Commentary on the 2019 Safer Care Victoria review of chiropractic spinal manipulation of children under 12 years.

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Abstract

In 2019, Safer Care Victoria (SCV) conducted a government-funded inquiry into the practice of spinal manipulation (SMT) of children under 12 years of age by chiropractors. SCV assembled an advisory panel, commissioned a Cochrane Collaboration Review, and invited submissions from consumers, health practitioners, insurers, education institutions, professional organizations, and interested stakeholders.

The report's principal findings were that while spinal manipulation of children results in very rare instances of harm, since evidence of the effectiveness of SMT is lacking, SMT cannot be recommended for children under 12 for a list of conditions or for general wellness.

Critique and Discussion

Five reviewers evaluated the Cochrane Review that formed a part of the inquiry using the Scottish Intercollegiate Guideline Network (SIGN) instrument. Two reviewers also evaluated the SCV report in its entirety. A strength of the report is the safety review and the information in the detailed responses from consumers. There were 29,599 online submissions received from across Australia, making it the largest survey of this kind. There were no reports of physical, mental, or financial harm to a child derived from this robust process. However, the report and the Cochrane Review contain weaknesses. 1) An internal contradiction erroneously reported a cerebrovascular incident (CVI) rate of 1:20,000 with SMT among children in the main text. 2) There was a departure from the inclusion/exclusion criteria for effectiveness studies. 3) The final recommendations disregard the submissions from consumers, the public, and practitioners.

Conclusion

While it has strengths, the SCV report is also flawed, and its final recommendations should be viewed with caution. The Cochrane Review within the report adds little to the body of knowledge or clinical practice for chiropractors managing children under 12.

Keywords (MeSH Terms): Child, Children, Infant, Chiropractic, Government, Manipulation, Safety, Spinal, Risk Assessment, Parents

Background and context

In 2016 and 2019, two videos posted online of chiropractors examining and treating infants in Australia created significant media attention. In an article after the second video appeared depicting an infant being held upside down, Jenny Mikakos, the Victorian minister for Health and Ambulance Services, confirmed she had written to the Chiropractic Board of Australia (CBA) within the Australian Health Practitioner Regulation Agency (Ahpra), demanding the CBA; "*Take the necessary action*". "*This vision is deeply disturbing – it's appalling that young children and infants are being exposed to such potential harm. The Chiropractic Board of Australia must condemn this practice as unprofessional and unacceptable and the Ahpra must act quickly to stop these rogue practitioners in their tracks*"[1,2] The role of CBA/Ahpra is to investigate notifications and to take appropriate, proportionate action to protect the public. It is unusual for a politician to intervene in this process publicly while singling out one profession or intervention.

Minister Mikakos announced a review of the chiropractic professions' care of children, saying: "*Ahpra's track record of delays (in investigations) is precisely why we've chosen to go it alone*."[3] She made multiple media appearances commenting on the perceived issue of safety. Over the following weeks, media outlets picked up the narrative nationally and internationally. In an article published by the Royal Australian College of General Practitioners (RACGP), Assoc Prof Ken Harvey, at the time a staff member at Monash University and President of a political medical advocacy group, the Friends of Science in Medicine (FSM), labelled the health regulator *a 'paper tiger'* and said such '*quackery*' should already be banned particularly on children. He also accused the regulator of being *"asleep at the wheel and it is just unconscionable that it allows these guys to get away with it*".[1]

On 8th March 2019, the Council of Australian Governments (COAG) Health Council (CHC) noted community concerns about spinal manipulation on children performed by chiropractors and decided that there was a need to consider whether public safety was at risk. On behalf of the CHC, minister Mikakos instructed Safer Care Victoria (SCV) to undertake an independent review of the practice of chiropractic spinal manipulation on children under 12 years.

On 14th March 2019, the Chiropractors Board of Australia (CBA) published an interim policy on spinal manipulation for infants and young children.[4] In this policy, the Board advised:

"…chiropractors to not use spinal manipulation to treat children under two years of age." The interim policy was proposed to be in place pending the outcomes of the independent review by SCV. SCV handed down its final report in October 2019. The draft report was circulated to its advisory panel for review and comment; however, the substantially altered final report was not shared with the panel prior to media statements and public release by the Minister.

On 1st November 2019, Health Ministers considered the independent review commissioned by the Victorian Minister for Health, undertaken by Safer Care Victoria (SCV), regarding the effectiveness and safety of chiropractic spinal manipulation of children under 12 years for any condition or symptom. Ministers considered several recommendations, including increasing penalties for advertising offences under the Health Practitioner Regulation National Law Act 2009, where a registered practitioner claims benefits of spinal manipulation in children with no evidence base. Ministers agreed to refer the findings and recommendations of this review to the Australian Health Ministers' Advisory Council (AHMAC) for further consideration and next steps. At the time of writing, no further outcomes have been advised by the Health Chief Executives Forum (HCEF), the advisory and support body of the Health Ministers' Meeting Forum, which replaced AHMAC.

