

ADVERSE EVENTS DUE TO CHIROPRACTIC AND OTHER MANUAL THERAPIES FOR INFANTS AND CHILDREN: A REVIEW OF THE LITERATURE

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ABSTRACT

Objective: The purpose of this study was to review the literature for cases of adverse events in infants and children treated by chiropractors or other manual therapists, identifying treatment type and if a preexisting pathology was present.

Method: English language, peer-reviewed journals and non-peer-reviewed case reports discussing adverse events (ranging from minor to serious) were systematically searched from inception of the relevant searchable bibliographic databases through March 2014. Articles not referring to infants or children were excluded.

Results: Thirty-one articles met the selection criteria. A total of 12 articles reporting 15 serious adverse events were found. Three deaths occurred under the care of various providers (1 physical therapist, 1 unknown practitioner, and 1 craniosacral therapist) and 12 serious injuries were reported (7 chiropractors/doctors of chiropractic, 1 medical practitioner, 1 osteopath, 2 physical therapists, and 1 unknown practitioner). High-velocity, extension, and rotational spinal manipulation was reported in most cases, with 1 case involving forcibly applied craniosacral dural tension and another involving use of an adjusting instrument. Underlying preexisting pathology was identified in a majority of the cases.

Conclusion: Published cases of serious adverse events in infants and children receiving chiropractic, osteopathic, physiotherapy, or manual medical therapy are rare. The 3 deaths that have been reported were associated with various manual therapists; however, no deaths associated with chiropractic care were found in the literature to date. Because underlying preexisting pathology was associated in a majority of reported cases, performing a thorough history and examination to exclude anatomical or neurologic anomalies before applying any manual therapy may further reduce adverse events across all manual therapy professions. (*J Manipulative Physiol Ther* 2015;38:699-712)

Key Indexing Terms: *Chiropractic; Manual Therapy; Safety; Infant; Children; Pediatrics; Patient Harm; Adverse Effects*

A 2010 survey of doctors of chiropractic across Europe and the United States¹ found that 5% to 11% of their client visits were pediatric patients, with an earlier worldwide study reporting in excess of 30 million chiropractic treatments are given to children

annually.² The safety of chiropractic care for infants and children has been questioned by health practitioners and community members.³⁻⁸ In Australia, the Friends of Science in Medicine has called for a ban on chiropractic care for children, claiming that heavy manipulation puts the lives of children at risk⁹ based on the inaccurate reporting of a child having suffered a neck fracture after chiropractic therapy (dural tension technique and cranial therapy). A report by the Australian Health Practitioners Registration Authority (AHPRA)¹⁰ cleared the chiropractor of any wrongdoing when expert radiological evidence showed the child had an undetected congenital cervical spondylolysis and there was no evidence of a fracture. Vohra et al⁸ note that chiropractic management of infants and children safety data is virtually nonexistent, and others also express concern about the lack of beneficial evidence supporting chiropractic care for children.¹¹ This further highlights the stated need for more randomized controlled trials (RCTs).¹ However, in contrast to this reported lack of evidence, Rome¹² insists that there has been a considerable number of research articles and textbooks published in Europe espousing the benefits of manual therapy for children and infants, particularly the work of Biedermann.¹³ A consensus

