Safer Care Victoria

# Chiropractic spinal manipulation of children under 12

## Independent review

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Authorised and published by the Victorian Government, 1 Treasury Place, Melbourne.

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ISBN 978-1-76069-066-3 (pdf/online/MS word)

Available at [www.safercare.vic.gov.au](http://www.safercare.vic.gov.au)

# Executive summary

On 8 March 2019, the Council of Australian Governments (COAG) Health Council (CHC) noted community concerns about spinal manipulation on children performed by chiropractors and agreed that there was a need to consider whether public safety was at risk.

On behalf of the CHC, the Victorian Minister for Health, the Hon. Jenny Mikakos MP, instructed Safer Care Victoria (SCV) to undertake an independent review of the practice of chiropractic spinal manipulation on children under 12 years. The findings of this review are to be provided to the Minister for reporting to the CHC.

To provide expert guidance and advice to inform the review, SCV established an independent advisory panel. The panel included expertise in chiropractic care, academic allied health, health practitioner regulation, healthcare evidence, governance, paediatrics and paediatric surgery, and musculoskeletal care, and had consumer representation.

The panel’s role was to provide advice to assist SCV in scoping the review, interpretation of the findings, and in developing their recommendations. In order to provide this advice, the panel decided to undertake a public consultation as well as consider evidence from the relevant complaints and regulatory bodies alongside a systematic review of the literature.

The review comprised a search for evidence of harm, a review of evidence of effectiveness, an online public consultation and an online consultation with health practitioners. Detailed descriptions of these different components of the review are provided in this report.

The scope of the review included spinal manipulation in children under 12 years of age. Spinal manipulation as defined in Section 123 of the *Health Practitioner Regulation National Law Act 2009 Health Practitioner Regulation National Law Act 200Health Practitioner Regulation National Law Act 2009* (Health Practitioner Regulation National Law Act 2009 National Law) is one of many techniques performed by chiropractors. For the purpose of collecting all relevant evidence, the panel agreed to a definition of spinal manipulation aligned to that defined in Section 123 of National Law. Spinal manipulation was defined as “any technique delivered by any health professional that involves a high velocity, low amplitude thrust beyond the physiological range of motion, impacting the spine, within the limits of anatomical integrity.”

The panel also determined that, while the recommendations are focused primarily on the chiropractic profession, other professions permitted to do spinal manipulation will likely be implicated should there be legislative or policy implications as a result of this review. Section 123 of National Law restricts the practice of spinal manipulation of the cervical spine to four health professions: chiropractic, osteopathy, medical and physiotherapy.

Further content regarding the review process and in-depth findings have been detailed in this report.

## Summary of findings

### Review of evidence of harm

An extensive search was undertaken to identify evidence of harm sustained by children who had received spinal manipulation. This included a literature review by Cochrane Australia, capture of patient complaints and practitioner notification data from Australian complaints and regulatory agencies, capture of Australian insurance claim data from the primary insurers for registered chiropractors, and stakeholder feedback from both online consultations. This extensive search identified very little evidence of patient harm occurring in Australia. In particular, there were no patient complaints or practitioner notifications that arose from significant harm to a child following spinal manipulation.

Three individual case reports were the only evidence of serious harm identified. Each of these reports related to spinal manipulative techniques performed outside of Australia and not limited to chiropractors. The practices described in these reports are not reflective of Australian chiropractic techniques. This does not mean spinal manipulation in children is not associated with any risk of any adverse effects. An extensive literature review did identify transient or minor adverse events but the prevalence was very low, albeit possibly more common in very young children.

There are two principle reasons why the search did not find strong evidence of harm in Australia. First, it is unlikely that spinal manipulation, as defined within the scope of the review, is a technique that is being routinely applied in Australia to young children or those with an immature spine. Second, skilled chiropractic care requires the practitioner to modify the force applied based on the age and developmental stage of the child. This means that children, particularly very young children, under the care of an Australian chiropractor are not likely to be receiving high impact manipulations.

Nonetheless, it is clear that spinal manipulation in children is not wholly without risk. Any risk associated with care, no matter how uncommon or minor, must be considered in light of any potential or likely benefits. This is particularly important in younger children, especially those under the age of 2 years in whom minor adverse events may be more common.

### Review of evidence of effectiveness

SCV commissioned Cochrane Australia to undertake a systematic review of the effectiveness and safety of spinal manipulation of children under 12 years for any condition or symptom, irrespective of the profession providing treatment.

The major finding of this review is that the evidence base for spinal manipulation in children is very poor. In particular, no studies have been performed in Australia.

Specifically, the comprehensive review of the literature failed to identify any strong evidence for the effectiveness of spinal manipulation for a variety of conditions for which children are widely offered chiropractic manipulations. These conditions included colic, enuresis, back/neck pain, headache, asthma, otitis media, cerebral palsy, hyperactivity and torticollis.

There was low certainty (weak) evidence that spinal manipulation may be beneficial for modestly reducing crying time in children with colic, or for reducing the number of wet nights in children with enuresis. For both conditions the evidence was also consistent with either no or worsening effects.

For the other conditions – headache, asthma, otitis media, cerebral palsy, hyperactivity, and torticollis – there was no evidence that spinal manipulation was effective.

Based on this review of effectiveness, spinal manipulation of children cannot be recommended for:

* headache
* asthma
* otitis media
* cerebral palsy
* hyperactivity disorders
* torticollis.

The possible, but unlikely, benefits of spinal manipulation in the management of colic or enuresis should be balanced by the possibility, albeit rare, of minor harm.

### Public consultation

SCV wished to hear from parents and guardians of children who had accessed chiropractic spinal care, exploring their experiences, both positive and negative. This was achieved through an online consultation process using the Victorian Government’s Engage.Vic platform. Through this platform, 21,824 submissions were received from members of the public who had accessed chiropractic spinal care for a child under 12 years. This is the largest number of submissions received to date through Engage.Vic or any public stakeholder engagement.