The Safer Care Victoria Inquiry process

Advisory panel

Safer Care Victoria established an independent expert advisory panel in mid-March 2019 to review chiropractic spinal care of children under 12 years of age. (p10) (NB: page numbers refer to the SCV final report and its' sections). This review was to allow SCV to make findings and provide recommendations to the health minister that could be taken to the Council of Australian Governments (COAG) Health Council (CHC) in October 2019.

Included on the panel were one practising chiropractor, two physiotherapists and five members of the medical profession, a representative from the Australian Chiropractors Association (ACA-CEO) and the Chiropractic Board of Australia (CBA Chairperson), and two community representatives. It is not documented, and it remains unclear how the expert advisory panel was selected.

While the videos that precipitated the inquiry depicted infants, the terms of reference were widened to include children under 12 years of age and clinical effectiveness for a list of conditions, including wellness. The rationale provided for considering effectiveness (p6) was *"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".* The inquiry focused on spinal manipulation in some parts (Cochrane) and chiropractic care of children more generally in other parts (e.g., organisational submissions and public surveys). It is well known that the chiropractic profession has a broad-based, multimodal approach to assessment and treatment beyond SMT,[5,6] exemplified by the phrase *'chiropractic is a profession, not a technique'*.[7] While the impetus to call the inquiry was stated on multiple occasions by the minister to be the 'safety of children', at inception, the inquiry was widened to include the effectiveness of SMT in a variety of conditions, without a stated scientific rationale either for the selection of each condition or the expansion to include all children under 12 years of age.(p4)

During the first panel meeting on 8th April 2019, it was decided 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 in the form of a systematic review.[8]

Data collection

Public consultation

Input was sought from the public to elicit the views of parents/guardians and practitioners and to explore their experiences. The public consultation consisted of a survey with several streams. 1) the public who had accessed chiropractic care for a child under 12 in the previous ten years; 2) the public who wanted to share their opinion of chiropractic care for children but had not accessed chiropractic care for a child under 12 in the last ten years; and 3) practitioners who treat children. The survey was on a government web-based platform and was open for four weeks, from 22nd May to 21st June 2019.

In the media release announcing the opening of the public survey by Safer Care Victoria (SCV) on the 21st of May 2019, minister Mikakos was explicit in her call for submissions.

> *"Now is the time for parents who have experienced the dangerous practice of child spinal manipulation to have a say and share their story."*
> *"We won't rest until babies are protected from practices we know to be harmful, and that we can be sure children under 12 are not being exposed to harm."*
> *"The risks of spinal manipulations on newborn babies outweigh any benefits, but more needs to be known about children under 12. We need a national approach and that may involve changes to the law if necessary".*[9]

Insurance claims

SCV requested de-identified data from all the principal insurance agencies that provide insurance for chiropractors. Information was sought regarding any historical claims made in relation to chiropractic spinal manipulation of a child under 12 years without time limits.

Outcomes of the inquiry

Public consultation

The response was much larger than anticipated, and SCV needed to engage an external company to perform the data analysis. Market research firm EY Sweeney was chosen to undertake an independent analysis of the data generated by the responses. There was a total of 29,599 responses received from the consultation survey. There were 21,824 submissions received from members of the public who had accessed chiropractic spinal care for a child under 12 years of age in the previous ten years. This is by far the largest number of submissions received through Engage Victoria. The next largest had approximately one-third of the number of responses (9,481), the Annual Victoria Police Community Sentiment Survey – 2022, open for eight weeks. As part of the SCV review, the public consultation is the largest known survey response of parents of children using any form of health care.[10,11] The volume of responses demonstrates how engaged consumers of chiropractic services and the Australian public were, and how important the topic of chiropractic care for children is to parents.

The survey data consisted of quantitative (Likert scale) and qualitative (open text field) data. EY Sweeney analysed the quantitative data and then developed a coding methodology for the analysis of qualitative survey data. The SCV staff required the code frames to be provided to them for approval before the analysis. (p10) EY Sweeney coded the qualitative responses for 6,000

survey participants. All 2,735 'Practitioner' survey responses were included, and a 10% sampling from the two pathways for 'General Public' respondents.