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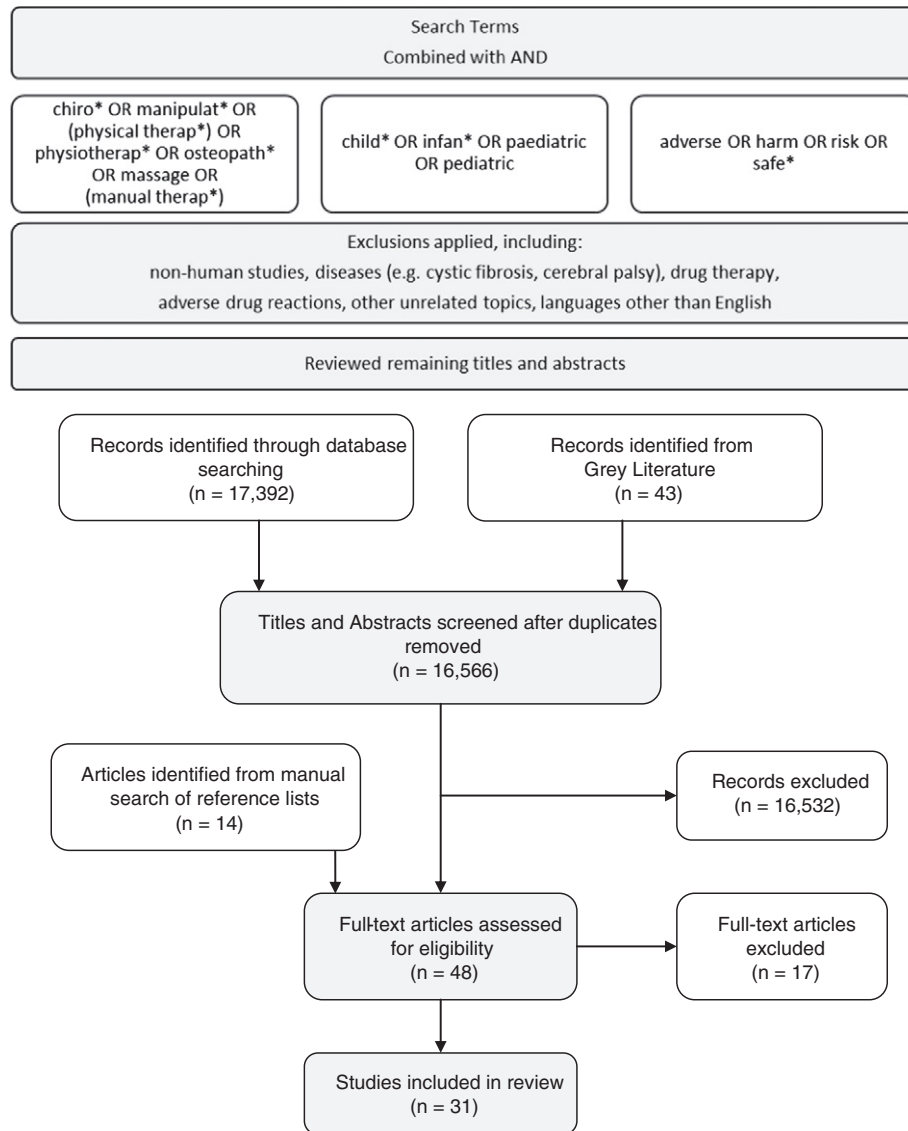


Figure 1. Search strategy.

document¹⁴ supported the recommendation for standards of chiropractic care developed for children and clearly outlined best practice for the chiropractic care of infants, children, and adolescents, including when a therapeutic trial is reasonable, using evidence-based practice, as well as altering technique selection and application based upon the unique anatomy and physiology of infants, children, and adolescents.

It is not clear if the publicized concerns about the safety of chiropractic and other manual treatments for infants and young children are supported by published evidence. Therefore, the purpose of this review is to examine all reported cases of serious adverse events caused by practitioners who apply manual therapies (ie, chiropractors/doctors of chiropractic, physical therapists, medical physicians,

doctors of osteopathy, and other manual therapists) when caring for infants and children, with particular focus on the types of treatment applied, the field of the treating practitioner, and whether a preexisting, undiagnosed pathology was present.^{8,15}

METHODS

The scientific literature was systematically searched using the terms summarized in Figure 1 in the locations listed in Table 1. The search of published peer-reviewed articles and gray literature included events documented by any manual therapy health provider (ie, chiropractors/