The public responses indicated very strong consumer satisfaction. Of all respondents, 99.7% (21,750) reported a positive experience with the chiropractic care of their children. The overwhelming majority of parents/guardians reported that chiropractic spinal care helped their child, with 98% (21,474) indicating that their child improved after treatment. It was clear that parents/guardians appreciated the time that their child’s chiropractor took to listen to their child’s symptoms and to engage with them and their child. A sentiment that was strongly expressed was the right of a parent/guardian to choose their child’s care.

Parents/guardians reported that they accessed chiropractic care for their child for a wide range of conditions and complaints, including maintaining general health and wellbeing. The most common conditions included posture concerns, colic, neck pain, difficulty with breastfeeding, back pain and headache.

A very small minority of respondents – 0.3% (74) – reported a negative experience. These experiences mostly related to concerns about the cost of treatment with no improvement in the condition, excessive use of X-rays, or perceived pressure to avoid medications or advice previously provided by other practitioners, including medical practitioners.

### Health practitioner consultation

SCV wished to hear from registered health practitioners – chiropractors, medical practitioners and other health practitioners – about perceived benefits of or concerns with spinal manipulation in children. This was also achieved through an online consultation process using the Engage.Vic platform.

A total of 2735 responses were received from practitioners, 85% (2315) of whom had provided spinal care to a child under 12 in the past three years. Of those providing care, 99.5% (2303) were chiropractors, 80.8% (1871 out of 2315) had treated children aged 0–3 months, and 88.5% (2049 out of 2315) had treated children aged 0–24 months. The most common benefits of spinal manipulation reported by practitioners were relief from pain, better sleep quality, more relaxed or settled child, able to feed and latch better, and improved mobility or range of motion.

There were responses from 13 practitioners who had provided care to a child who had previously received spinal care from a different practitioner. These responses raised concerns about the risk of delayed access to appropriate care as a result of seeking non-evidence based spinal care (e.g. delayed diagnosis of scoliosis). No examples or experiences of serious harm were reported through this consultation.

## Summary of recommendations

These recommendations are based on the findings as outlined earlier in this report. In arriving at the recommendations, SCV has sought to strike a balance between diverse, and, at times, directly opposed, views. In particular, SCV sought to make recommendations that would both respect a parent’s or guardian’s right to choose appropriate healthcare options for their child while ensuring that children, particularly the very young who are less able to communicate adverse effects, are safe.

This was not easy. To say that the lack of strong evidence of either effectiveness or serious harm failed to provide robust foundations for recommendations would be an understatement. Nonetheless, in the absence of evidence of effectiveness and the awareness of the potential for harm expressed by the need for Section 123 of the National Law, SCV took a ‘first do no harm’ approach.

### Improving safety

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| Recommendation 1 | Spinal manipulation, as defined in Section 123 of National Law, should not be provided to children under 12 years of age, by any practitioner, for general wellness or for the management of the following conditions: developmental and behavioural disorders, hyperactivity disorders, autism spectrum disorders, asthma, infantile colic, bedwetting, ear infections, digestive problems, headache, cerebral palsy and torticollis. Section 123 of National Law defines spinal manipulation as “moving the joints of the cervical spine beyond a person’s usual physiological range of motion using a high velocity, low amplitude thrust.”[[1]](#footnote-1)This recommendation is also supported by the current statement on advertising regarding inappropriate claims of benefit, made by the Chiropractic Board of Australia.[[2]](#footnote-2)  |
| Recommendation 2 | All national boards of the health practitioners permitted to perform spinal manipulation (chiropractic, osteopathy, medical and physiotherapy) should consider Recommendation 1 when reviewing their current policies, if any, on spinal manipulation of children. |
| Recommendation 3 | Prior to treatment, practitioners offering spinal manipulation for children should provide parents or guardians with written information about the proposed benefits and possible risks of care.In their statement on paediatric care, the Chiropractic Board of Australia already expects practitioners to provide parents such information. This recommendation would require that the information is provided in written form. |
| Recommendation 4 | The national boards should periodically review notification data to identify any trends or evidence of harm that may require changes in policy, in line with the principles of risk-based regulation.  |

### Improving quality

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| Recommendation 5 | Given the lack of Australian-based clinical trial evidence, the practitioner groups permitted to provide spinal manipulation (chiropractic, osteopathy, medical and physiotherapy) urgently undertake research to develop an evidence base for spinal manipulation on children, ceasing practice where the evidence shows no benefit.Health Ministers should consider whether relevant funding bodies (e.g. NHMRC, MRFF) specifically allocate funding for a priority targeted research call to address this evidence gap. |
| Recommendation 6 | Practitioner groups that provide spinal manipulation (chiropractic, osteopathy, medical and physiotherapy) must lead on developing evidence-based guidance on spinal manipulation of children for both practitioners and consumers, using National Health and Medical Research Council endorsed methods.Such guidance material should form the basis of written information for parents, advising them of proposed benefits and potential risks of intended care (see Recommendation 3).  |
| Recommendation 7 | Consideration should be given by the Chiropractic Board of Australia to various models of advanced training in paediatric chiropractic care, particularly in spinal manipulation.In the longer term, the post registration training on offer to chiropractors with a special interest in paediatric care should be assessed against the evidence-based guidelines. |

