these cases. There is limited evidence that some sensorimotor changes are effected by chiropractic care alone.^{45, 57}</p>
<i>Evidence gaps</i>	<p>Combining manual therapy and exercises approaches (manipulation, proprioceptive neuromuscular facilitation, acupuncture on trigger points and range-of-motion exercises) with tailored sensorimotor control programs may be appropriate to address altered cervical afferent input as well as secondary adaptive changes.⁵⁸ There is still limited research to report the clinical importance of manual therapy alone within this area. This can risk further extrapolation if not reported in a robust manner. High-quality clinical trials with large study populations are required before any strong claims regarding improved health outcomes can be made. Importantly, the extent to which these maladaptive changes causes any significant additional impact on health (including cost of care) has yet to be identified.</p>
<i>Evidence translation</i>	<p>Basic science research and small population clinical trials within this area are insufficient to directly inform clinical practice.</p>

REDUCED BRAIN GREY MATTER

What is known	Recent studies have demonstrated that some physical and mental co-morbidities are associated with chronic spinal pain. ⁵⁹⁻⁶³ Reduced grey matter volume has been reported in people with chronic spine pain, ⁶⁴⁻⁶⁶ and such changes may be reversed in patients who successfully respond to treatments that reduce their pain. ⁶⁷
Evidence gaps	From Haldeman: <i>'Although these changes have been reproduced, their exact clinical importance remains unknown and there is a risk to extrapolate or misquote this new research in the same manner as any other theory that purports to prove that SMT has a clinically important impact on the nervous system.'</i>
Evidence translation	Basic science research and small population clinical trials within this area are insufficient to directly inform clinical practice.

CLINICAL RESEARCH

This section provides an overview of the evidence related to a broad range of clinical conditions. The evidence cited draws heavily from reviews by Clar et al. (2014)³² and Bronfort et al. (2014)³³ with level of evidence rating for many of the conditions from the same authors (**Appendix 1 and 2**).

SPINAL CONDITIONS

ACUTE BACK PAIN: SPINAL MANIPULATION/MOBILISATION

Current evidence	Clinical practice guidelines (CPGs) recommend a conservative approach to referral for imaging and intervention, with SMT recommended when patients do not improve, ⁶⁸ but the advice may not generalise to all populations with acute low back pain (LBP). There are considerable differences between international guidelines in relation to recommending manual therapy for management of acute LBP. ^{69, 70} Spinal manipulation for acute back pain has been studied extensively with a recent Cochrane systematic review (high level evidence: 1a) demonstrating a lack of effectiveness when treating acute LBP with manipulation alone. ⁷¹ When considering individual trials (moderate level evidence: 2b), there is demonstrated clinical effectiveness for spinal manipulative therapy for management of acute back pain. ⁷²
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Evidence gaps and opportunities	Clinical practice guidelines (CPGs) ⁷³ usually recommend simple analgesia (e.g. paracetamol) as a first-line therapy for managing acute back pain, which has been demonstrated to be ineffective in reducing time to recovery. ⁷⁴ Exercise as therapy for acute LBP also has shown minimal benefit, but may be beneficial to help prevent recurrence. ⁷⁵ Currently, SMT is classed as an optional therapy (i.e. not as a first-line care). ⁷⁶ Studies that seek to subgroup participants by their projected pattern of recovery may show increased effect due to selecting likely responders to care. ⁷⁷ Likewise, studies that test the validity of clinical prediction rules offer opportunity to test the generalisability of existing studies that recommend SMT for subpopulations. ⁷⁸⁻⁸⁰
Evidence rating	Positive moderate level evidence

CHRONIC LOW BACK PAIN: SPINAL MANIPULATION/MOBILISATION

What is known	A recent Cochrane systematic review demonstrated the lack of effectiveness for spinal manipulation alone for managing chronic low back pain. ⁸¹ Manual therapy combined with exercise has shown some benefit and is typical of how the clinician would manage this condition. ⁸²⁻⁸⁴
Evidence gaps and opportunities	Few single-modality interventions have demonstrated effectiveness for managing chronic conditions. The biopsychosocial model of care has demonstrated effectiveness, ⁸⁵ but such studies are not typically the focus of chiropractic research. Large multi-centre multimodal pragmatic care trials are needed, where chiropractic management is part of the delivered care intervention after subgrouping by using validated algorithms based on risk such as the STarT Back Screening Tool. ⁸⁶
Evidence rating	Positive high level evidence

CHRONIC LOW BACK PAIN: MASSAGE

What is known	Massage may also be recommended for the treatment of subacute and chronic LBP. ⁸⁷ This review concluded that massage (particularly acupressure-style massage) might be beneficial to subacute and chronic low back pain, especially if combined with education and exercises.
Evidence gaps and opportunities	The 2009 Cochrane review suggests more research is required to assess return-to-work rates and cost effectiveness.
Evidence rating	Positive moderate level evidence

SCIATICA AND BACK-RELATED LEG PAIN: SPINAL MANIPULATION/MOBILISATION

What is known	One literature synthesis reports weak evidence for the use of manipulation for patients with LBP and radiating leg pain, sciatica or radiculopathy. ⁸⁸ More recent studies concur broadly with Lawrence et al. (2010), ^{89, 90} reporting greater effect sizes with decreasing study quality (a type of study bias).
Evidence gaps and opportunities	Chiropractic manipulation may be effective for reducing symptoms of sciatica in adults. It is not clear if these manual treatment techniques are more beneficial than advice alone, surgery or the McKenzie method.
Evidence rating	Favourable inconclusive evidence for spinal manipulation

MID BACK/THORACIC PAIN: SPINAL MANIPULATION

What is known	Schiller (2001) reported a small randomised trial for mid back pain. ⁹¹ More recently, González-Iglesias et al. (2009) included an additional RCT ⁹² which did not change the conclusion of Schiller.
Evidence gaps and opportunities	It is not yet clear whether manual therapy is more effective than placebo or no treatment for non-specific mid back pain.
Evidence rating	Favourable inconclusive evidence for spinal manipulation

ACUTE/SUBACUTE NECK PAIN: SPINAL MANIPULATION/MOBILISATION

What is known	Moderate-quality evidence exists to support thoracic spinal manipulation/mobilisation for acute and subacute non-specific neck pain. ⁹²⁻⁹⁵ One low-quality, ⁹⁶ three medium-quality ⁹⁷⁻⁹⁹ and two high-quality RCTs ^{100, 101} examined cervical spinal manipulation or mobilisation alone for neck pain. There was no clear consensus between studies, with lower-quality studies reporting larger positive treatment effects. Similar improvements were reported in the manipulation and/or mobilisation intervention groups compared to active treatment. However, some trials reported no improvement when compared to the control group.
Evidence gaps and opportunities	High-quality randomised studies with adequate follow-up time periods (up to one year) will help to clarify this area.
Evidence rating	Favourable inconclusive evidence for cervical spinal manipulation/mobilisation (delivered in isolation) for treatment of neck pain

ACUTE WHIPLASH-ASSOCIATED DISORDERS: MOBILISATION WITH EXERCISE

What is known	Gross et al. (2004) ¹⁰² concluded that mobilisation with exercises appears to be more beneficial than usual care or other physical therapies for whiplash associated disorders.
Evidence gaps and opportunities	There is no high-quality evidence to support (HVLA) spinal manipulation of the neck for acute whiplash.
Evidence rating	Positive moderate evidence for mobilisation and exercises for treatment of acute whiplash-associated disorders

CHRONIC NECK PAIN: SPINAL MANIPULATION/MOBILISATION WITH EXERCISE

<p>What is known</p>	<p>Moderate-quality evidence exists in support of spinal manipulation/mobilisation combined with exercise for chronic non-specific neck pain. The effect size for spinal manipulation is similar to mobilization for chronic non-specific neck pain.^{102, 103} Strong recommendations exist for manipulation, manual therapy and exercise in combination with other modalities compared to stretching, strengthening and endurance exercises alone. Moderate recommendations exist for the treatment of acute neck pain with manipulation and mobilisation in combination with other modalities, and for mobilisation as well as massage in combination with other therapies. Weak recommendations exist for the treatment of acute neck pain with exercise alone for the treatment of chronic neck pain with manipulation alone. Thoracic manipulation and trigger point therapy are not recommended for the treatment of acute neck pain.¹⁰⁴ Manual therapy and supervised exercise interventions, and low-level laser therapy are more effective than no treatment, sham or alternative interventions. None of the active treatments was superior to any other in either the short or long term.¹⁰²</p>
<p>Evidence gaps and opportunities</p>	<p>More high-quality research is needed to further elucidate the role of manual therapy when combined with specific exercise programs.</p>
<p>Evidence rating</p>	<p>Moderate positive level evidence to support spinal manipulation/mobilisation with exercise</p>