Table 1. Literature Search Results

Database	Abstracts Screened	Articles Meeting the Inclusion Criteria (Excluding Duplicates)
Embase	762	12 articles: Miller et al, ³⁹ Wilson et al, ⁴¹ Zimmerman et al, ⁵² Humphreys, ²¹ Alcantara et al, ^{25,35-38} Posadzki and Ernst, ²⁴ Simonian and Staheli, ⁴³ and Marchand ¹⁶
AMED	3	1 article: Vohra et al ⁸ Manual search of reference list revealed additional 8 articles: Shafir and Kaufman, ⁵³ Ziv et al, ⁵⁴ Jacobi et al, ⁴⁶ L'Ecuyer, ⁵⁵ Klougart et al, ⁵¹ Rageot, ⁴⁷ Held, ⁶⁶ LeBeouf et al ⁵⁰
Biological Abstracts, 1980-April 2009	15	None
Biosis Previews, 1969-2008	1	None
Ovid Medline, 1948-June 2009	7	None
Maternity and Infant Care	0	–
Psychology Information 1967-April week 2 2009	0	–
Ovid (Books@Ovid; Search All Ovid Journals)	155	1 article: Biedermann ¹³
Index to Foreign Legal Periodicals 1985-2009	0	–
Scopus	12	1 article: Gotlib and Rupert ¹⁹
Science Direct	241	1 article: Spiegelblatt ⁴⁵
Index to Chiropractic Literature	15,691	3 articles: Pistolese, ¹⁷ Gleberzon et al, ²⁰ and Brand et al ¹⁸
PubMed Central	1	None
ICPA independent chiropractic Web site	4	None
Google Scholar	3	None
JVSR Web site reviewed	257	None
NCBI (National Library of Medicine)	16	None
CINAHL	224	14 articles: Struewer et al, ⁴⁰ Miller and Benfield, ²⁶ Doyle, ⁴⁴ Holla et al, ⁴² Hayes and Bezilla, ²⁷ Hayden et al, ²⁸ Dobson et al, ²² Pohlman and Holton-Brown, ²³ Sawyer et al, ²⁹ Koch et al, ^{30,31} Bronfort et al, ³⁴ Philippi et al, ³² Rowe et al ³³ Manual search of reference lists revealed additional 6 articles: Wiberg et al, ⁵⁹ Straub et al, ⁶⁰ Sandell et al, ⁶¹ Balon and Aker, ⁶² Khorshid et al, ⁶³ Olafsdottir et al ⁶⁴
Gray literature searched including leading chiropractic pediatric texts printed in the United States and Australia and Australian newspapers	43 items	None (relevant newspaper articles cited in introduction)

AMED, The Allied and Complementary Medicine Database; CINAHL, Cumulative Index of Nursing and Allied Health Literature; JVSR, Journal of Vertebral Subluxation Research.

doctors of chiropractic, physical therapists, medical physicians, doctors of osteopathy, and other manual therapists). Throughout this article, the term *physical therapist* (a term used in the United States) is used in preference to physiotherapists (used in other countries to refer to the same professional type).

Only articles published in the English language were searched. All available articles published from the inception of searchable bibliographic databases to March 2014 were included. EMBASE, AMED, BIOSIS previews, MEDLINE, Maternity and Infant Care, OVID, CINAHL, Psychinfo, PubMed, INDEX to Foreign and Legal Periodicals, SCOPUS, Science Direct, Index to Chiropractic Literature, and PubMed Central databases were searched.

Web sites, books, and gray literature were searched including Google Scholar and 2 chiropractic Web sites, the International Chiropractic Pediatric Association and Journal of Vertebral Subluxation Research. The bibliog-

raphies of seminal articles were screened to identify any additional articles.

Abstracts were screened for those discussing manual therapy of any kind on infants and children. After reading the relevant full texts, articles were included in this review if they clearly discussed adverse events (mild, moderate, or severe). Articles were excluded if they were commentaries not reporting case information, the details of adverse event data collection were not clear, there was no discussion of adverse events, or the articles did not discuss manual therapy with children.