### Eliminating false advertising

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| Recommendation 8 | The Australian Health Practitioner Regulation Agency (AHPRA) and the national boards should continue to audit practitioners in the application of their guidance regarding advertising. |
| Recommendation 9 | The national boards should consider whether explicitly prohibitive advertising statements are issued regarding spinal manipulation in children where there is evidence of no benefit, as detailed in Recommendation 1. |
| Recommendation 10 | Health Ministers should consider increasing penalties for advertising offences under Section 133 of the National Law, where a registered practitioner claims benefits of spinal manipulation in children that have no evidence base (see Recommendation 1).The current penalty for advertising offenses under Section 133 of the National Law is a maximum of $5000 for an individual and $10,000 for a corporation. These are substantially lower than penalties allowable under the National Law for falsely claiming to be a registered practitioner ($60,000 for an individual and $120,000 for a corporation) or for misleading advertising under Australian consumer law ($220,000 for an individual). |

# Independent review

## Background

The *Health Practitioner Regulation National Law Act 2009* (National Law) recognises the protected practice of spinal manipulation of the cervical spine. Section 123 of the National Law restricts the practice of spinal manipulation of the cervical spine to four health professions; chiropractic, osteopathy, medical and physiotherapy. The definition of spinal manipulation for the purpose of this restriction “means moving the joints of the cervical spine beyond a person’s usual physiological range of motion using a high velocity, low amplitude thrust”.[[3]](#footnote-3)

The restriction on practice to the four health professions was introduced as a proactive step to protect the public from a high-risk technique being performed on them by inadequately trained providers.

At the time of introduction, it was noted that the evidence base for the technique, both with regards to effectiveness or harm, was limited. Nonetheless, implicit in the restriction was the acknowledgement that spinal manipulation, particularly rotary or forceful manipulation of the cervical spine, has inherent risks of harm.

Indeed, at the time of introducing the restriction on practice the Australian Chiropractors Association (ACA) (formerly the Chiropractors Association of Australia) advocated for tougher restrictions. Specifically, the ACA argued for the restricted practice to include whole spine manipulation and to exclude health practitioners not specifically registered and/or suitably qualified to perform spinal manipulation.[[4]](#footnote-4)

It is also generally acknowledged that children are more vulnerable to injury from spinal manipulation than adults. This is because excessive movements beyond physiological norm and safety are made possible by the incomplete anatomical development of the child, particularly a very young child.

In 2017, the Chiropractic Board of Australia (the Board) released a position statement on paediatric care. This statement references the Code of Conduct for registered chiropractors and guidelines for advertising, including the Board’s specific statement on advertising.[[5]](#footnote-5)  The Board continues to monitor compliance with their guidance and act when required.

The following is an excerpt from the Board’s June 2017 position statement:

The Board expects practitioners to make sure their clinical practice is consistent with current evidence and/or best-practice approaches. Practitioners should critically evaluate their strengths and weaknesses and use continuing professional development (CPD) and other educational tools to ensure their knowledge and skills are appropriate for their work.

The Board expects practitioners to:

* discuss their proposed management plan with the patient’s parent and/or guardian
* inform the parent and/or guardian about the quality of the acceptable evidence and explain the basis for the proposed treatment
* provide patients (or parent and/or guardian) with information about the risks and benefits of the proposed treatment and the risks of receiving no treatment
* understand that children have significant anatomical, physiological, developmental and psychological differences and needs from adults and that their healthcare management requires specific skills and expertise; including informed consent, examination, diagnosis, referral of ‘red flags’ and contraindications to care
* modify all care and treatment (including technique and force) to suit the age, presentation and development of the patient
* promptly refer patients to the care of other registered health practitioners when they have conditions or symptoms outside a chiropractor’s scope of practice, for example ‘red flags’, and
* communicate effectively with other health practitioners involved with the care of the patient such as the patient’s general practitioner or paediatrician.[[6]](#footnote-6)

In August 2018, a Melbourne-based chiropractor posted on social media a video of a technique being performed on a two-week-old baby. This video generated much public concern at the time. In February 2019, the video was brought to the attention of the Victorian Minister for Health, after which prompt action was taken to urge the Australian Health Practitioner Regulation Agency (AHPRA) to take immediate action.

In an interview with ABC Radio Melbourne, the president of the Australian Chiropractors Association, Anthony Coxon, said he was "disturbed" by some of what was shown in the video, and he welcomed the investigation by the chiropractic board and AHPRA. "There are things within that video that I have concerns over," he said.[[7]](#footnote-7)

In response to the concerns noted by the CHC and to protect the public, on 14 March 2019 the Board published the *Interim policy on spinal manipulation for infants and young children.[[8]](#footnote-8)* In this policy, the Board advised “chiropractors to not use spinal manipulation to treat children under two years of age.” The interim policy was to be in place pending the outcomes of an independent review by SCV – this review.

The Victorian Minister for Health, the Hon. Jenny Mikakos MP, asked SCV, as Victoria’s healthcare quality and safety improvement agency, to lead an independent review into chiropractic spinal manipulation of children under 12 years.

## Independent expert advisory panel

### Role of the panel

SCV established an independent expert advisory panel to oversee and advise on the review, enabling SCV to make findings and provide recommendations to the Victorian Minister for Health by October 2019.

Specifically, the panel was engaged to:

* develop and endorse the scope of the resulting review
* set the parameters for the literature searches and systematic review
* determine the questions to be asked through the public and health practitioner consultations
* use all evidence gathered to inform SCV’s findings and final recommendations.

The panel met on nine occasions throughout a six-month review period to provide oversight and consider information as it became available.

### Panel membership

The Minister for Health appointed the Chief Executive Officer of SCV to chair the panel. Panel members were selected to include experts in chiropractic care, academic allied health, healthcare evidence, governance, paediatrics and paediatric surgery, and musculoskeletal care. Reflecting how SCV approaches all matters of healthcare improvement, the advisory panel had strong and effective consumer representation.