CHRONIC NECK PAIN: MASSAGE

<p>What is known</p>	<p>Massage therapy may be effective for non-specific chronic neck pain,¹⁰⁵ from one study in which a greater proportion of massage patients reported a clinically significant improvement in disability and pain at four and 10 weeks compared to self-care, while the differences between groups were not statistically significant at 26 weeks.</p>
<p>Evidence gaps and opportunities</p>	<p>Little evidence exists to compare different massage therapies. The trial design did not separate whether improvement was attributable to the patient-provider interaction, home practice recommendations or patient expectations. Future studies could investigate the optimal treatment frequency, number and length of each massage, allowing for other non-specific treatment effects.</p>
<p>Evidence rating</p>	<p>Moderate-quality evidence for massage as a treatment for chronic neck pain</p>

HEAD AND HEADACHE DISORDERS

MIGRAINE: SPINAL MANIPULATION

<i>What is known</i>	A 2004 Cochrane systematic review concluded that spinal manipulation was an effective option for the care of migraine headache. ¹⁰⁶ A 2011 systematic review concluded that RCTs suggest that massage therapy, physiotherapy, relaxation and chiropractic SMT <u>might</u> be equally as effective as propranolol and topiramate in the prophylactic management of migraine. ¹⁰⁷ Few single-modality interventions provide robust evidence.
<i>Evidence gaps and opportunities</i>	Well-conducted RCTs are needed, without the many methodological shortcomings of the evaluated RCTs on manual therapies, before conclusion can be made. ¹⁰⁷ Current headache CPGs are not supported by high-level evidence and identify the potential need for a multimodal and collaborative approach to managing headache. ¹⁰⁸ There is weak-to-moderate evidence to support other non-pharmacological approaches to migraine. ¹⁰⁹ Future research may need to consider greater patient subgrouping (across underlying migraine triggers) to better evaluate high responders from low responders to this method of care. Future research may consider the value of manual therapies within a multi-disciplinary environment and encompass the biopsychosocial approach.
<i>Evidence rating</i>	Moderate positive evidence for spinal manipulation as a treatment for migraine

TENSION-TYPE HEADACHE: SPINAL MANIPULATION/MOBILISATION

<i>What is known</i>	A recent systematic review of RCTs for spinal manipulation reported mostly high methodological quality (Jadad score 2–4). Four RCTs suggested that spinal manipulations are more effective than drug therapy, spinal manipulation plus placebo, sham spinal manipulation plus amitriptyline or sham spinal manipulation plus placebo, usual care or no intervention. One RCT showed no difference in daily hours of headache, pain intensity and daily analgesic use compared to soft tissue therapy plus placebo laser. ¹¹⁰ The evidence for spinal manipulation as a treatment option is mostly positive. A recent systematic review comparing multimodal manual therapies found multimodal manual therapies were associated with moderate effectiveness in the short term, with similar effectiveness at longer follow-up, for reducing headache frequency, intensity and duration in tension-type headache. ¹¹¹
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<p>Evidence gaps and opportunities</p>	<p>The evidence for spinal manipulation alone in the relief of tension-type headache is encouraging, but inconclusive with the low quantity of the available data preventing robust conclusions. Evidence is stronger for multimodal manual therapies. However, due to the heterogeneity of the interventions, results are not able to be generalised.¹¹¹ A recent systematic review concluded that the evidence that spinal manipulation alleviates tension type headaches was encouraging, but inconclusive.¹¹⁰ Future studies that focus on spinal manipulation alone should be in line with accepted standards of trial design and reporting (CONSORT guidelines), be adequately powered, use validated outcome measures, control for non-specific effects and minimise other sources of bias. Reporting of these studies should be such that results can be independently replicated (externally validated).¹¹⁰ Future research is needed to explore the effects of manual therapies alone and in combination.¹¹¹ Currently, there is moderate evidence to support the benefit of tricyclic antidepressants in preventing migraine and tension-type headaches, although with greater adverse effects¹¹² including the risk of medication-overuse headache.¹¹³</p>
<p>Evidence rating</p>	<p>Inconclusive favorable evidence for multimodal manual therapies for the treatment of tension headache</p>

CERVICOGENIC HEADACHE: SPINAL MANIPULATION WITH AND WITHOUT EXERCISES

<p>What is known</p>	<p>One recent systematic review found spinal manipulation combined with physical therapy may be effective.¹¹⁴ Another review reported results such that 6 of the 9 RCTs suggested spinal manipulative therapy was more beneficial in treating the headaches compared to physical therapy, light massage, drug therapy, or no intervention.¹¹⁵ The more recent review found combination of therapist-driven cervical manipulation and mobilization with cervico-scapular strengthening was the most effective for decreasing pain outcomes in cervicogenic headache.¹¹⁶</p>
<p>Evidence gaps and opportunities</p>	<p>There are many and inconsistent outcome measures reported across studies, making any pooling of data (meta-analysis) difficult. Additionally, many studies contain a high risk of observer bias.¹¹⁶ Only one study included a control group (no treatment), and RCTs mostly included participants with infrequent cervicogenic headache.¹¹⁴ More research is needed to validate the diagnostic criteria for cervicogenic headache. Future efficacy-based research will need to use subjects with a greater headache frequency, more standardised outcome measures and reduce observational bias. A more multimodal approach to cervicogenic headache, including a combination of manual therapies with structured exercise, needs to be considered. There is no high-quality evidence for drug treatments for cervicogenic headache.</p>

Evidence rating	Moderate positive evidence for spinal manipulation and spinal mobilisation as a treatment for cervicogenic headache
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CERVICOGENIC DIZZINESS: CERVICAL SPINE MANIPULATION/MOBILISATION

What is known	A high-quality systematic review ¹¹⁷ included five RCTs and eight non-controlled cohort studies. Studies were moderate quality with one high-quality RCT. Six of the studies (two RCTs) used manipulation/mobilisation only as an intervention, while the rest used a multimodal approach without any vestibular rehabilitation intervention.
Evidence gaps and opportunities	The authors conclude: <i>'There is moderate evidence to support the use of manual therapy, in particular spinal mobilisation and manipulation, for cervicogenic dizziness. The evidence for combining manual therapy and vestibular rehabilitation in the management of cervicogenic dizziness is lacking. Further research to elucidate potential synergistic effects of manual therapy and vestibular rehabilitation is strongly recommended.'</i>
Evidence rating	Inconclusive favourable evidence

TEMPOROMANDIBULAR JOINT DYSFUNCTION: MOBILISATION AND MASSAGE

What is known	Two recent systematic reviews evaluating the benefit of manual therapy for temporomandibular joint (TMJ) dysfunction have been published. ^{118, 119} Comparative effectiveness and safety results of manual therapy for TMJ disorders remain inconclusive for myofascial, mobilisation, massage or manipulation (osteopathic).
Evidence gaps and opportunities	In the highest-quality RCT of 49 participants with temporomandibular closed lock, the participants either received physical therapy (including joint mobilisation, exercises and massage) or a control treatment. All pain variables decreased, and all function variables increased significantly over time for both groups, but there was no significant difference between groups. ¹²⁰
Evidence rating	Favourable inconclusive evidence for mobilisation and massage for TMJ dysfunction

NON-MUSCULOSKELETAL CONDITIONS (PAEDIATRIC POPULATION)

The use of SMT for the management of non-musculoskeletal conditions remains controversial, given the lack of robust neurobiological rationale to underpin this type of care.¹²¹ A current review of the evidence supports this position, i.e. there is no *high-quality* evidence for or against the efficacy of manual therapy for non-musculoskeletal paediatric conditions.³² Future investment in this field must be carefully considered/questioned. Any statement asserting the safety and/or effectiveness of chiropractic care for the paediatric patient is not currently supported by high-level (robust) evidence.¹²²