The full text of each document was analyzed to identify the nature of the adverse event; the practitioner type; technique applied; and evidence of any undiagnosed, preexisting pathology. *Adverse events* were defined as mild (transient effects lasting <24 hours, eg, crying or discomfort), moderate (requiring medical/general practitioner treatment), or severe (requiring hospital treatment)¹⁶

RESULTS

The search captured 17435 potential articles, and of that, 48 published, peer-reviewed articles were reviewed (Table 1), 31 of which met the selection criteria (all 31 articles are summarized in Appendix A). Included were 5 systematic reviews of the literature,^{8,17-20} 5 narrative reviews,²¹⁻²⁵ 4 cross-sectional surveys,^{16,26-28} 6 randomized controlled trials,²⁹⁻³⁴ 4 Practice Based Research Network (PBRN) survey studies,³⁵⁻³⁸ 4 case studies and 1 case series,³⁹⁻⁴³ and 2 discussion papers.^{44,45} The details of all adverse events results are summarized in Table 2. This includes 15 instances of serious adverse events involving the application of some form of manual therapy on children younger 18 years. Moderate and mild adverse events are also described (Table 2).

High-velocity, low-amplitude thrust (HVLA) spinal manipulative therapy (SMT) was applied in 10 of the 15 cases of serious adverse events. In addition, in 8 of the 15 cases of a serious adverse event, it was revealed that before the application of chiropractic or manual therapy, there was present a preexisting but undetected underlying pathology or existing neurologic symptoms. Three deaths were recorded, and 2 of these were in infants under 3 months of age who had previously been healthy.

DISCUSSION

This review of the literature varies from previous reviews in that it looks into the adverse events for all types of manual therapists and not just chiropractors and combines this information with the type of technique that was used and also finally the presence of any preexisting pathology. This review of the literature identified that some authors suggest that adverse events can occur after manual therapies; however, the reported incidence appears to be rare and may be heightened by preexisting pathologies or the use of inappropriate techniques or inappropriately applied techniques. Three deaths have been reported to be associated with any type of manual therapy: a 3-month-old infant treated by a physical therapist using both electrical current and spinal manipulation⁴⁶; a craniosacral therapist incorrectly applying craniosacral therapy⁴²; and a death reported in France in the 1960s with no details of the therapist type or technique used, although it is known that the child had underlying pneumonia.⁴⁷ All 3 of these deaths were associated with European-based practitioners in a region where regulation of chiropractic care is relatively recent. These 3 deaths reflect similar findings from previous reviews that misdiagnosis, failure to recognize the onset or progression of neurological symptoms, improper technique, SMT performed in the presence of clotting disorders, or poor spinal structural integrity increases the likelihood of an adverse event.⁴⁸

This review found that HVLA thrust techniques were more often reported as the technique used in adverse events

in infants and children and further research is required to determine if this is the result of the specific manipulations involved in HVLA, is an artifact of the greater frequency with which this treatment is used across all therapy types, or is the result of limitations in the experience and training of the manual therapist. It is also necessary to determine whether particular techniques or forces are more appropriate for different ages, perhaps in accordance with the known osteoligamentous tensile strength limits, the anatomical development of the spine and nervous system in the child, and the potential for subcatastrophic events, especially in infants less than 3 months of age.⁴⁹

In addition to the 15 serious events that have been reported, there have been 775 mild to moderate adverse events. This includes 604 cases of crying, soreness, or transient headache,^{16,26,33,36-38,50} and 1 case of syncope⁵¹ recorded after chiropractic care. There were a further 35 cases of soreness or transient headache^{27,32} after osteopathic treatment. Finally, there were 50 cases of transient apnea (returned to normal in 4 breaths) with vegetative responses³⁰ and 87 cases of short lasting (seconds) marked bradycardia, in infants after SMT to the upper cervical spine in otherwise healthy children from medical manipulators.³¹ These responses to manual medical therapy were recorded as part of an experiment in a hospital setting, and further investigation of this potentially serious physiological phenomenon in infants less than 3 months of age is warranted.

Manual medicine practitioners in Europe tend to use SMT for children from birth,^{12,13} and radiographs are almost always undertaken to exclude skeletal pathology before the application of SMT. The use of ultrasound, before full cervical spine ossification, pediatrician screening, and appropriate neurologic examination to screen out those children with an underlying pathology and to refer them appropriately, should be a consideration for all those using manual therapy in infants with congenital torticollis or unusual body posturing.