The Terms of Reference for this review can be found in **Appendix A** of this report.

|  |  |
| --- | --- |
| Professor Euan Wallace AM | Panel Chair, Chief Executive Officer, Safer Care Victoria |
| Dr Alison Wray | Paediatric Neurosurgeon, Royal Children’s Hospital |
| Professor Andrew Wilson | Chief Medical Officer, Safer Care Victoria |
| Mr David Harding | Physiotherapist, Paediatric Orthopaedic Clinic, Monash Children’s Hospital |
| Adj. Associate Professor Donna Markham | Chief Allied Health Officer, Safer Care Victoria |
| Ms Emma Gierschick | Consumer representative |
| Dr Genevieve Keating | Chiropractor, Educator and Director, Dynamic Neuro-development |
| Professor Katrina Williams | Professor of Paediatrics and Head of Department, Monash University and Paediatrician, Developmental Paediatrics, Monash Health |
| Ms Keree Bradshaw | Consumer representative |
| Adj. Associate Professor Matthew Fisher | Chief Executive Officer, Australian Chiropractors Association |
| Mr Michael Johnson | Paediatric Orthopaedic Surgeon, Royal Children’s Hospital  |
| Professor Terry Haines | Professor and Head of School, School of Primary and Allied Health Care, Monash University |
| Dr Wayne Minter AM | Chair, Chiropractic Board of Australia |

## Scope of the review

The announcement of the review generated significant public interest and some concern. When the review was announced, the footage shared in the media appeared to show potentially harmful manipulative techniques being performed by Australian-registered chiropractors.

During the design of this review it was recognised that there are strong and diverse views of chiropractic care, both among the public and health practitioners. Reflecting this, it was a purposeful decision that the advisory panel established by SCV was not only expert but also diverse and included experienced consumer representation.

In advising SCV on the scope of the review, the independent expert advisory panel recommended SCV include both a public and practitioner consultation, and a systematic review of evidence to inform overall findings and the development of evidence-based recommendations.

Section 123 of National Law restricts the practice of spinal manipulation to four health professions: chiropractic, osteopathy, medical and physiotherapy. Based on the events that triggered the review, the recommendations are necessarily focused on the chiropractic profession. However, it was clear from the outset that findings related to the technique, as defined in Section 123 of National Law, would likely have implications for the other three professions permitted to perform spinal manipulation in children.

SCV noted that the findings of this review could potentially have a significant impact on the scope of practice of chiropractors, osteopaths, physiotherapists, and medical practitioners. Further, given the widespread interest in the review and it was noted that review findings may attract the attention of overseas regulators.

To adequately consider the safety and efficacy of spinal manipulation in children, the early meetings of the panel focused on agreeing the following parameters:

* chiropractic practices or adjustments considered in scope
* conditions typically treated by the identified practices
* age ranges or groupings aligned to the relevant practices.

SCV commissioned Cochrane Australia to undertake a systematic review of the safety and effectiveness of spinal manipulation on children under 12 years for any condition or symptom.

For the purpose of collecting all relevant evidence, irrespective of profession, the panel agreed to the definition of spinal manipulation as any technique delivered by any health professional that involves a high velocity, low amplitude (HVLA) thrust beyond the physiological range of motion, impacting the spine, within the limits of anatomical integrity.

Using a definition so closely aligned to that detailed in Section 123 of National Law allowed SCV to align findings to the current legislative position and ensure that any recommendations did not contradict existing legislation. By defining the scope of the review to a technique, it also ensured that evidence searches related to other practitioner groups performing the technique (as defined) were within scope for consideration.

However, there was a downside to so tightly defining the technique of spinal manipulation that was within scope. This means that studies were excluded where the author did not provide sufficient detail to confirm the techniques reflected those detailed in Section 123 of National Law. The advisory panel considered this weakness in the approach but agreed that if harm existed, it would most likely arise from the definition of spinal manipulation being used.

It was also agreed by the advisory panel that the scope of the public and practitioner consultation would extend to include all chiropractic spinal care for children under 12 years. This decision was made because it was anticipated that many respondents would not be sufficiently informed to know whether their child or patient had received HVLA manipulation or other chiropractic manipulation. Further, a more general call for experiences was considered necessary to facilitate the inclusive and diverse consultation that SCV was seeking, maximising the reach and allowing access to differing opinions from both the public and practitioners.

## Review timeline

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| --- | --- |
| 2019 |  |
| March  | Independent panel establish |
| April  | Panel meeting 1 and 2 |
| May | Panel meeting 3 and 4Public consultation working group met twiceConsultation opened 22 MaySystematic review protocol finalised |
| June | Panel meeting 5Consultation closed 22 June |
| July | Panel meeting 6 |
| August  | Panel meeting 7 and 8Systematic review finalised |
| September | Final panel meeting |
| October | SCV’s final report submitted to Victorian Health Minister |

# Public consultation

Working with patients (consumers), their families and carers is central to how SCV does its work. Noting the extent of public interest following the announcement of this review, inviting public input was critical to capturing personal stories for consideration by the panel.

The panel considered options for consulting with the public and planned the approach and scope of consultation. A public consultation expert was engaged to advise and support the panel during the planning period.

With a goal to open consultation in May 2019, the panel convened a time-limited working group to formulate the content on behalf of the group.

The panel agreed to an online survey targeted to both the public and practitioners interested in sharing their opinions and experiences of chiropractic spinal care. The working group met on two occasions in early May and put significant thought into the sequencing, style, and response options for survey questions. Six different survey pathways were carefully developed so that participants could respond to the pathway most applicable to them. These pathways can be found in Figure 1. The surveys developed included a combination of quantitative and qualitative responses.

The panel agreed to using the Victorian Government’s online engagement platform Engage.Vic as the portal for submissions.

As detailed previously, the public consultation was deliberately designed to include all chiropractic spinal care provided to children under 12 years, and not just the specific technique of spinal manipulation. This was agreed by the panel to ensure that, irrespective of how a technique has been communicated to the consumer, all experiences related to chiropractic spinal care of children under 12 were welcomed and considered.