ASTHMA: CHIROPRACTIC AND OSTEOPATHIC SPINAL MANIPULATION AND MASSAGE

What is known	Bronfort reports moderate-quality evidence that spinal manipulation is <u>not</u> effective (similar to sham manipulation) for the treatment of asthma in children and adults, regarding lung function and symptom severity as reported in a Cochrane review in 2005 and a systematic review in 2009. ^{123, 124} There was inconclusive favourable evidence for osteopathic manipulative treatment from one RCT for change in asthma symptoms and lung function in children. ¹²⁵ There is inconclusive evidence in an unclear direction regarding the effectiveness of home massage to improve asthma symptoms and lung function in children. ¹²⁶ More recently, Clar et al. provided an updated summary of the literature on this topic. ³² No significant differences were seen in respiratory parameters, symptoms or subjective measures between comparison groups in the studies. Improvements were generally seen using subjective measures in uncontrolled studies (no comparison against another group: i.e. a control group) that was either taking another treatment or no treatment at all.
Evidence gaps and opportunities	Review authors concluded that <i>'there is insufficient evidence to support the use of manual therapies for patients with asthma. There is a need to conduct adequately-sized RCTs that examine the effects of manual therapies on clinically relevant outcomes. Future trials should maintain observer blinding for outcome assessments, and report on the costs of care and adverse events. Currently, there is insufficient evidence to support or refute the use of manual therapy for patients with asthma.'</i>
Evidence rating	Inconclusive (unclear) evidence of osteopathic manual therapy for asthma

INFANTILE COLIC: SPINAL MANIPULATIVE THERAPY AND MASSAGE

<p>What is known</p>	<p>There have been two high-quality published systematic reviews to assess the effectiveness of SMT for colic.^{128, 129} Both systematic reviews concluded there is limited evidence manual therapy is more effective than sham therapy for the treatment of colic.</p>
<p>Evidence gaps and opportunities</p>	<p>The latter concludes: <i>'Quality of the evidence is mixed: the studies included were generally small and methodologically prone to bias, which makes it impossible to arrive at a definitive conclusion about the effectiveness of manipulative therapies for infantile colic. Taken together, the evidence seems to suggest that there may be benefits in terms of reduction in crying hours from low-quality evidence for a reduction in daily hours of crying of over one hour and for a greater proportion of patients reporting resolution of their infants' colic symptoms. The majority of the included trials appear to result in significant reductions in reported crying hours per day and in a greater proportion of parents reporting clinically significant reduction in daily crying. If one excludes the poorer-quality evidence, these benefits do not reach statistical significance: most studies had a high risk of performance bias introduced, owing to the fact that the assessors (parents) were not blind to who had received the intervention and when combining only those trials with a low risk of such performance bias, the results did not reach statistical significance. We cannot quantify any risk of adverse effects when using manipulative therapies for the treatment of infantile colic.'</i></p> <p>Since this systematic review, a study¹³⁰ was conducted that reported no adverse events and positive results when removing the risk of performance bias (parent assessors) while reporting other limitations (small sample size and patients discharged part way through the study if they improved early, such that any relapse would not be recorded). Further rigorous randomised trials that track adverse events with parental blinding are needed. There are significant methodological limitations to most of the studies reported, with no high-quality basic science research to underpin the associated biological mechanisms to support this type of care to date.</p>
<p>Evidence rating</p>	<p>Favourable inconclusive evidence for cranial osteopathic manual treatment, massage and spinal manipulation</p>

ATTENTION DEFICIT/HYPERACTIVITY DISORDER (ADHD): MANUAL THERAPY

What is known	One medium-quality systematic review ¹³¹ and two low-quality osteopathic RCTs ^{132, 133} were identified on the use of manual therapy in children or adolescents with attention deficit/hyperactivity disorder (ADHD). The systematic review authors found no studies fulfilling their inclusion criteria for chiropractic treatment in children or adolescents with ADHD.
Evidence gaps and opportunities	There are significant methodological limitations in most studies reported and no high-quality basic science research to underpin the associated biological mechanisms to support this type of care to date. There is currently no credible hypothesis for the management of neuro-developmental syndromes (e.g. ADHD) using SMT, nor robust evidence of effect. Investment in research in the absence of plausible underlying hypotheses must be carefully considered/questioned.
Evidence rating	Inconclusive (unclear) evidence for manual therapy for ADHD

NOCTURNAL ENURESIS: SPINAL MANIPULATION

What is known	Two systematic reviews evaluated the benefit of manual therapy for nocturnal enuresis have been published. ^{134, 135} They included only two randomised clinical trials on the use of spinal manipulation for nocturnal enuresis. They concluded there is insufficient evidence to make conclusions about the effectiveness of spinal manipulation for the treatment of enuresis.
Evidence gaps and opportunities	Active chiropractic adjustment had better results than sham adjustment; however: the results from these low-quality trials with small study populations need to be conducted using high-quality trials. There are significant methodological limitations in the studies reported and a lack of high-quality basic science research to underpin any biological mechanism to support this type of care to date. Investment in research in the absence of plausible underlying hypotheses must be carefully considered/questioned.
Evidence rating	Inconclusive (favourable) evidence for spinal manipulation for nocturnal enuresis

OTITIS MEDIA: SPINAL MANIPULATION

What is known	In one low-quality trial, the intervention group were sicker at baseline than the control patients and the study had a high (25%) dropout rate. The ideal number of treatment sessions needed to produce a beneficial outcome has yet to be determined and would be needed to perform cost-effectiveness analysis. Two other reviews that specifically addressed spinal manipulation by chiropractors for non-musculoskeletal pediatric ^{127, 136} conditions found insufficient evidence to comment on manual treatment effectiveness or ineffectiveness for otitis media.
Evidence gaps and opportunities	There is currently no established or credible underlying hypothesis for the management of otitis media using SMT, nor strong evidence of an effect. Investment in research in the absence of plausible underlying hypotheses must be carefully considered/questioned.
Evidence rating	Inconclusive evidence in an unclear direction for manipulative therapy for otitis media

NON-MUSCULOSKELETAL CONDITIONS (ADULT POPULATION)

ASTHMA: SPINAL MANIPULATION

What is known	There is moderate-quality evidence that spinal manipulation is not effective (similar to sham manipulation) on lung function and symptom severity for the treatment of asthma in children and adults. ^{123, 124}
Evidence gaps and opportunities	<p>The Cochrane review states '<i>Various manual forms of therapy are used to try and relieve asthma. Chiropractic and osteopathic techniques aim to increase movement in the rib cage and the spine to try and improve the working of the lungs and circulation. Other manual techniques include chest tapping, shaking, vibration, and postures to help shift and cough up phlegm. Massage is also used. Various therapists use these techniques, including chiropractors, physiotherapists, osteopaths and respiratory therapists.</i>' Essentially, the review found that there is not enough evidence from trials to show whether any of these therapies can improve asthma symptoms, and more research is needed. In a later review, the authors concluded that some patients may experience chiropractic care as beneficial, but overall there were no significant effects in any outcomes versus sham treatment.¹³⁷</p> <p>There may be underlying biomechanical hypotheses (e.g. rib cage restriction in asthmatic breathing) that suggest a role for manual therapy in the management of asthma. However, little evidence of effect exists to date.</p>

Evidence rating	Inconclusive (unclear) evidence for the use of spinal manipulation in treating asthma (2014). Changed from previous moderate (negative) evidence (2010).
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HYPERTENSION: UPPER CERVICAL SPINAL MANIPULATION

What is known	One systematic review evaluating the benefit of manual therapy for hypertension has been published. ¹³⁴ Two RCTs that evaluated the effectiveness of manual therapy for the treatment of stage I hypertension were included in this systematic review, ¹³⁸ including the use of spinal manipulation and instrument-assisted spinal manipulation. The review found no evidence of effectiveness for spinal manipulation. Since the review, a small pilot study with a high risk of bias found Upper Cervical Chiropractic Association (NUCCA) upper cervical manipulation to be more effective than sham manipulation in lowering blood pressure in patients with Stage I hypertension. ¹³⁹ A more recent medium-quality systematic review with an additional medium-quality non-randomised clinical trial included the results of five RCTs (Gonstead chiropractic adjusting, NUCCA technique, Diversified adjustment, Activator instrument, and osteopathic manipulative therapy). ¹⁴⁰
Evidence gaps and opportunities	Strong evidence supports advice on lifestyle interventions including diet, exercise, moderate alcohol consumption and smoking cessation where appropriate for some types of hypertension. Weaker evidence supports relaxation therapies including biofeedback, meditation or muscle relaxation for some types of hypertension. There is currently no established basic science research to underpin the management of hypertension using spinal manipulation, nor strong evidence of a lasting effect. There are significant methodological limitations in most studies reported and no high-quality basic science research to underpin the associated biological mechanisms to support this type of care to date. Investment in research in the absence of plausible underlying hypotheses must be carefully considered/questioned.
Evidence rating	Moderate-quality negative evidence that diversified spinal manipulation is <u>not</u> effective when added to a diet in the treatment of stage I hypertension. Inconclusive (unclear) evidence for the effectiveness of Gonstead full spine chiropractic care or osteopathic manipulative therapy for hypertension. Inconclusive evidence in a favourable direction regarding upper cervical NUCCA manipulation for stage I hypertension. Inconclusive evidence in an unclear direction regarding instrument-assisted spinal manipulation for hypertension.