The quantitative results showed that 99.7% (n=21,750) of parents who had accessed chiropractic care for their child in the last ten years were supportive of chiropractic care for children. With regards to informed consent, 99.1% of parents were satisfied with information regarding the benefits of treatment, 95.8% were satisfied with the information regarding risks of treatment, 78.9% were satisfied with information regarding alternative options available, and 99.2% were satisfied with their involvement in decisions about care. A secondary analysis of the data summed across the four Likert scales of consent (benefits and risks), involvement in decisions, and their child's improvement revealed that 21,950 (99.6%) were affirmative that chiropractic care benefitted their child (Figure 1). A small minority of respondents, 0.3% (n=74) reported a neutral or unsupportive response.[12] (p19, 25) A senior SCV clinician reviewed all unsupportive and neutral responses for potential harm and found no reports of any adverse events or harm in these 74 responses.(p18)

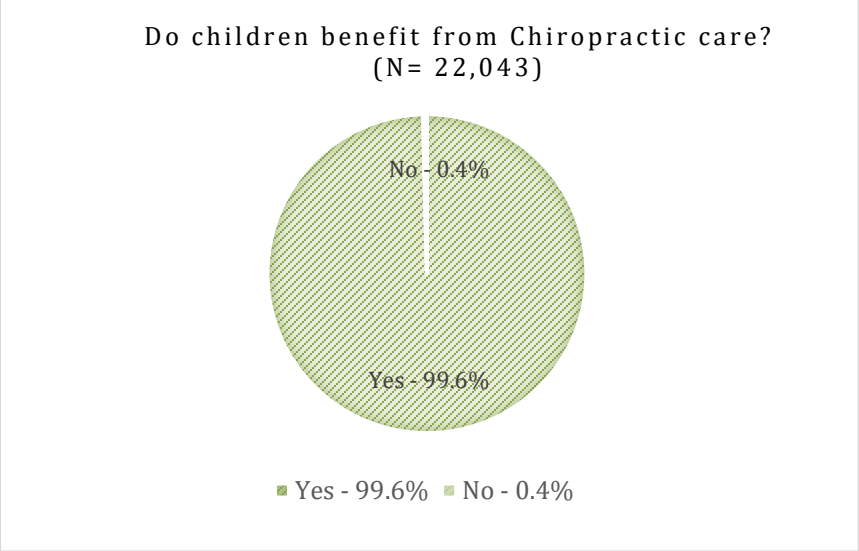

Figure 1: Analysis of Responses Regarding the Benefit of Chiropractic Care for Children[11]

Health practitioner consultation

A total of 2,735 responses were received from practitioners, 85% (2,315) of whom had provided spinal care to a child under 12 in the past three years. Responses were received from 13

practitioners who had provided care to a child who had previously received spinal care from a different practitioner who raised concerns about the risk of delayed access to appropriate care. However, no examples or experiences of serious harm were reported through this consultation.[12](p5)

Insurance claims

SCV requested and received 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.[12](p27)

Systematic Review

The Cochrane Review is contained in the final report as Appendix C. It is not available elsewhere beyond the SCV website and does not report formally being peer-reviewed beyond the listed four authors in its methodology. By definition, a Cochrane Review should be peer-reviewed. According to the Cochrane Handbook for Systematic Reviews of Interventions or Cochrane Handbook for Diagnostic Test Accuracy Reviews, *"Each Cochrane Review is a peer-reviewed systematic review that has been prepared and supervised by a Cochrane Review Group (editorial team)."*[13] Cochrane publishes its reviews on its database Cochrane Database of Systematic Reviews (CDSR: https://www.cochranelibrary.com/cdsr/reviews),[13] and often in the broader scientific literature, however, neither appears to have occurred in this case. The authors, led by Sally Green, a physiotherapist (Co-Director of the Australasian Cochrane Centre), Steve McDonald, Melissa Murano, and Sue Brennan appear all connected with Monash University (at least based on email addresses). These affiliations are not listed in the report. (p1/67 of Appendix C) There is no mention of the editorial team that supervised this review if it occurred.

Critique Methodology

Five reviewers independently evaluated the Cochrane systematic review using the modified SIGN (Scottish Intercollegiate Guideline Network) checklist (Table 1). We also consulted the Scale for

The Quality Assessment of Narrative Review Articles (SANRA), although it was not formally rated using the instrument.[14,15] Two reviewers evaluated the report in its entirety, including the design. In addition to the publicly available report, author GK, a member of the advisory panel, requested and received the deidentified data set of responses from the public to perform a secondary analysis of the data for her PhD dissertation. This dataset consisted of responses from the public who had accessed chiropractic care for a child under 12 years of age in the previous ten years and the public who had not accessed chiropractic services for a child under 12 in the last ten years but wanted to share their opinion of chiropractic care for children. These data formed the basis of a doctoral thesis and associated papers in the peer-reviewed literature and were useful in contextualising the presentation of qualitative data in the SCV report.[10,11]

Critique

The final report made 12 recommendations; however, this critique will specifically address recommendation #1 since it is the basis of all subsequent recommendations. The subsequent recommendations refer to policy (2), informed consent (3), notification data (4), research and funding (5), advanced training (6), and advertising (8-10).