This public consultation was designed to elicit the views, both supportive and unsupportive, of parents/guardians and practitioners, and to explore specific experiences. Public consultation was open from 22 May to 21 June 2019. A total of 29,599 online surveys were submitted from across Australia.

## Analysis of survey inputs

SCV engaged market research firm EY Sweeney to undertake an independent analysis of the data generated by the responses.

To ensure that all responses met the public consultation validation criteria, and to protect the privacy of respondents as per the *Privacy and Data Protection Act 2014* and *Health Records Act 2001*, data cleansing was completed by SCV.

Data cleansing included the removal of any duplicate responses, based on previously agreed set of rules. Multiple entries from the same person were assessed against guidance outlined in the frequently asked questions on the survey platform. For example, multiple responses from one respondent but relating to different children in their care were allowed. Practitioner survey streams requiring an AHPRA registration number were cross checked with registration data to confirm validity.

All data sets were de-identified ahead of being transferred to EY Sweeney via a secure file transfer portal.

Post data cleansing, a total of 29,054 (98%) valid survey responses remained. Figure 1 below shows the total number of responses and the number of responses removed based on the defined data cleansing methodology.

Figure 1. Survey response number by survey stream and removal post data validation

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
|   | Total responses received | Number of duplicate responses for removal (SCV) | Responses with invalid AHPRA details for removal (SCV) | Responses with invalid postcode for removal (EY)\* | Total number of responses for analysis | Total number of quantitative responses processed | Total number of qualitative responses processed |
| Public |
| 1. Member of the public who has accessed care in the past 10 years | 22,045 | 42 |  | 179 | 21,824 | 21,824 | 2,724 |
| 2. Member of the public who has not accessed care in the past 10 years | 4,558 | 25 |  | 38 | 4,495 |  | 541 |
| Total public | 26,603 | 67 | n/a | 217 | 26,319 | 21,824 | 3,265 |
| Practitioner |
| 3. Practitioner who has provided care in the past 3 years | 2,542 | 172 | 46 | 9 | 2,315 | 2,315 | 2,315 |
| 4. Practitioner who has not provided spinal care. However, has provided care for a child who has received care | 88 | 0 | 4 | 0 | 84 | 84 | 84 |
| 5. Practitioner who has not provided spinal care in the past three years | 100 | 4 | 4 | 0 | 92 |  | 92 |
| 6. Practitioner would prefer not to provide AHPRA number | 266 | 17 |  | 5 | 244 |  | 244 |
| Total practitioner | **2,996** | **193** | **54** | **14** | **2,735** | **2,399** | **2,735** |
| Total | **29,599** | **260 (29,339)** | **54 (29,285)** | **231 (29,054)** | **29,054** | **24,223** | **6,000** |

EY Sweeney developed a coding methodology for the qualitative survey data. The methodology applied is outlined below:

* In addition to analysis of the quantitative responses for all 24,223 valid surveys, EY coded the qualitative responses for 6000 survey participants. This was considered sufficient to reach saturation of content themes without risk of the analysis being unreliable.
* To ensure that coverage of all six survey pathways was achieved, it was agreed to divide the selection of the 6000 surveys for coding of qualitative responses. All 2735 of 'Practitioner' survey responses across the four pathways were included and 3265 from the two pathways for 'General Public' respondents.
* A sample 3265 (or 10%) of the General Public responses yields an estimated margin-of-error of ±1.7% with a population of 26,319, at a 95% confidence interval. Increasing the coding beyond this number of responses was considered to have minimal, if any, effect on the accuracy of findings.
* Although EY recognises that text analysis software exists to facilitate automated coding of open-text responses, and thus not require sampling, it was their professional advice that the risk of miscategorising of responses through such an approach was too high. Accordingly, EY manually read and coded sufficient responses to reach thematic saturation and so extract the key messages.
* To avoid unintended bias, 3265 General Public submissions were drawn randomly from the data set provided by SCV for coding.

Where the panel felt that further clinical review of responses was required, clinicians from within SCV completed this review. However, the survey was designed to capture opinion and personal experience and was not developed to capture detailed clinical information.

## Summary of public responses

The full EY Sweeney report is provided in Appendix B. Detailed here are summary findings.

#### Two survey pathways were made available as a part of the public consultation:

* Member of the public who has accessed spinal care for a child under 12 in the past 10 years
* Member of the public who has not accessed spinal care for a child under 12 in the past 10 years

The distribution of responses from across Australia are shown in Figure 2 below.

Figure 2. Location of responses from all general public surveys



The submissions from public respondents who had accessed chiropractic spinal care for a child were overwhelmingly positive. Of the 21,824 respondents, 21,750 (99.7%) were supportive of the care received.

### Age of children

* A little over half of the respondents, 54.5% (11,894), who had accessed care in the past 10 years reported that the care was provided to a child aged 0–3 months.
* Three quarters – 73.1% (15,953)– of respondents indicated that the care was provided was for a child aged 2 years or younger.
* Half of the respondents (10,934) indicated that they accessed spinal care for a child over a continuous period (across multiple age brackets).

### Conditions for which care was being sought

* For members of the public who have accessed care in the past 10 years, the main reasons for seeking chiropractic spinal care were posture concerns (31.7%), colic (28.7%), neck pain (23.5%), difficulties with breastfeeding (22.6%), back pain (21.9%), headache (14.9%), and other (48.8%). Other included general health and wellbeing/preventative care (17.4%) and sleep issues (4.1%).

### Other care providers

* Of those who accessed spinal care for a child, 68.9% (12,142 from a data set of 17,622 responses) reported that they had also consulted a General Practitioner about the problem.
* Two in five, 43.9% (7,736 from a data set of 17,622 responses), respondents reported that they also consulted a Maternal and Child Health Nurse.