DYSMENORRHEA: SPINAL MANIPULATION

<i>What is known</i>	Two systematic reviews have evaluated manual therapy for dysmenorrhea, ^{134, 141} where four trials examined the use of spinal manipulation and one examined osteopathic manipulative techniques. The Cochrane review concluded that there was no evidence for spinal manipulation as a treatment for primary and secondary dysmenorrhea. The other concluded that the evidence was equivocal regarding chiropractic care for dysmenorrhea.
<i>Evidence gaps and opportunities</i>	There were significant methodological limitations in the studies reported, and no high-quality basic science research to underpin the associated biological mechanisms to support this type of care to date. Investment in research in the absence of plausible underlying hypotheses must be carefully considered/questioned.
<i>Evidence rating</i>	Moderate-quality negative evidence against

PREMENSTRUAL SYNDROME: SPINAL MANIPULATION AND MASSAGE

<i>What is known</i>	Three systematic reviews evaluating the benefit of manual therapy for premenstrual syndrome have been published ^{134, 142, 143} which concluded that the evidence is 'not promising' and 'equivocal' while reporting that high-quality studies are needed to draw firm conclusions.
<i>Evidence gaps and opportunities</i>	Significant methodological limitations in studies reported and no high-quality basic science research to underpin the associated biological mechanisms to support SMT to date. Investment in research in the absence of plausible underlying hypotheses must be carefully considered/questioned.
<i>Evidence rating</i>	Inconclusive evidence in a favourable direction for massage therapy treatment of premenstrual syndrome and inconclusive evidence in an unclear direction for spinal manipulation for premenstrual syndrome.

PNEUMONIA AND CHRONIC OBSTRUCTIVE PULMONARY DISEASE (COPD): SPINAL MANIPULATION/MOBILISATION

<p><i>What is known</i></p>	<p>One high-quality Cochrane review assessed chest physiotherapy in adults with pneumonia,¹⁴⁴ which included two RCTs using osteopathic manipulation techniques. The trials reported no changes to mortality, cure rate, fever duration, chest x-ray change or duration of oral antibiotic therapy, while hospital stay was significantly reduced by two days and duration of total antibiotic therapy and intravenous therapy were reduced by two days in the osteopathy versus control groups. The review authors concluded that further high-quality evidence was needed to recommend chest physiotherapy. One medium-quality systematic review of manual therapy for COPD,¹⁴⁵ which also included a new medium-quality RCT of osteopathic manipulative treatment in elderly patients with chronic obstructive pulmonary disease (COPD), assessed osteopathic spinal manipulation, massage, muscle stretching, and passive movements. The review included seven studies (five RCTs) of manual therapy for COPD, however six had a high risk of bias. After the osteopathic interventions, changes in respiratory parameters were variable, but an improvement was generally seen in subjective parameters. The authors concluded that there was no evidence to support or refute the use of manual therapy techniques in clinical practice to improve lung function in COPD patients.</p>
<p><i>Evidence gaps and opportunities</i></p>	<p>There appears to be an underlying biomechanical hypothesis (e.g. rib cage restriction) that may underlie a role for manual therapy. However, little evidence of effect exists to date.</p>
<p><i>Evidence rating</i></p>	<p>Inconclusive (favourable) evidence for osteopathic manipulative treatment of pneumonia in older adults (2010). Update: Inconclusive (favourable) evidence for osteopathic manipulative treatment in patients with COPD (2014).</p>

PREGNANCY/POSTPARTUM

What is known	As with the chiropractic management of paediatric conditions, there exists only emergent evidence in support of pregnancy and related conditions. ¹⁴⁶⁻¹⁴⁸ There is evidence that multimodal care during pregnancy is superior to obstetrics care alone for low back and pelvic pain, ¹⁴⁹ and that chiropractic care is a popular choice for the pregnant patient. ¹⁵⁰
Evidence gaps and opportunities	Studies in this category typically lack randomisation or control groups, rendering any evidence for intervention as low-moderate in quality, but probably with a low level of risk. ¹⁵¹ Formal integration within an established care setting (e.g. midwifery, post-natal clinics) will facilitate both adequately powered trials and an opportunity for care in a multi-disciplinary setting.
Evidence rating	Inconclusive (favourable) evidence for spinal manipulative therapy for back pain during pregnancy. Inconclusive (unclear) evidence for manual therapy during labour or delivery.

BALANCE/FALLS RISK (ELDERLY)

What is known	One low-quality RCT on the effects of chiropractic care in elderly adults with impaired balance ¹⁵² and a protocol of an ongoing trial on the effects of manual therapy treatments for people with cervicogenic dizziness and pain. ¹⁵³
Evidence gaps and opportunities	Reporting of falls was unreliable, and there were unequal numbers of visits between groups with more falls reported for patients with more visits. There was no significant difference in scores on the Berg Balance Scale, Pain Disability Index, depression or dizziness. More basic science research is needed to further underpin the associated biological mechanisms, and the degree to which these underlying mechanisms increase falls risk.
Evidence rating	Inconclusive (favourable) evidence for the effectiveness of manipulation/mobilisation for cervicogenic dizziness. Inconclusive (unclear) evidence for diversified chiropractic treatment in the improvement of balance in elderly people.

MUSCULAR AND JOINT CONDITIONS

The scope of sporting-type injuries treated by the chiropractor is wide and is often concerned with both spinal and extremity multimodal/multi-disciplinary care, particularly at the elite level.¹⁵⁴ A number of systematic reviews demonstrate fair evidence for chiropractic intervention in the management of soft tissue injuries.¹⁵⁵ Aside from the challenge of creating robust evidence of effect, political challenges that amount to a lack of acceptance of 'sports chiropractic' as a sub-discipline may be a barrier to future practice-led research.¹⁵⁶⁻¹⁵⁸

FIBROMYALGIA: MASSAGE AND SPINAL MANIPULATION

What is known	A very small number of medium-quality systematic reviews have assessed manual therapy in patients with fibromyalgia and concluded that there is insufficient evidence to support the effectiveness of manual therapy in the treatment of fibromyalgia. ¹⁵⁹⁻¹⁶³ While there is some evidence of a significant improvement in the clinical global impression of improvement and the clinical global impression of severity, and a significant reduction in pain, most of these differences were not maintained one year after the treatment.
Evidence gaps and opportunities	There are methodological limitations in the studies reported and a lack of high-quality basic science research to underpin the associated biological mechanisms to support chiropractic management of people with fibromyalgia at this time. More effectiveness studies are needed to evaluate clinical management in this subgroup.
Evidence rating	Inconclusive (favourable) evidence for the use of chiropractic spinal manipulation in fibromyalgia. Inconclusive (favourable) evidence for the effectiveness of craniosacral therapy and massage/myofascial release therapy for fibromyalgia.

MYOFASCIAL PAIN SYNDROME: MASSAGE

What is known	Rickards (2006) provides the most recent systematic reviews assessing the effectiveness of manual therapy in myofascial pain syndrome. ²²³ Three additional medium quality RCTs ^{224, 225, 226} assessed outcomes immediately after a single treatment and therefore longer term effects are unclear.
Evidence gaps and opportunities	There are methodological limitations in studies reported to date. More effectiveness studies are needed to evaluate clinical management in this condition.