Recommendation #1 states, *"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. This recommendation is based on the lack of evidence of effectiveness for these conditions and the current statement on advertising regarding inappropriate claims of benefit, made by the Chiropractic Board of Australia." (p6)*

Results of critique

Firstly, it is salient to observe that, in our opinion, the inquiry directly questioned its own relevance when explaining why it found so little evidence of harm. It speculated that there are two principle

(sic) reasons for the lack of evidence of harm. Quote, "*1) 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, 2) 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". (p3)*

Thus, the inquiry speculates (without citation of evidence) that the intervention (SMT) is not being routinely used in Australia, and if it was, chiropractors, by virtue of their training, skill, and expertise, are able to deliver it safely. Given this statement early in the report, it begs the question, 'then why conduct the inquiry?' We attempt to answer this question in due course but believe the answer lies in a single word. Politics.

We propose that *all* positions in this debate are 'political' regardless of where one sits on the 'continuum', including ourselves as authors, Minister Mikakos, and possibly the authors of the final SCV and Cochrane reviews. There are no absolutes in evidence-based practice. All healthcare stakeholders, including regulators, must be able to 'trust the evidence'. The nature of science articulated eloquently in the works of Popper,[16] is that it must bear scrutiny. One cannot assume that because the research was done by Cochrane, it cannot be flawed. The Cochrane Collaboration has, of course, been extensively criticised from within its own ranks.[17]

It appears that the authors of the inquiry's SCV final report essentially disregarded the responses from the 21,750 consumers who reported 99.7% satisfaction with the chiropractic care of their children and instead focussed solely on the findings of the Cochrane review. This is a self-evident dissonance. The obvious question remains, *'Why spend a significant amount of time and taxpayer funds on an inquiry and then disregard the main results?'*. The inquiry could simply have commissioned the Cochrane review and received the outcome it apparently expected. The compelling impression is that the unexpected strength of the responses combined with the absence of reports of physical, mental, or financial harm, which, after all, was the original term of reference, may have taken the inquiry and, thus, the minister by surprise. Whilst, indeed, popularity does not correlate with clinical effectiveness, the consumer response does contain valuable insights into the perspectives of consumers in the absence of reports of harm.

It is somewhat curious that the Cochrane review has not been published elsewhere in the intervening years, either in the scientific literature or the Cochrane database. The usual editorial peer review outside of the authors is not described in the methods of the review or the report. In our opinion, the review is more accurately categorised as a 'Rapid Review'. The Review is divided into two distinct sections: effectiveness and safety, and different methodologies were employed for each part which created challenges in the critique. The rationale for adding effectiveness to the original inquiry terms of reference is expressed as, if there is no effect, treatment cannot be defended regardless of safety profile. We will address the fallacy inherent in this statement in due course. The results of the evaluation of the review are presented in Table 1. The average scores indicate the review to be of 'low' to 'acceptable' quality.

	R1	R2	(R3)	(R4)	(R5)	Average
SIGN score	7	7	8	8	5	7

Systematic review rating SIGN) (10-12= high quality, 8-9 = acceptable quality, <8 = low quality) (R3-5 were external reviewers)

Table 1: SIGN scores of Cochrane Review

Strengths of the SCV report lie in the design, the response sample size and the independent nature of the data collection and analysis as a government-funded inquiry. The public and those accessing chiropractic services for their children answered the survey in an emphatic, unequivocal, virtually unanimous voice.

Some weaknesses were identified in the wider report. These are summarised in Table 2. There was an inconsistent and uncited definition of SMT, a serious internal inconsistent reporting of cerebrovascular incident (CVI) rate with SMT of children, and in our opinion, misrepresentation of risk from German sources. There was also inconsistent application of the inclusion/exclusion criteria for effectiveness studies.

Issue	**Detail**
Inconsistent, uncited definition of SMT	The report's executive summary states that the definition of spinal manipulation used was aligned with the National

	Health Practitioner Law Act 2009, which reads, "*manipulation of the cervical spine means moving the joints of the **cervical** spine beyond a person's usual physiological range of motion using a high velocity, low amplitude thrust*".(p3) This differs slightly but significantly from that stated in the executive summary of the SCV report and the Cochrane Review, where 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**".*(p11)
Risk and public safety assumption	Concerning risk, the summary states (without citation), "*…This is particularly important in younger children, especially those under the age of 2 years **in whom minor adverse events may be more common***".(p3)
Error in the report.	There is a significant error of transcription on pages 2 & 25 of the report and the Cochrane Review pages 2 & 35, which state: "*These studies reported rates spanning one minor treatment aggravation per 1812 consultations to one cerebrovascular incident in **20,000 visits**."* The incidence quoted of 1:20,000 should read **1:*120,000***.[18] The correct figure is contained in Table 7(p32)
Misinterpretation/misrepresentation.	The report cites two papers by Koch et al.; "*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*".(p25)

Table 2: Flaws identified in the SCV Report and Cochrane Review: Definition of SMT, CVI with SMT of children & German sources.