### Parent/guardian reported outcomes

* 63.0% (1400 of 2223) of respondents reported that the chiropractic care was effective in treating children under 12 years of age.
* 87.3% (19,052 of 21,824 responses) indicated that the child was ‘much improved’ after treatment. A further 11.1% (2,422 of 21,824 responses) stated that the child was ‘somewhat improved’.
* 45.1% (705 of 1,563 responses) of respondents who accessed care reported that they felt the chiropractor had adequately explained the treatments and that they had felt informed during the process.
* 23.0% (359 of 1563 responses) stated that they valued the two-way communication when interacting with the chiropractor and felt that they were listened to.
* 99.1% (21,628 of 21,824) of respondents indicated that they were either ‘satisfied’ or ‘very satisfied’ with information provided by the chiropractor about the benefits of treatment.
* Similarly, 95.8% (20,907 of 21,824) of respondents indicated that they were ‘satisfied’ or ‘very satisfied’ with information provided about the risks of the treatment.

When members of the public who had accessed chiropractic care for their child responded about why this review was important to them, it was very clear that they strongly valued the freedom of parental choice when it came to choosing the care they believed most suited to their family.

* 31.3% (696 out of 2223) emphasised that a parent/guardian should have the right to choose the care they feel is most appropriate for their child.
* 26.6% (591 out of 2223) expressed the view that chiropractic care should not be banned.

There was a very small minority of respondents – 0.3% (74 of 21,824 responses) – within the General Public group who reported negative experiences. The panel felt that it was important to review each of those 74 responses to screen for evidence of any potential harm. These were reviewed in detail by a senior clinician within SCV. There were no responses that were suggestive of any significant adverse effects following chiropractic care.

Instead, the negative experiences related to concerns about the cost of treatment with no resultant improvement in the condition being treated, excessive use of X-rays, or practitioner pressure to avoid medications or advice previously provided by other health practitioners.

## Summary of practitioner responses

The full EY Sweeney report is provided in Appendix B. Detailed here are summary findings.

#### Four survey pathways were made available to practitioners:

* Practitioner who has provided spinal care for a child under 12 in the past three years
* Practitioner who has not provided spinal care for a child under 12 in the past three years. However, has provided care for a child who has received spinal care from another practitioner
* Practitioner who has not provided spinal care for a child under 12 in the past three years
* Practitioner who would prefer not to provide their Australian Health Practitioner Regulation Agency (AHPRA) number.

Figure 3. Location of responses from all practitioner surveys



The overwhelming majority – 99.5% (2303 of 2315) – of practitioners who responded as having provided spinal care to a child under 12 within the past three years were registered chiropractors.

Of the practitioner respondents who have provided care (essentially chiropractors), 80.8% (1871 of 2315) reported treating children aged 0–3 months and 88.5% (2049 of 2315) reported treating children aged 0–24 months.

### Practitioner reported outcomes

* Drawn from all 2315 responses from practitioners who have provided care, the top five benefits reported, in order of most prevalent, were: relief from pain, better sleep quality, more relaxed or settled child, able to feed and latch better, and improved mobility or range of motion.
* In contrast to those practitioners who had provided spinal care, almost half – 47.6% (40 of 84) – of the practitioners who had provided care to a child who had previously received spinal care from another practitioner, reported that the spinal care had had no benefits.

### Reports of adverse effects

* 63.0% (1458 of 2315) of practitioners providing care reported that no adverse effects related to chiropractic spinal care had been observed or reported.
* 13.0% (301 of 2315) of responses indicated that mild short-term soreness had been observed or reported.
* Thirteen practitioners who responded as having provided care to a child who had previously received spinal care from another practitioner noted concern about the risk of delayed access to what the responding practitioner viewed as being appropriate care as a result of seeking spinal care.

### Freedom of choice

* A small proportion – 7.7% (124 of 1606 responses) – of the practitioners providing care mentioned the importance of the rights of parents/guardians to choose care for their child.

The concept of the zone of parental/guardian discretion was considered during panel deliberations. This refers to the zone of parental/guardian choices; to either choose to refuse treatment or choose treatment that may be at odds with what their medical practitioner advises.

The choice for a parent/guardian to have a HVLA spinal manipulation technique applied to their child was tested by the panel with specific consideration to both potential harm and effectiveness. Several panel members felt that as long as the parent/guardian had clear decision-making capacity and authority, was provided with sufficient information and opportunity to understand the evidence underlying the risks, benefits and alternatives that may be available, they should be allowed to make this choice.

The full consultation summary report prepared by EY Sweeney can be found in **Appendix B** of this report.

## Submissions from professional and learned organisations

In addition to the online survey, SCV invited professional and learned organisations with an interest in this review to make a written submission for the panel to consider. Nineteen submissions were received from organisations.

It is worth noting that the organisation submissions primarily related to chiropractic spinal care of children in general rather than to only the specific high velocity, low amplitude technique. The responses received provided representative perspectives from across all professions permitted to perform spinal manipulation as defined in Section 123 of National Law.

The panel reviewed all submissions. Three key themes were apparent:

* evidence
* education
* safety/harm.

As the statutory regulator for the chiropractic profession, the Board provided an outline of its statutory functions and responsibilities. The Board has demonstrated a willingness to respond, with the provision of strengthened guidance to chiropractors, when issues of concern are raised.

### Evidence

Irrespective of the varying views noted by membership organisations and associations representative of chiropractic and other relevant professions, it was widely acknowledged that there is an urgent need to improve the evidence base for chiropractic practices and to develop best-practice guidelines. Specifically, it was widely agreed that there was insufficient evidence to appropriately guide clinical care.