Evidence rating	<p>Inconclusive (favourable) evidence for ischaemic compression (manual or using an Activator instrument) in the deactivation of upper trapezius trigger points. Inconclusive (non-favourable) evidence indicating that trigger point release is not as effective as ischaemic compression in deactivating active upper trapezius trigger points and improving associated neck pain (not evaluated in the UK evidence report). Inconclusive (favourable) evidence for an integrated neuromuscular inhibition technique in the management of neck pain with active upper trapezius trigger points.</p>
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SHOULDER GIRDLE PAIN/DYSFUNCTION: MANIPULATION/MOBILISATION

What is known	<p>Two systematic reviews evaluated the benefit of manual therapy for shoulder pain.^{166, 167} Five of the trials evaluated mobilisation and one evaluated the use of manipulation and mobilisation for shoulder pain. Another study with a moderate risk of bias found that massage was more effective than no treatment for pain, function and range of motion (ROM) over a two-week period in patients with shoulder pain.¹⁶⁸ Another high-quality RCT found myofascial treatments (ischaemic compression, deep friction massage and therapeutic stretch) effective for soft tissue disorders of the shoulder.¹⁶⁹</p>
Evidence rating	<p>Moderate favourable evidence for the addition of manipulation/mobilisation to medical care for shoulder girdle pain and dysfunction.</p> <p>Inconclusive evidence in a favourable direction for massage in the treatment of shoulder pain.</p> <p>Moderate (positive) evidence for using myofascial treatments (ischaemic compression, deep friction massage and therapeutic stretch) for soft tissue disorders of the shoulder.</p>

ROTATOR CUFF PAIN: MANIPULATION/MOBILIZATION

What is known	Systematic reviews evaluated the benefit of manual therapy for shoulder mobilisation when added to exercise for rotator cuff disease. ^{157, 166, 167} A medium-quality RCT compared therapy using the fascial distortion model with classic manual therapy in 60 patients with frozen shoulder. ¹⁷⁰ Another high-quality RCT compared the effectiveness of end-range mobilisation/scapular mobilisation treatment in addition to standard physical therapy, compared to standard therapy alone in 34 patients with frozen shoulder syndrome. ¹⁷¹
Evidence rating	Moderate (positive) evidence for the use of manual therapy (manipulation/mobilisation) combined with exercise in the treatment of rotator cuff disorders.

ADHESIVE CAPSULITIS: HIGH GRADE MOBILISATION

What is known	Beyond previous systematic reviews, one recent study with a low risk of bias found that from three to 12 months post diagnosis, high-grade mobilisation techniques were more effective than low-grade techniques for active ROM, passive ROM and shoulder disability for adhesive capsulitis. ¹⁷²
Evidence rating	Moderate favourable-quality evidence that high-grade mobilisation is superior to low-grade mobilisation to reduce disability, but not pain, in adhesive capsulitis. Inconclusive evidence in an unclear direction for a comparison of anterior and posterior mobilisation in adhesive capsulitis.

TENNIS ELBOW (LATERAL EPICONDYLITIS): MOBILISATION WITH EXERCISE AND MANUAL TENDER POINT THERAPY

What is known	One systematic review of medium-quality evaluated the effectiveness of manipulative therapy in treating adults with lateral epicondylitis. The review identified and included 13 randomised and non-randomised trials of fair quality overall. ¹⁷³ Results indicated benefit from Mulligan's mobilisation with movement (versus no treatment, placebo or corticosteroid injection) and manual therapy applied to the cervical spinal region (versus placebo). Cyriax physiotherapy was found to be more effective than conventional therapy (stretching, exercise, and modalities), but less effective than corticosteroid injection or supervised exercise. Another systematic review of various physical therapy treatments for lateral epicondylitis in adults (medium-quality) indicated that in the short term (six months or less), corticosteroid injections were more beneficial than physical therapy (elbow manipulation and exercise) or Cyriax physiotherapy, while in the longer term (six months or longer), there was no difference between physical therapy (elbow manipulation and exercise) versus corticosteroid injections or no treatment. Radial head mobilisation was more effective compared to standard treatment (ultrasound, massage, stretching and exercise for wrist) at a follow-up of 15 weeks. ¹⁷⁴
Evidence rating	Inconclusive (non-favourable) evidence was found for the treatment of lateral epicondylitis (tennis elbow) with manipulation alone. Inconclusive (favourable) evidence of manual therapy in reducing symptoms in patients with lateral epicondylitis, when combined with other treatments (exercise, traditional physiotherapy, local management and standard therapy), compared to no treatment, or baseline values (within-group change).

CARPEL TUNNEL SYNDROME: MANIPULATION/MOBILIZATION

What is known	Three medium quality systematic reviews, ¹⁷⁵⁻¹⁷⁷ and one high-quality systematic review ¹⁷⁸ on the effectiveness of manual therapy in carpal tunnel syndrome.
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<p>Evidence gaps and opportunities</p>	<p>Clar et al. concluded: <i>'there is limited evidence that carpal bone mobilisation is more effective with respect to symptom improvement than no treatment in the short term in the treatment of carpal tunnel syndrome. There was no evidence found for the effectiveness of neurodynamic treatment versus carpal bone mobilisation in the short term, for the effectiveness of a neurodynamic technique plus splinting compared with a sham therapy plus splinting group in the short term, or for the effectiveness of Graston instrument-assisted soft tissue mobilisation plus home exercises compared with soft tissue mobilisation plus home exercises in the midterm. There was no evidence for the effectiveness of chiropractic therapy compared with medical treatment in the midterm.'</i></p>
<p>Evidence rating</p>	<p>Inconclusive (favourable) evidence for carpal bone mobilisation and for trigger point therapy in the treatment of carpal tunnel syndrome. Inconclusive (unclear) evidence for neurodynamic treatment, soft tissue mobilisation (with or without Graston instrument) and diversified chiropractic care in the management of carpal tunnel syndrome.</p>

HIP OSTEOARTHRITIS: MANIPULATION/MOBILISATION WITH EXERCISE

<p>What is known</p>	<p>One systematic review evaluating manual therapy for hip pain has been published¹⁷⁹ and concluded that there is limited evidence for manipulative therapy combined with multimodal or exercise therapy for hip osteoarthritis. One RCT evaluating the effectiveness of hip manipulation for the treatment of hip osteoarthritis was included in the published systematic review.¹⁸⁰ In a medium-quality cohort study assessed the effects of osteopathic manipulative treatment on distance walked, days to independent negotiation of stairs, length of hospital stay, need for supplemental analgesics and perception of pain in 76 adult participants who had knee or hip arthroplasty.¹⁸¹</p>
<p>Evidence rating</p>	<p>Moderate-quality evidence that hip manipulation is superior to exercise for the treatment of the symptoms of hip osteoarthritis. Inconclusive (favourable) evidence for osteopathic manual therapy for surgery rehabilitation.</p>

KNEE OSTEOARTHRITIS: MANIPULATION/MOBILISATION WITH EXERCISE

<i>What is known</i>	One systematic review evaluating the benefit of manual therapy for knee pain (osteoarthritis knee pain and patellofemoral pain syndrome) included 10 RCTs evaluating the effectiveness of manual therapy. ¹⁷⁹ The review covered manual therapy techniques including spinal mobilisation, spinal manipulation, knee mobilisation and knee manipulation. It concludes that there is fair evidence for manipulative therapy of the knee and/or full kinetic chain (sacroiliac to foot), combined with multimodal or exercise therapy for knee osteoarthritis and patellofemoral pain syndrome.
<i>Evidence rating</i>	Moderate-quality evidence that manual therapy of the knee and/or full kinetic chain (sacroiliac to foot) combined with multimodal or exercise therapy is effective for the symptoms of knee osteoarthritis. Inconclusive evidence in a favourable direction that massage therapy is effective for the symptoms of knee osteoarthritis.

PATELLOFEMORAL PAIN SYNDROME

<i>What is known</i>	One systematic review evaluated the benefit of manual therapy for patellofemoral pain syndrome. ¹⁷⁹
<i>Evidence rating</i>	Moderate quality evidence that manual therapy of the knee and/or full kinetic chain (SI to foot) combined with multimodal or exercise therapy is effective for patellofemoral pain syndrome.