Table 3 outlines the inconsistent inclusion/exclusion of papers considered when determining the effectiveness of SMT for infants and children in the Cochrane Review. The description of the intervention from the full texts of the papers demonstrates exclusion for several papers, with descriptions closely matching those included. We list four papers as examples that specifically describe an intervention that does not fit the definition of the National Law, or the definition used by the Cochrane reviewers.

	Intervention description
Included papers (n=13) (4 examples)	1. Olafsdottir 2001[19]: Randomised controlled trial of infantile colic treated with chiropractic spinal manipulation, *"Dysfunctional articulations were manipulated and mobilised using **light fingertip pressure**". **NOT HVLA/SMT^*** 2. Wiberg 1999[20]; The short-term effect of spinal manipulation in the treatment of infantile colic: a randomised controlled clinical trial with a blinded observer. *"Those articulations found to be restricted in movement were manipulated/mobilised with specific **light pressure with the fingertips**". **Not HVLA/SMT^*** **3.** Accorsi 2014 [21]; Effect of osteopathic manipulative therapy in the attentive performance of children with attention-deficit/hyperactivity disorder. *"Manipulative techniques used included myofascial release, craniosacral, balanced ligamentous tension, and balanced membranous tension*"—**not HVLA/SMT^** 4. Haugen 2011[22]; Physiotherapist Manipulation (moderate force): *"Manipulation is conducted with the child supine and the head in neutral position, without extension of any structures. Only very moderate force is used".* **Not HVLA/SMT^**
Excluded papers n=27 (5 examples)	1. Miller 2012 [23]; 'Treatments were pragmatic, individualized to examination findings, and consisted of chiropractic manual therapy of the spine. Specifically, this involved **low force tactile**

	pressure to spinal joints and paraspinal muscles where dysfunction was noted on palpation. The manual therapy, estimated at 2 N of force, was given at the area of involvement without rotation of the spine.'
2.	Nemett 2008 [24]; MPT-OA (manual physical therapy based on an osteopathic approach) treatments were customized for each child based on results from the initial MPT-OA evaluation and included **gentle mobilization** of body tissues to relieve movement restrictions, thereby achieve balanced alignment and mobility and postural symmetry, with particular attention to the thoracolumbar spine, thoracic and pelvic diaphragms, pelvis, pelvic organs, and lower extremities.'
3.	Steele 2014 [25]; 'The protocol used **myofascial release and balanced ligamentous tension** techniques to the pelvis, abdominal diaphragm, torso, and cervical area as well as osteopathy in the cranial field.'
4.	Duncan 2008 [26]; 'Osteopathic **manipulative treatment** was limited to the use of direct or indirect techniques of osteopathy in the cranial field, myofascial release, or both.'
5.	Pizzolorusso 2014[27]; OMT techniques used: **indirect myofascial release**, balanced ligamentous tension, balanced membranous tension.'

Table 3: Inconsistent inclusion/exclusion of effectiveness papers

*^ and **bold** = our comment/notation*

Summary of critique

The evaluation of the report and the Cochrane Review and SCV Final Report unearthed significant flaws listed in Table 4.

1.	The report and Cochrane Review failed to define spinal manipulation (SMT) accurately or consistently, or cite a primary source, and thus poor framing of the research question may have led to subsequent methodological deficiencies.

2. The report erroneously and inconsistently ascribed a cerebrovascular incident (CVI) rate of 1:20,000 from one ~35-year-old, observational (survey) source in the main text and executive summary.
3. Papers purporting to question safety were included despite the medical practitioner authors of the original papers (German) reaching different conclusions.
4. The inclusion/exclusion criteria for papers on effectiveness were not adhered to, resulting in the inclusion of papers with interventions indistinguishable from some excluded.
5. Data from consumers was disregarded in the final recommendations

Table 4: Summary of flaws in the SCV report

The SCV report is flawed, and the recommendations contained therein should be viewed with caution. The Cochrane Review within the report adds little to the body of knowledge or clinical practice.