Below is an excerpt from the submission made by the Australian Chiropractors Association, reportedly the largest chiropractic body in Australia, representing more than3000 members:

In keeping with the National Scheme and to ensure public benefit, the Australian Chiropractors Association (ACA) proposes the following:

* That the profession conducts a trial of monitoring of care including outcomes of children under 12 years of age
* That the profession continues to further refine industry-led standards and clinical guidelines informed by best practice. This would include continuing professional development and consensus approaches to care including inter-professional understanding and action
* That the profession continues to further commit to expanding knowledge translation from research into clinical practice within the industry
* That the profession and health research agencies increase support for further research into chiropractors and their role in the healthcare of children.[[9]](#footnote-9)

### Education

There is currently no requirement for specialist training in paediatric chiropractic care. The Council on Chiropractic Education Australasia reviews and provides accreditation of pre-registration chiropractic education. The chiropractic profession does not have agreed and accredited specialist pathways, as exist in the medical profession.

However, while not mandatory for practice, advanced postgraduate training courses do exist and are generally considered useful in enhancing the knowledge and skills of the chiropractor workforce in specific interest areas, such as in paediatric care. Such practitioner development and training is currently offered by several different bodies. There does not appear to be any formal accreditation process or best-practice guidelines to ensure consistency across the post registration training offered.

The Council on Chiropractic Education Australasia submission states: “All accredited chiropractic programs include education in such areas as the health, developmental stages, common conditions and treatment, co management and referral options for children under (and over) the age of 12 years.”

Submissions received from three tertiary institutions referenced a desire for further research to support development of industry-led standards and guidelines. It was recommended within two of those submissions that once guidelines are developed, standardised post-graduate paediatric training for the chiropractic profession is likely to facilitate improved health outcomes.

The views expressed by the tertiary institutions was echoed in the position presented by Chiropractic Australia, a membership-based organisation supporting the profession.

Chiropractic Australia’s submission to this review states: “For those chiropractors who wish to offer a more focused paediatric practice, that is for those who wish to practice paediatric chiropractic as a special interest, we believe that additional accreditation and training standards should be in place and that training for endorsed paediatric practice must be undertaken under the auspices of universities.”

### Safety/harm

Submissions made by bodies representative of the medical or physiotherapy professions raised concerns related to the potential harm of chiropractic spinal manipulation on children under 12 years. In particular, there was specific concern about potential risks of harm associated with spinal manipulation of very young children, i.e. those under 2 years of age.

However, no specific or confirmed instances of proven harm were presented in any submission. Nonetheless, it was the professional view of those groups that in the absence of evidence of benefit, the risks of harm were sufficient to recommend banning chiropractic spinal manipulation of children.

# Systematic review of literature for evidence of effectiveness and safety

In assessing the diverse views presented within the submissions, the panel agreed on the need for investment in properly conducted research, preferably in Australia, and the value that such research would provide the profession in quantifying both effectiveness and safety.

During the first panel meeting on 8 April 2019, it was agreed that Cochrane Australia would be engaged to undertake an appraisal of the evidence for both the safety and effectiveness of spinal manipulation on children under 12 years of age.

Spinal manipulation was defined by the experts on the panel as being any technique delivered by any health professional that involves a high velocity, low amplitude thrust beyond the physiological range of motion, impacting the spine, within the limits of anatomical integrity.

The literature search captured studies referring to children under 12 years of age, including babies and infants, treated with spinal manipulation from any healthcare professional for any condition or indication.

If studies included adolescents or adults, in addition to children, and it was impossible to extract data separately for children, the studies were included provided most participants were under 12 years or the mean age of participants was less than 12.

Cochrane identified existing, high-quality systematic reviews that had assessed the evidence for spinal manipulation on children. To avoid unnecessary duplication, Cochrane identified the subset of evidence on the effectiveness and safety of spinal manipulation on children from these existing reviews, and included relevant studies published before or after their completed search dates.

The full systematic review report prepared by Cochrane Australia can be found in **Appendix C** of this report.

## Effectiveness review

Thirteen studies (including 11 randomised trials) were considered in scope for the effectiveness review. There were no Australian-based studies. The majority of studies included were undertaken in the USA or Europe. Nine of the included studies were based on chiropractic practitioners performing spinal manipulation as defined. The conditions covered in those studies included colic (three studies), enuresis, back/neck pain, headache, asthma (two studies), otitis media, cerebral palsy, hyperactivity (two studies) and torticollis.

Overall, there was very little evidence to support the use of spinal manipulation for any of the conditions studied. For the majority of the conditions, the evidence showed there was no benefit. However, for two conditions – infant colic and enuresis (bed wetting) – there was uncertainty.

#### The following is an excerpt from the Cochrane Systematic Review report:

Based on meta-analysis of three studies, Cochrane found low certainty evidence that, in infants with colic, mean crying time may be reduced among infants who received spinal manipulation compared to a control (sham, no treatment, active comparator) (0.71 hours (43 minutes) per day lower, 95% CI 1.87 (112 minutes) lower to 0.46 (28 minutes) higher; 3 trials, 156 infants). However, the confidence interval is wide and includes a possible increase in crying time.

Cochrane also found low certainty evidence that the mean number of wet nights may be reduced among children with enuresis who received spinal manipulative therapy compared to sham spinal manipulative therapy (1.6 fewer wet nights per fortnight, 95% CI 3.2 fewer to 0 more; 1 trial, 57 participants). However, the confidence interval is wide and includes the possibility of no effect. For other conditions there was either no evidence of effect, or no data available from which to draw a conclusion.[[10]](#footnote-10)

When presented with the findings from Cochrane’s systematic review, the panel discussed the absence of strong evidence for chiropractic spinal manipulation. The consumer representatives were particularly surprised at the lack of evidence. The panel also requested advice from Cochrane on the design of potential future research.

Cochrane shared the following suggestions as key considerations when designing studies:

* Providing detail and clarity of the intervention being studied or applied
* Ensuring studies are adequately powered (appropriate sample size)
* Developing core outcome measures, that can preferably be compared against other or future studies.