MAINTENANCE CARE

CHRONIC LOW BACK PAIN: SPINAL MANIPULATION

<i>What is known</i>	Preliminary evidence exists to support the role of spinal manipulation in the long-term management of low back pain, ^{182, 183} where maintenance spinal manipulations after intensive manipulative care may be beneficial to patients to maintain their subjective post-intensive treatment disability levels. In a another study, only the group given spinal manipulations during a 10-month follow-up period showed more improvement in pain and disability scores. Furthermore, the mean pain and disability scores in the non-maintained SMT group returned back near pre-treatment levels. ¹⁸⁴
<i>Evidence gaps and opportunities</i>	Future studies are needed to confirm the finding in a larger group of patients with chronic low back pain.
<i>Evidence rating</i>	Inconclusive favourable

CHRONIC NECK PAIN: SPINAL MANIPULATION/MOBILISATION

<i>What is known</i>	Limited evidence has demonstrated an advantage of spinal manipulation combined with rehabilitative exercise versus spinal manipulation alone with long-term follow-up. Further studies are needed to examine the cost effectiveness of these therapies and how spinal manipulation compares to no treatment or minimal intervention. ¹⁸⁵ In another study of 183 patients with non-specific neck pain, short-term results (at seven weeks) have shown that MT (mobilisation) speeded recovery compared with GP and PT care, while long-term, GP treatment and PT caught up with MT at the 13-week and 52-week follow-ups. ¹⁸⁶ Manual therapy with exercise was reported to have long-term improvements in pain, disability and patient-perceived recovery in patients with mechanical neck pain when compared to a program comprising advice, a mobility exercise and sub-therapeutic ultrasound. ¹⁸⁷
<i>Evidence gaps and opportunities</i>	These results suggest that treatments including SMT with supervised rehabilitative exercise should be considered for chronic neck pain sufferers.
<i>Evidence rating</i>	Inconclusive

SAFETY AND ADVERSE EVENTS

<p>What is known</p>	<p>There have been five recent systematic reviews¹⁸⁸⁻¹⁹² investigating adverse events as a result of manual therapy. A more recent systematic review found no strong evidence for causation of stroke from SMT applied to the cervical spine.¹⁹³ It concludes: <i>'the quality of the published literature on the relationship between chiropractic manipulation and CAD is very low. Our analysis shows a small association between chiropractic neck manipulation and cervical artery dissection. This relationship may be explained by the high risk of bias and confounding in the available studies, and in particular by the known association of neck pain with CAD and with chiropractic manipulation. There is no convincing evidence to support a causal link between chiropractic manipulation and CAD. Belief in a causal link may have significant negative consequences such as numerous episodes of litigation.'</i> Overall, most review authors report that mild-to-moderate adverse events of transient nature were relatively frequent, including worsening symptoms, increased pain, soreness, headache, dizziness, tiredness, nausea and vomiting. Approximately half of the individuals receiving manual therapy experienced mild-to-moderate adverse events, which had resolved within 24–74 hours. Clar et al. reports that evidence indicating serious adverse events after manual therapy were very rare e.g. cerebrovascular events, disc herniation, vertebral artery dissection, cauda equine syndrome, stroke, dislocation, fracture and transient ischaemic attack.</p>
<p>Evidence gaps and opportunities</p>	<p>Evidence on the safety of manual therapies in children or paediatric populations in clinical trials is scarce.</p>
<p>Evidence rating</p>	<p>The lack of high-quality evidence on adverse events in manual therapy warrants caution. This is due to the relative paucity of evidence and poor methodological quality of adverse events data within primary studies to date. More high-quality research is needed to assess the risk of adverse events for individual interventions towards different conditions and within different patient populations.</p>

SECTION 3: SUMMARY AND OPPORTUNITIES

This report has provided a summary of evidence for manual therapies in the domains of basic science and clinical research (including safety). This document has not included a summary of research for the domains of cost effectiveness, patient education or health promotion. Furthermore, the authors recognise that the information provided within this document may not be complete and that information may have been missed or new information may have been published that has not been included.

FUNDING FOR RESEARCH PROJECTS AND MRES SCHOLARSHIPS

BASIC SCIENCE RESEARCH

Basic science (lab-based) research aims to discover or elucidate underlying biological mechanisms. In contrast, high-quality clinical trial designs (typically RCTs) are the gold standard required to assess whether a clinical intervention provides worthwhile improvement to patient health. Combined, these research domains can inform our understanding of what constitutes an effective therapy. However, the results of basic science research alone are not suited to informing frontline clinical diagnosis or care.

Unfortunately, claims regarding the benefit of SMT on 'enhancing' CNS function have been overstated. This appears to be the result of the (inappropriate) translation of basic science research to inform either clinical care or ongoing passive care, where inferences have been made beyond the original study design. There is little doubt that this practice has negatively impacted upon the reputation and standing of the chiropractic profession within the broader scientific and healthcare community, as well as within the public domain (e.g. via ongoing negative media attention and breaches in advertising). In a 2015 summary of neurophysiological basic science research, Dr Scott Haldeman reported: *'claims that this research is sufficiently advanced to understand the relationship between SMT and the nervous system as clinical fact or any claim to justify SMT in the treatment of specific conditions based on these theories should be viewed with scepticism.'*⁴⁴

BASIC SCIENCE RESEARCH: NEUROPHYSIOLOGY

The RSSRO highlights some promising areas for future basic science research and where findings may be of significance to future clinical research. For example, dysfunction of the cervical receptors in some neck disorders can alter afferent input via a number of mechanisms such as trauma, functional impairment of the receptors, changes in muscle spindle sensitivity and the vast effects of pain at many levels of the nervous system. Emerging evidence suggests that this may cause a measurable change to the integration and tuning of some aspects of sensorimotor control through cervical joint position sense, eye movement control and postural stability, which can result in dizziness and unsteadiness in some patients with neck disorders.⁵⁵ As a result, this has led to some early recommendations for clinical assessment and management of sensorimotor control disturbances in neck disorders, which includes the use of chiropractic manual therapies (including SMT) along with specific exercises and tailored sensorimotor control programs. Importantly, the extent to which these maladaptive changes cause any significant additional impact on personal health or healthcare costs has not yet been quantified.

Central sensitisation is a condition of the nervous system that is associated with the amplification of pain sensation and may be present in patients with persistent pain. Nijs et al. has summarised a number of considerations important to future research, including manual therapy research, in this area.¹⁹⁴ Preliminary evidence demonstrates a widespread analgesic effect after manual joint mobilisation for chronic osteoarthritis,^{195,196} but this is not sustained (30–45 min post-intervention). Plausible hypotheses include the excitation of descending anti-nociceptive pathways. A theoretical framework has been developed to facilitate investigation of this phenomenon.^{197,198} Nijs et al. caution that future research must examine whether repeated manual therapy has the capacity to result in long-term activation of descending anti-nociceptive pathways, or whether repeated manual therapy

(via peripheral nociceptive stimulation) may in fact contribute to the process of central sensitisation.¹⁹ There exists no robust translational evidence to support ongoing manual therapy alone (mobilisation/manipulation) for the chronic pain patient or that SMT is a proven therapy for many chronic conditions associated with central sensitisation. Furthermore, the risk of therapy dependence in this population is high, and is associated with negative health outcomes.¹⁹⁹

In a constrained financial and competitive research funding environment, and when giving consideration to the increased demands being placed upon the quality and level of clinical research to support frontline care, it is important to note that basic science research has more limited application clinically; it will less often influence government funding for public health initiatives and it has less influence on the decision-making of third-party providers or regulatory authorities. In such an environment, research impact must be a key consideration. When considering funding for basic science research, it is critical that such research designs are performed with scientific rigor and are based on hypotheses that are supported by a sufficient underlying biological plausibility and that are likely to inform future clinical research.

CLINICAL RESEARCH

The RSSRO highlights promising areas for future clinical research. These include research for manual therapy interventions where the existing evidence is underpinned by plausible biological mechanisms and where the evidence quality rating is moderate or high for a positive effect. As a result, support for future methodologically robust research is likely to be promising where: (i) research designs test the initial positive treatment effects (e.g. by delivering therapy to a larger, or more general population); and (ii) there is a high likelihood that the research will contribute to solving public health issues as identified by the GBD and AIHW.

As examples, back pain, neck pain and headaches have been identified by the AIHW to have a multibillion-dollar financial impact on healthcare costs and a significant burden on the personal health, finances and work productivity of the Australian public. Support for further research that demonstrates the improved management of these conditions would align with government healthcare policy, attract multi-disciplinary research collaborations and larger externally funded research grants from the NHMRC and Australian Research Council (ARC).

In contrast, the clinical research section also documents a significant number of lower-quality clinical research where the evidence for interventions for some conditions are reported as either: (a) inconclusive or negative; or (b) without a plausible underlying biological mechanism. For example, the evidence for interventions for most non-musculoskeletal conditions is often identified by a quality rating of inconclusive, or by higher-quality studies demonstrating a negative effect. This suggests that future, more methodologically robust research may not find evidence of effect (or find stronger evidence for a negative effect) for the intervention tested.

Research has identified that unimodal approaches of care typically demonstrate small effects, and that multimodal (or multi-disciplinary) care delivers superior outcomes. Future research funding decisions should consider the greater potential benefit of multimodal approaches and/or more integrated research designs within a multi-disciplinary setting in order to deliver greater health outcomes than single interventions alone. This is particularly true for seeking solutions to chronic conditions. Funding support for translational research designs (e.g. clinical decision support aids), should also be considered.