There was significant controversy at the end of the review process. The draft report was circulated to the panel for review and comment. The final report was not shared with the panel before it was released publicly by the Minister. The questions of the independence of the review and the controversy surrounding the report were raised in Victorian parliament by Mr Tim Quilty MP on 14th November 2019.[28]

Discussion

Our paper seeks to advance the practice of chiropractic by critiquing published works, in this case, the politically charged SCV inquiry into SMT of children under 12 years of age. Allowing flawed research to remain unchallenged as the 'best available evidence' may result in substandard clinical care or, in this case, restriction of access to services. The SCV review is already being cited and incorporated into the scientific narrative.[29] For example, Milne et al. (2022) have taken the narrow focus of the inquiry on SMT a step further to include mobilisation. However, Milne also commits the common error in the application of evidence-informed practice by ignoring evidence for comparators, including natural history, assuming that other interventions have more substantial evidence, a proposition without justification.[30]

Definition of SMT

The differing definitions of SMT used throughout are not sufficiently precisely or consistently articulated, nor is a primary source cited in the summary report or the Cochrane Review. This lack of precision is a significant shortcoming for a project as politically sensitive and important as this. There was inconsistent use of both the terminology and definition in the report and the Cochrane review. There is robust debate around the definition of SMT, more generally. Scholars from within and outside the chiropractic profession have theorised and criticised the (out)dated definition used by the National Law and the SCV inquiry for many years, dating back to Sandoz's theories in the 1960's.[31-33] These debates have highlighted the limitations of this definition.[34-38]

The reference provided (reference #3 p8 Footnote) in the report's summary is not a primary source; instead, it is an inactive link to an unrelated Ahpra page.[Australian Health Practitioner Regulation Agency: Reporting a criminal offence (https://www.ahpra.gov.au/Notifications/Raise-a-concern/Reporting-a-criminal-offence.aspx).] *This link was an error when published, it has not subsequently become inactive.*

Whichever definition was used, it should have been consistent *and,* most importantly, cited from a primary source in the peer-reviewed literature. It is not sufficient in our view to cite only the National law in this context as a scientific work. The National Law refers only to SMT of the cervical spine, whereas the inquiry and Cochrane definitions included SMT of the entire spine.(p11)

Risk assumption

The rationale for the ascription of risk in the SCV report is an unrelated submission by the (former) Chiropractors' Association of Australia (CAA) to Section 123 of the National Law, which restricts the practice of spinal manipulation of the cervical spine to four health professions, (p8) again, no primary source is cited from the scientific literature.

Error of reported Cerebrovascular Incident (CVI) rate

A significant mistake in the purported rate of CVI is repeated several times in the text of the systematic review, the body of the report and the executive summary of both sections. There is an internal inconsistency where the correct figure is reported in Table 7. (p32) Characterisation of this error as a 'typo' or 'copy and paste error' is simply not acceptable from a work branded

with the prestige of The Cochrane Collaboration. The primary source of this citation (Klougart 1996) reports 1 case of a male child aged 10, losing consciousness (fainting) on two occasions, whereby treatment was discontinued without any reported ongoing harm to the child.(p32) According to standard neurological practice and definition, a transient fainting episode (syncope) does not constitute a cerebrovascular incident (CVI).[39] The incorrect categorisation in the original paper by Klougart does not justify perpetuating the error in the SCV report. The one incident referred to in the Klougart paper, published in 1996, was a recalled account of a 10-year-old male having occurred in 1984. This was not a case report as such, but rather one instance in a retrospective Scandinavian survey dataset collected in 1989 from clinical records of the period 1978-1988.

Misrepresentation of autonomic sequelae

The German medical practitioner authors of several cited studies[40,41] report very different conclusions than the SCV report and, in fact, describe the autonomic sequelae (flushing, sweating, decreased heart rate and change in respiratory rate) as a rationale for linking what they term Kinetic Imbalance due to Suboccipital Strain (KISS) to the pathogenesis of sudden infant death syndrome (SIDS). The researchers (medical practitioners) were not reporting the autonomic effects in a negative light. In fact, the authors state in the same paper:

> "*In many cases, chiropractic treatment seems to be the most successful therapy which helps to treat such disorders. Therefore, chiropractic treatment and manual therapy have become increasingly popular over the past decade. Although retrospective studies about complications in manual therapy are available for adults, no special data about children are given. There is a demand for empirical analysis and if possible prospective as well as retrospective study. Nevertheless, no incidence has been reported up to now.* ***We can report more than 20,000 children treated without serious complications****."*[40]*(p174)*
> *(**bold** our emphasis)*

While the review authors conclude that SMT has not been shown to have a positive clinical effect on non-musculoskeletal (non-MSK) conditions, they cite the Koch papers to demonstrate autonomic effects only as adverse events.