## Safety review

Interpretation of the safety findings was informed by the acknowledgement that best practice care requires a modification of force based on the age and developmental stage of a child. The panel advised SCV that Australian chiropractors are trained with that specific awareness and incorporate it into their daily practice.

Based on the parameters defined by the panel, Cochrane identified 10 studies for inclusion in the safety component of the literature review. Studies were included from around the world based on intervention description, agnostic of practitioner type.

Across all 10 studies there was a total of 159 adverse effects noted. Only one study had been based in Australia. It reported two adverse events from a treatment population of 171.

#### The following is an excerpt from the Cochrane Systematic Review report:

Six of these studies aimed to determine the rates of adverse events occurring across populations of infants and children undergoing spinal manipulative therapy. These studies reported rates spanning one minor treatment aggravation per 1812 consultations to one cerebrovascular incident in 20,000 visits. Two related studies investigated physiological responses to spinal manipulation in children and reported apnoea and skin flushing in 50 of 199 treated infants; and in a separate study, severe but short-lasting bradycardia in almost 50% of infants less than three months old, and in 87 of 695 children over four months.

Four studies described five individual cases of adverse effects from spinal manipulative therapy in infants or children. Of these, three were classified as severe and two as moderate. Of the three reports of a serious adverse event, one resulted in death. The technique employed in this case was described as the Vojta technique and involved forced active rotation and head retraction performed by a physiotherapist (case report from Germany in 2001). Other serious adverse events were loss of consciousness with recovery and hospitalisation for drowsiness and weakness. Though the prevalence of adverse outcomes is very low, the risk cannot be ignored. Any risk associated with care provided must be considered on balance with potential benefits. [[11]](#footnote-11)

In summary, the review of the literature revealed that the potential risk of harm from spinal manipulation in children was rare and, when it did occur, was typically minor in severity. However, as reported by Cochrane, “consistent with the findings of other systematic reviews, due to the paucity of studies and the lack of reported information on the specific treatment techniques employed, it is difficult to draw conclusions about the safety and effectiveness of spinal manipulation in children.”

## Additional evidence collected

In addition to the systematic review of literature, SCV also requested information from AHPRA, the Health Complaints Commissioner (Victoria), the Office of the Health Ombudsman (QLD), and relevant profession-based councils in New South Wales.

### Notifications and complaints data

AHPRA undertook a search of available information in its notifications database. The data reflected notifications that AHPRA had received relating to chiropractic spinal care for children under 12 over the past 10 years.

Below is a summary of the notifications data:

* Nineteen notifications about 18 practitioners
* Four notifications remain open
* One matter was retained by the health complaints entity to manage (not referred to AHPRA)
* Six notifications resulted in no further action
* Eight matters were acted on by the Board.

Of the 15 investigations completed to date, the Chiropractic Board of Australia took further action in 53.3% of cases. Actions taken included issuing a caution, placing conditions on a practitioner’s registration, and the practitioner providing an undertaking to the Board.

AHPRA does not manage all notifications or complaints made about health practitioners in Australia. In NSW, notifications are managed by 15 professional councils (supported by the Health Professional Councils Authority) and the Health Care Complaints Commission (HCCC).

The Health Care Complaints Commission identified three cases related to chiropractic spinal manipulation of a child under 12 years. There was a discrepancy noted between the data held by the Chiropractic Council of NSW and the HCCC. The discrepancy has been actioned for investigation.

In Queensland, the Office of the Health Ombudsman (OHO) receives all complaints about health practitioners and determines which of those complaints are referred to a National Board/AHPRA to manage. The Office of the Health Ombudsman reported that since its inception on 1 July 2014 it has not received any complaints relating to spinal manipulation of children under 12 years.

The Victorian Health Complaints Commissioner (HCC) reported no complaints against a chiropractor related to the treatment of a child.

The details of complaints and notifications were considered by the panel. There were no complaints or notifications that related to significant harm to a child as a result of chiropractic spinal manipulation.

The only issue that was of concern to the panel was the discrepancy between data sets. Accurate reporting on a national level is wholly reliant on consistency in the capture, coding and management of data. The relevant bodies are exploring the apparent data inconsistencies.

### Insurance claims

SCV requested de-identified data from the principal insurance agencies that provide insurance for chiropractors. Information was sought regarding any claims made in relation to chiropractic spinal manipulation of a child under 12 years.

No cases were reported where an insurance agent has had to defend or settle such a claim.

# Acknowledgements

This review would not have been possible without the assistance of the advisory panel members:

|  |  |
| --- | --- |
| Professor Euan Wallace AM | Panel Chair, Chief Executive Officer, Safer Care Victoria |
| Dr Alison Wray | Paediatric Neurosurgeon, Royal Children’s Hospital |
| Professor Andrew Wilson | Chief Medical Officer, Safer Care Victoria |
| David Harding | Physiotherapist, Paediatric Orthopaedic Clinic, Monash Children’s Hospital |
| Adj. Associate Professor Donna Markham | Chief Allied Health Officer, Safer Care Victoria |
| Emma Gierschick | Consumer representative |
| Dr Genevieve Keating | Chiropractor, Educator and Director, Dynamic Neuro-development |
| Professor Katrina Williams | Professor of Paediatrics and Head of Department, Monash University and Paediatrician, Developmental Paediatrics, Monash Health |
| Keree Bradshaw | Consumer representative |
| Adj. Associate Professor Matthew Fisher PhD | Chief Executive Officer, Australian Chiropractors Association |
| Mr Michael B. Johnson | Paediatric Orthopaedic Surgeon, Royal Children’s Hospital  |
| Professor Terry Haines | Professor and Head of School, School of Primary and Allied Health Care, Monash University |
| Dr Wayne Minter AM | Chair, Chiropractic Board of Australia |

We thank them for their contributions.

We would also like to acknowledge the many organisations and individuals for their contributions to the review – we appreciate their time and commitment to sharing their experience and views.

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