In conclusion, a body of high-quality clinically focused research will increase the scientific rigour of the profession and will increase the opportunity for chiropractic care to be included in primary care clinical practice guidelines. This approach will be realised through long-term support for academic research, and represents a sustainable and ethically responsible pathway towards increased market share, funding opportunities and the scope of chiropractic care.

CLINICAL RESEARCH: ASYMPTOMATIC CARE

The delivery of ongoing patient management, encompassing manual therapies, exercise and health promotion, has been identified as part of the *Chiropractic Paradigm*^{5, 200, 201} and is accepted as an intrinsic part of the chiropractic model of practice for some of the profession.^{202, 203} One goal of maintenance care is to improve overall health in a largely asymptomatic population. Components of maintenance care often include adjustments/spinal manipulation, exercise, patient education and nutritional advice including vitamin supplementation.²⁰³⁻²⁰⁵ Hawke et al. reports that the term 'maintenance care' may be synonymous with chiropractic 'wellness care'²⁰⁶ which is similarly described as '*active patient participation*' towards '*achieving the best health possible*' by '*pursuing an optimal level of function*' that may be optimised through the use of '*a combination of health care strategies such as chiropractic adjustments, manipulative therapy, manual therapies, exercise, diet/nutrition counselling, and lifestyle coaching*'.²⁰⁷

In a recent consensus document, Hawke et al. stated: '*despite previous attempts to define wellness care in chiropractic practice, there is currently no standard protocol for how it is practiced and disagreement as to its benefits or whether it is appropriate. At the heart of the disagreement is the belief by some that periodic visits by asymptomatic patients for periodic spinal manipulation will improve overall health, prevent disease, and/or decrease recurrence of spine pain. However, there is no firm evidence that supports this theory*'.⁵

CLINICAL RESEARCH: CHRONIC DISEASE CARE

The majority of chronic health conditions span more than one health domain, and as a result often require multimodal and/or multi-disciplinary approaches to provide the best care. The biopsychosocial model of care, as described by Waddell nearly 20 years ago, remains the current approach, particularly when addressing chronic conditions.¹⁹⁹ The clinical elements of this model includes aspects of physical dysfunction, beliefs and coping, level of distress, illness behaviour and social interactions. Central to this model is recognising the relationship between physical and psychological dysfunction.

Ongoing long-term disease management is popular among chiropractors, osteopaths and physiotherapists for conditions such as low back pain.²⁰⁸ However, there is a paucity of high-quality longitudinal research examining chiropractic care for chronic conditions (e.g. RCTs) with sufficient long-term follow-up to assess ongoing health benefits. The most studied condition is chronic back pain, usually through application of the biopsychosocial model of care.²⁰⁹⁻²¹¹ In contrast, ongoing manual therapy (passive care) even in the presence of symptoms has been associated with therapy dependence and a decrease in patient self-efficacy, both of which can lead to, or increase negative health outcomes and passive care dependency.^{209, 212}

Regarding chiropractic intervention, high-quality research relating to maintenance care for chronic disease is sparse. Before further high-quality clinical research into this area can be recommended, a number of profession-specific preparatory measures must be considered. Namely, (i) minimise heterogeneity when describing the continuum of care delivered after resolution or plateau of presenting symptoms (e.g. define 'maintenance care', 'supportive care', 'wellness care', etc.); (ii) analyse clinical practice patterns of care (including long-term); and (iii) identify conditions that are appropriate to the application of this type of care.²⁰¹ Some of these measures have begun, with recommendations for more robust study designs and adverse events reporting.¹³⁴

CLINICAL RESEARCH: VITALISTIC CONSTRUCT

In a recent survey of 100 chiropractic clinics in Australia, Brown et al. reported that approximately one in five respondents sought chiropractic care for maintenance of general health and wellbeing.¹⁰ It is unclear what percentage of these do so within a vitalistic paradigm (the majority of survey respondents [70%] sought care for musculoskeletal disorders). Hawke et al. also reported that some patients do not seek spinal manipulative care specifically for the treatment of a specific condition, but for reasons of general health including for general wellness and disease prevention.²¹³ More recent trends in chiropractic have seen 'vitalism' redefined as a '*characterising paradigm or framework (which) usually refers to organismic and systems approaches to biology rather than magical thinking*'.²¹⁴ Regardless of updated theoretical constructs and definitions, studies that have aimed to validate

vitalistic principles (e.g. broad health effects from the delivery of passive therapy to an asymptomatic population) have serious methodological flaws.^{215, 216} These flaws can include the failure to establish an underlying plausible biological mechanism of effect, confounding (e.g. non-specific effects of therapy), measurement bias (e.g. lack of validated measurement tools), and inferior study designs (e.g. case studies, lack of randomisation or lack of patient/therapist blinding).

Furthermore, research exploring the vitalistic maintenance care model can be subject to publication and/or reporting bias.²¹⁷

CHIROPRACTIC REPRESENTATION AND ENGAGEMENT

The RSSRO is intended to inform discussion with stakeholders and policymakers outside the profession. This can include representation and engagement with the media, healthcare policymakers, scientific community and other healthcare professions.

There is a growing scrutiny of the evidence to support some aspects of chiropractic care. This is partly the result of many practitioners (e.g. on social media and websites) making unsupported claims about the health benefits of chiropractic care to certain patient groups and conditions. Greater external scrutiny is likely to be directed towards care that is unsupported by high-quality external evidence and where it is directed towards vulnerable patient groups.

While there are some areas of chiropractic care that are supported by high-quality clinical research, there are many areas of chiropractic care that are not. The excessive promotion of 'safety' or 'clinical certainty' where there is inconclusive or low-quality research evidence to support such claims will damage the reputation and standing of the profession with key stakeholders, as well as public perception of the profession through the media. Trust in chiropractic care will require leadership and representation of the profession to be cognisant of those areas of clinical care that are not supported by high-quality evidence.

CONTINUING PROFESSIONAL DEVELOPMENT (CPD)

The RSSRO may be used to inform the awarding of FLA hours for courses within continuing chiropractic education. The RSSRO provides information to assist reviewers' understanding of the level of research quality prior to awarding FLA hours for conferences or seminars. In particular, caution is advised before awarding FLA hours for interventions that are supported by negative, weak or inconclusive evidence as highlighted in this document.

CLINICAL DECISION-MAKING

Whenever possible, only the highest-level evidence should inform clinical decision-making. While there has been significant discourse as to the challenges of applying rigorous trial designs to the clinical encounter,^{218, 219} RCTs remain the gold standard for minimising bias in research that seeks to measure therapeutic effect.

In broad terms, there is a hierarchy applied to the evidence for a given clinical question in the clinical setting.²²⁰ The level and quality of research evidence within that hierarchy is largely determined by the study design. For example, when determining the effectiveness of a treatment, a systematic review of a number of RCTs (high-level evidence: level 1a) is superior evidence to a case-control study (level 3b) or expert opinion (low-level evidence: level 5).²²¹ Bronfort et al. states that 'it is essential to recognise what each piece of the evidence-based practice offers' and that 'patient values and preferences do not provide sound evidence of a treatment's effectiveness and may be misleading'²²² and that patient satisfaction can still exist where treatment may not have been effective.

Further, the clinician must be aware that improvements in patient health may be due to factors outside the delivered intervention. For example: placebo effect; patient health-seeking activities external to care; a patient's desire to satisfy practitioner expectations; the natural history of the disease; practitioner

observation bias; or clinical tests that are unreliable or lack applicability to the target condition.

The RSSRO advise caution when planning care based on low-quality evidence (e.g. spinal manipulation for the treatment of non-musculoskeletal conditions). While lack of evidence does not mean the intervention may lack efficacy, it does not follow that further research will support improved health outcomes from that intervention. Indeed, further research to assess the efficacy of SMT for some non-musculoskeletal conditions may find a negative effect, i.e. evidence to show SMT is not effective for the tested condition. This is more likely where the intervention is not underpinned by plausible biological mechanisms. As such, these findings highlight the need for clinicians to educate patients about the quality of the existing evidence for a given chiropractic intervention for a given condition, and to inform patients about more appropriate treatment interventions that are available outside the profession, before informed consent can occur.²²²

GRADES OF EVIDENCE

For research rated as high quality evidence, one can be confident the effect estimate presented lies very close to the true value, thus there is a very low probability of further research completely changing the presented conclusions. For research rated as moderate quality evidence, one can be confident from this rating that the presented effect estimate lies close to the true value, but it is also possible that it may be substantially different, so further research may change the conclusions.