Although this review has looked at all types of manual therapies involving children, it should be noted that in terms of chiropractic treatments, the number of treatments for the population is extensive; however, there are no reported deaths and only 7 severe adverse events,^{41,47,51-55} 4 of which were associated with an underlying preexisting pathology⁵²⁻⁵⁵ and the health status of 1 other child unknown before care.⁴⁷ The HVLA spinal manipulation was the technique that was reported to be most common of these rare recorded adverse events associated with chiropractic care.

Chiropractors are trained to use techniques that best suit the age and condition of the patient. Undergraduates are taught to modify the level of force during manipulation such as when used on a child and a variety of techniques can be considered for neonates or infants.^{56,57} In a study of 956 European chiropractors,¹⁶ more than 96% reported treating

Table 2. Adverse Events After Manual Therapy

Original Report	No. of Adverse Events	Adverse Event	Practitioner Type	Technique	Relevant Underlying Pathology	Further Cited by
Serious Adverse Event						
Shafir and Kaufman ⁵³	1	Quadriplegia; regressed to paraplegia (18 mo postoperatively)	Chiropractor	Flexion, extension, axial loading and unloading	Congenital torticollis; spinal cord astrocytoma	Vohra et al ⁸ Doyle ⁴⁴ Pistolesse ¹⁷ Spigelblatt ⁴⁵ Humphreys ²¹
Ziv et al ⁵⁴	1	Progressive neuromuscular deficits in legs; paraplegia	Chiropractor	NS	Osteogenesis imperfecta	Vohra et al ⁸ Humphreys ²¹ Doyle ⁴⁴
Zimmerman et al ⁵²	1	Severe headache, vomiting, left facial weakness, diplopia, ataxia	Chiropractor	Rapid manual rotations of the head with flexion and hyperextension	Preexisting symptoms of headaches and transient cranial nerve deficits after gymnastics session	Vohra et al ⁸ Spigelblatt ⁴⁵ Doyle ⁴⁴ Humphreys ²¹ Pistolesse ¹⁷
L'Ecuyer ⁵⁵	1	Neck pain, progression to drowsiness and weakness, hospitalization	Chiropractor	NS	Congenital torticollis	Vohra et al ⁸ Humphreys ²¹
Klougart et al ⁵¹	1	Loss of consciousness	Chiropractor	SMT (Gonstead technique)	Nil	Vohra et al ⁸ Humphreys ²¹ Doyle ⁴⁴
Wilson et al ⁴¹	1	7th and 8th posterior rib fractures	Chiropractor	Infant held upside down grasping firmly around rib cage in assessment; Activator instrument applied to the thoracic spine	Nil	
Rageot ⁴⁷	3	Anterior dislocation of atlas and fracture of odontoid axis at C2 Dislocation of atlas Death	Chiropractor NS NS	SMT SMT SMT	Unknown Dorsolumbar injury caused by fall Pneumonia	Vohra et al ⁸ Doyle ⁴⁴ Humphreys ²¹
Jacobi et al ⁴⁶	1	Subarachnoidal hemorrhage and death	Physical therapist	Vojta technique (spinal manipulation and electrical current)	Nil	Vohra et al ⁸ Brand et al ¹⁸ Spigelblatt ⁴⁵ Doyle ⁴⁴
Simonian and Stahel ⁴³	2	Leg fractures	Physical therapist	High-velocity long-lever thrusts for leg contractures	In 1 child only: congenital amyoplasia and 1 child normal	
Held ⁶⁶	1	Respiratory failure	MD	Passive assisted range of motion of cervical spine	Minor head trauma	Vohra et al ⁸ Humphreys ²¹ Doyle ⁴⁴
Holla et al ⁴²	1	Death	Craniosacral therapist (not registered with relevant national body)	Forced, held, flexion of entire vertebral column.	Nil	Dobson et al ²²
Struewer et al ⁴⁰	1	Hemothorax	Osteopath Physician	Seated rotational and extension high velocity thrust	Nil	
Mild to Moderate Adverse Events						
Alcantara and Ohm ³⁵	17	Soreness	Chiropractors	SMT	NR	Humphreys ²¹ Doyle ⁴⁴
Alcantara et al ³⁸	2	Soreness	Chiropractors	SMT	NR	
Alcantara et al ³⁶	9	Soreness	Chiropractors	SMT	NR	
Alcantara et al ³⁷	3 (chiropractor reported) 2 (parent reported)	Stiffness; soreness	Chiropractors	SMT, varied	NR	Humphreys ²¹ Doyle ⁴⁴