Misapplication of Inclusion/Exclusion criteria

We found an inconsistent inclusion of several effectiveness papers, while others describing similar interventions were excluded. This is perhaps best illustrated by the inclusion of the well-known Olafsdottir paper.[19] To quote Olafsdottir, *"The type of spinal manipulation used in this study was a form of modified fingertip mobilisation; a very light manipulation was performed. This procedure is somewhat different from the manipulative procedures commonly employed by chiropractors when treating adults. Characteristically a controlled force is delivered to spinal joints in a specific direction with high velocity, often accompanied by joint "crack" or vacuum phenomenon.* ***In this study, the typical joint 'cracks' were not heard in any of the infants****".*[19] This paper explicitly does *not* meet the definition of SMT in the National Law or the definitions used in the inquiry or the Cochrane Review.

Some of the excluded papers report positive results, e.g., Pizzolorusso (2014)[27] and Miller 2012.[42] For comparison, we provided several examples of included and excluded papers with descriptions of the papers' interventions.

Final Remarks

Minister Mikakos made repeated statements describing the treatment of children by chiropractors as 'dangerous', chiropractors as 'rogue practitioners', and sought public reports of harm to children by chiropractors. However, no physical, financial, or emotional harm was reported in the consumer responses. The public responded with positive reports of their children being helped by chiropractors and their desire to maintain the right to make healthcare choices for their families. These results are consistent with emerging evidence that spinal manipulation may even improve psychological outcomes.[43] When questioned in parliament concerning the volume of the response, the Minister appeared to rationalise the response rate by 'crediting' chiropractors with encouraging their patients to make submissions. Given that the demographic target of the survey was consumers of chiropractic services for children, this rationale fails.

The recommendation (#1) that suggests denial rather than a 'trial of care' based on lack of effectiveness would *ipso facto* exclude other usual medical care interventions for children under 12, for which the evidence base is also equivocal. For most conditions, evidence regarding the

effectiveness of paracetamol (Acetaminophen) is insufficient to draw firm conclusions, and there is strong evidence that paracetamol is not effective in reducing spinal pain.[44,45] Yet it is still routinely utilised for children of all ages for various conditions, including infants. Conversely, there is compelling evidence of harm in using this type of medication with children. In Australia and New Zealand, paracetamol overdose, secondary to medication errors, is the leading cause of paediatric acute liver failure, which has caused deaths.[46] Further, Acetaminophen exposure in early childhood has been associated with the development of asthma, rhino-conjunctivitis, and eczema.[47,48] Acetaminophen exposure during pregnancy has also been associated with asthma,[49] and recurrent lower respiratory tract infections (LRTIs) in children.[50] Maternal exposure to Acetaminophen is associated with a significantly increased risk of childhood neurodevelopmental disorders in a dose-response fashion.[51-53]

The inquiry focused on the delivery of SMT by chiropractors, which appears at odds with the National Law (2009), which applies similar standards and constraints on all practitioners as does the Ahpra shared code of practice.[54] To remove SMT, without evidence, from chiropractors' (or any other practitioners') clinical repertoire for children under 12 years of age is, in our view, unjustifiable. In contrast, a recent Delphi study by Dice[55] contains a reasoned discussion of the provision of manual care (including SMT) to pre-adolescent children (including infants) by physical(physio) therapists. We cite the significant findings of a recent RCT[56] of high-velocity SMT manual medical treatment in infants with postural and movement asymmetries and postural preference. The intervention studied was *HVLA on infants*, performed by medical practitioners and physiotherapists.

It appears that due to time constraints, the review essentially relied on updating previous works. The search strategy relied on three other primary sources; Todd[57], Parnell Prevost[58] and Dreihuis.[59] Todd (2015) is incorrectly included as a 'systematic review' (p35 & 67). Although indeed a high-quality study, Todd used the term 'systematically' to describe only the meticulous nature of the search, not the study design, another example of the Cochrane authors' lack of attention to detail. The Cochrane safety review had only one searcher/reviewer, again, a weakness in our view.

Formal clinical practice guidelines for any professions in the treatment or management *where they exist* for the conditions listed in the SCV report are often based on weak to moderate evidence, notably; colic (irritable infants)[60], headache[61], otitis media[62], cerebral palsy[63], enuresis[64], and torticollis.[65,66] In addition, the bedrock of usual medical care, pharmaceuticals, often carry advisories not to be (over) used due to no effect or risk of adverse events. This includes; over-the-counter analgesic medications (Paracetamol/Ibuprofen),[67] Anti-reflux medications, Anticholinergic medications, Colic mixtures, Simethicone[60] and antibiotics.[68] The prescription of proton pump inhibitors (PPIs) for the treatment of reflux with excessive crying has been increasing.[69-71] These medications have been shown to be ineffective for excessive crying and most gastroesophageal reflux and are associated with acute gastroenteritis, community-acquired pneumonia, adverse bone health, and food allergy.[71-73] Adverse events and side effects are known following the application of physiotherapeutic interventions such as ultrasound,[74] extracorporeal shock-wave therapy,[75,76] interferential therapy,[77,78] and even therapeutic heat.[79] These are all interventions commonly used in Australia with low-moderate level evidence of effectiveness.