For low-quality evidence research rated as inconclusive (favourable, unclear) evidence, clinicians cannot be confident of the treatment effect estimate. The true value of the treatment effect may be substantially different to findings reported from studies with this rating. Further research may support or reverse the observed effect. Other effective alternatives should be recommended where available.

For inconclusive non-favourable evidence patients should be advised that this treatment is likely not effective and more effective treatments should be recommended where available. For research rated high and moderate quality negative evidence, patients should be actively advised against the use of this treatment so a more effective alternative should be recommended where available.

SUMMARY

Clinicians have an ethical, legal and professional responsibility to deliver care and provide advice that is based upon current best evidence. This will require clinicians to regularly evaluate the evidence in support of (or against) a considered intervention. In doing so, clinicians must also consider the evidence for interventions outside of chiropractic care that is also available in each circumstance. Where there exists a lack of robust evidence in support of an intervention, the decision to treat must be supported by plausible biological science and informed patient agreement. Clinicians and researchers must be cognisant of the potential harms to their patients (including false optimism) and to the reputation of the profession that can result from overstated evidence of effect, or misinterpretation of biological process when delivering care.

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APPENDICES

APPENDIX 1: RATING LEVEL OF EVIDENCE - DEFINITIONS

Appendix 1 is reproduced from Bronfort et al. (2010)³³

Level of Evidence	Actions Supported
High- and moderate-quality POSITIVE evidence	<ul style="list-style-type: none">• Support public favourable claims regarding effectiveness• Advise patients that this is an effective treatment choice
Inconclusive favourable evidence	<ul style="list-style-type: none">• Do not support any public claims regarding effectiveness• Recommend an effective alternative if available• Advise patients that this is a treatment option in the absence of an effective treatment
Inconclusive evidence in an unclear direction	<ul style="list-style-type: none">• Recommend effective alternative if available• Advise patients that the effectiveness of this treatment option has not been established
Inconclusive non-favourable evidence	<ul style="list-style-type: none">• Advise patients that this treatment option is unlikely to be effective• Recommend effective alternative if available
High- and moderate-quality negative evidence	<ul style="list-style-type: none">• Advise patients against this as a treatment option• Recommend effective alternative if available

APPENDIX 2: RATING LEVEL OF EVIDENCE – PER CONDITION

Appendix 2 is reproduced from Bronfort et al. (2010)³³

SPINAL CONDITIONS

Condition	Intervention	Evidence Rating		
		Inconclusive	Moderate	High
Acute low back pain	Spinal manipulation/mobilisation		Moderate-quality positive evidence	
Chronic low back pain	Spinal manipulation/mobilisation			High-quality positive evidence
Chronic low back pain	Massage		Moderate-quality positive evidence	
Sciatica/radiating leg pain	Spinal manipulation/mobilisation	Favourable inconclusive evidence		
Mid back/thoracic pain	Spinal manipulation	Favourable inconclusive evidence		
Acute/subacute neck pain	Cervical spine manipulation/mobilization	Favourable inconclusive evidence		
Acute/subacute neck pain	Thoracic spine manipulation/mobilisation		Moderate-quality positive evidence	
Acute whiplash-associated disorders	Mobilisation with exercise		Moderate-quality positive evidence	
Chronic neck pain	Spinal manipulation/mobilization with exercise		Moderate-quality positive evidence	
Chronic neck pain	Massage		Moderate-quality positive evidence	

Pregnancy-related low back pain	Spinal manipulation/mobilisation	Inconclusive (favourable) evidence		
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HEAD AND HEADACHE DISORDERS

Condition	Intervention	Evidence Rating		
		Inconclusive	Moderate	High
Migraine headache	Spinal manipulation		Moderate-quality positive evidence	
Migraine headache	Massage		Moderate-quality positive evidence	
Tension headache	Spinal manipulation alone	Inconclusive unclear evidence		
Tension headache	Multimodal manual therapies	Inconclusive favourable evidence		
Cervicogenic headache	Spinal manipulation		Moderate-quality positive evidence	
Cervicogenic headache	Mobilisation		Moderate-quality positive evidence	
Cervicogenic headache	Spinal manipulation/mobilization with exercise		Moderate-quality positive evidence	
Cervicogenic dizziness	Spinal manipulation/mobilization	Inconclusive favourable evidence		

Temporomandibular joint dysfunction	Mobilisation/massage	Favourable inconclusive evidence for mobilisation and massage		
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NON-MUSCULOSKELETAL CONDITIONS (PAEDIATRICS)

Condition	Intervention	Evidence Rating		
		Inconclusive	Moderate	High
Asthma	Spinal manipulation, massage and osteopathic manipulative therapy (OMT)	Inconclusive (unclear) evidence for OMT		
Colic	Manual therapies: spinal manipulation, cranial OMT, massage,	Favourable inconclusive evidence		
ADHD	Manual therapy	Inconclusive (unclear) evidence		
Nocturnal enuresis	Spinal manipulation	Inconclusive (favourable) evidence		
Otitis media	OMT	Inconclusive evidence in an unclear direction		

NON-MUSCULOSKELETAL CONDITIONS (ADULTS)

Condition	Intervention	Evidence Rating		
		Inconclusive	Moderate	High
Asthma	Spinal manipulation	Inconclusive unclear evidence		
Stage I Hypertension type	Gonstead spinal manipulation or OMT	Inconclusive unclear evidence		
Hypertension	Upper cervical spinal manipulation (NUCCA)	Inconclusive favourable evidence		
Hypertension	Instrument assisted spinal manipulation	Inconclusive unclear evidence		
Dysmenorrhea	Spinal manipulation		Moderate-quality negative evidence	
Premenstrual syndrome	Massage	Inconclusive favourable evidence		
Premenstrual syndrome	Spinal manipulation (OMT)	Inconclusive unclear evidence		
COPD	Spinal Manipulation	Inconclusive favourable evidence		
Labour or delivery	Manual therapy	Inconclusive (unclear) evidence		
Falls risk (Elderly)	Diversified SMT	Inconclusive (unclear) evidence		

MUSCULAR AND JOINT CONDITIONS

Condition	Intervention	Evidence Rating		
		Inconclusive	Moderate	High
Fibromyalgia	Spinal manipulation	Inconclusive (favourable) evidence for SMT Inconclusive (favourable) evidence for cranio-sacral therapy		
Fibromyalgia	Massage and myofascial therapy	Inconclusive (favourable) evidence		
Myofascial pain syndrome	Massage	Inconclusive favourable evidence		
Shoulder girdle pain/dysfunction	Manipulation/mobilisation		Moderate favourable evidence	
Shoulder girdle pain/dysfunction	Massage	Inconclusive favourable evidence		
Shoulder girdle pain/dysfunction	Myofascial treatments (ischaemic compression, deep friction massage, therapeutic stretch) for soft tissue disorders		Moderate favourable evidence	
Rotator cuff pain	Manipulation/mobilisation combined with exercise		Moderate favourable evidence	

Adhesive capsulitis	High grade mobilization is superior to low-grade mobilisation for reduction of disability, but not pain		Moderate favourable evidence	
Adhesive capsulitis	Anterior and posterior mobilisation	Inconclusive unclear evidence		
Tennis elbow (lateral epicondylitis)	Manipulation	Inconclusive (non-favourable) evidence		
Tennis elbow (lateral epicondylitis)	Mobilisation with exercise and Manual tender point therapy	Inconclusive (non-favourable) evidence		
Carpel tunnel syndrome	Manipulation/mobilisation and trigger-point therapy, neurodynamic treatment, soft-tissue mobilisation (with or without Graston instrument), and diversified chiropractic care	Inconclusive favourable evidence		
Hip osteoarthritis	Manipulation/mobilisation is superior to exercise		Moderate favourable evidence	

Hip osteoarthritis	Osteopathic manual therapy for surgery rehabilitation	Inconclusive favourable evidence		
Knee osteoarthritis	Manipulation/ mobilisation with exercise		Moderate favourable evidence	
Knee osteoarthritis	Massage therapy	Inconclusive favourable evidence		
Patellofemoral syndrome	Manual therapy of the knee and/or full kinetic chain (SI to foot) combined with multimodal or exercise therapy		Moderate favourable evidence	

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