Adherence to clinical practice guidelines in most healthcare sectors is generally poor.[80,81] In any case, evidence-based recommendations in management plans should consider the relative safety, effectiveness and benefits of not only that recommended but options including natural history.[82,83] Judgement on 'non-adherence' should be tempered by the findings of a recent meta-analysis of Cochrane Systematic Reviews. Just 1 in 20 of 1,567 interventions in the analysis was found to have high-quality evidence supporting their benefits, and harms are under-reported. Less than half are supported even by moderate-quality evidence.[30] When measured against this standard, the lack of effectiveness for SMT for the list of conditions included by SCV becomes more contextualised.

The quantitative results in the SCV report from consumer submissions regarding involvement in decisions about care, risks and benefits of care, and improvement with the care provided were all above 95%. Curiously, SCV chose to highlight results from a 10% sampling of the *optional* qualitative data open text fields to report; *"63.0% (1400 of 2223), of respondents reported that the chiropractic care was effective in treating children under 12 years of age*" and *"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".(p18) While this reporting is not strictly speaking incorrect, it is misleading to readers when there is accurate and representative quantitative data from the 21,824 consumers. The review included the public consultation to inform the process and assist the panel in reaching relevant conclusions. In our view, due consideration and weighting in the report were not given to the upper 99% of responses.

The implication that a positive consumer experience tells us nothing in relation to healthcare is incorrect in our view. Anecdotal experience, testimonials, case studies, and even ecological or observational studies are not used in relation to efficacy or clinical effectiveness. However, an independent government-conducted study such as the SCV survey speaks volumes concerning the public's experience with chiropractic care and their right to choose healthcare for their family. A total of 29,599 online surveys were submitted from across Australia. Despite the public statements by minister Mikakos, extensive negative coverage by media outlets, and mainstream medical stakeholders, no examples of harm to a child in Australia were unearthed through this extensive consultation process. Submissions from educational institutions, medical organisations and advocates also failed to produce verified reports of harm.

Conclusions

Given the public statements by fringe medical advocates and organisations with a history of attacks on the chiropractic profession, the opportunity for bias within the outcome of the SCV inquiry could be called into question. Indeed, the opaque nature of the panel selection, the perception of influence by minister Mikakos and the presumption of negative findings prior to the inquiry by the minister, along with the substantial cost to taxpayers, should all be matters of deep concern to consumers of healthcare in Australia.

Despite apparent pre-emptive efforts to solicit reports of harm of chiropractors treating children from the public and practitioners, none were forthcoming. If Minister Mikakos expected to demonstrate the risk to children younger than 12 years from chiropractors, she was unsuccessful. While the cost to taxpayers has not been disclosed publicly, the resources to conduct the inquiry that resulted in such a resounding endorsement of chiropractic care of children would certainly be

beyond the profession. The inquiry commissioned a rapid (systematic) review that was unable to unearth evidence of harm to a single child in Australia. Insurance providers likewise corroborated that there has never been a claim for harm to a child in Australia by a chiropractor. The widened terms of reference to include effectiveness only illustrated that spinal manipulation (SMT) fares similarly to other commonly used interventions for childhood conditions and has a superior safety profile to many. However, the importance of this safety profile was not highlighted in the report, as the recommendations focus on the lack of current evidence for effectiveness. It should be noted that any proposal of legislative change must be considered in its application to National Law and the implications for all health professions regarding the setting benchmarks for levels of evidence of harm and effectiveness for other interventions.

It is worth reflecting that the chiropractic profession has undergone multiple independent investigations. These include an Australian Commission of Inquiry, the Webb Report,[84] a Royal Commission (NZ-Aotearoa), [85], and an anti-trust court case in the USA, the famous 'Wilk Case'.[86] The SCV inquiry appears to be the latest to confirm the safety of the chiropractic profession, this time for managing children in Australia. That said, the profession should certainly take heed of the need to build the evidence base for the management of people with conditions beyond musculoskeletal, and the management of children highlighted by these inquiries.

SCV should address the errors, including the withdrawal of the report pending correction and an erratum being published. The panel and the various parties that made submissions to the inquiry should also be advised of the errors and flaws in the report. Future inquiries should include comparative studies of the safety and effectiveness of other commonly used healthcare interventions for children.

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