(continued on next page)

Table 2. (continued)

Original Report	No. of Adverse Events	Adverse Event	Practitioner Type	Technique	Relevant Underlying Pathology	Further Cited by
Marchand ¹⁶	23 moderate 534 mild	Soreness; headache Crying; sleeplessness	Chiropractors	Varied and not specified which lead to either adverse reaction Modified SMT Craniosacral therapy Activator instrument	NR	
Rowe et al ³³	2	Minor transient soreness	Chiropractor	HVLA spinal manipulation (Diversified) Technique	Adolescent idiopathic scoliosis	Gotlib and Rupert ¹⁹
Sawyer et al ²⁹	2	Mid-back soreness and increased irritability	Academic chiropractor	HVLA (motion palpation and light touch of specific spinal segments)	NR	Vohra et al ⁸ Gotlib and Rupert ¹⁹ Humphreys ²¹ Doyle ⁴⁴ Pohlman and Holton-Brown ²³
Leboeuf et al ⁵⁰	5	Severe headache and stiff neck	Chiropractic students (5th year of study)	SMT	NR	Vohra et al ⁸ Spiegelblatt ⁴⁵ Gotlib and Rupert ¹⁹ Humphreys ²¹ Pistolese ¹⁷ Doyle ⁴⁴
Miller and Benfield ²⁶	4	Increased crying (<24 h)	Chiropractic students	Varied: cervical spinal SMT and adjustment of pelvis	NR	Humphreys ²¹ Doyle ⁴⁴
Koch et al ³¹	87	Moderate to severe bradycardia	Medical manipulator	Unilateral mechanical impulse to the high cervical spine	NS	Brand et al ¹⁸ Doyle ⁴⁴
Koch et al ³⁰	50	Apnea of short duration	Medical manipulator	Suboccipital impulse ("short, gentle thrust")	NR	Brand et al ¹⁸
Philippi et al ³²	4	Increased vomiting; excessive crying	Osteopath	Tissue and fascial release to cranial and dural connections	NR	
Hayes and Bezilla ²⁷	31	Worsening symptoms (7) Behavior problems/irritability (10) Pain/soreness (8) Headache (2) Dizziness/flu-like symptoms/treatment reaction/tiredness (1 each)	Osteopathic physician	OMT applied in all cases. OMT included HVLA, CS, MFR, lymphatic pump and cranial treatment (CR)	NR NR NR NR	Humphreys ²¹ Doyle ⁴⁴

CS, counterstrain; HVLA, High-velocity, low-amplitude thrust; MFR, myofascial release; NR, not reported; NS, not specified; OMT, osteopathic manipulative therapy; SMT, spinal manipulative therapy.

children, and they estimated that they reduced the magnitude of their thrusts with infants under 1 year of age by 90% of that used on adults, with the level being gradually increased in line with the age of the child. Chiropractors, osteopaths, physical therapists, and manual medicine practitioners all use very similar modified SMT and stretching techniques when treating very young infants and children.¹²

Limitations

This literature review may have missed relevant articles because the search was only conducted in English publications. A further limitation would be that the terms referring to manipulation vary considerably in the literature and so what is described as spinal manipulation can vary to be very light touch to the use of a mechanical instrument to that of a modified HVLA thrust.⁵⁸ Biedermann¹³ is a

European medical manual therapist with decades of experience and none of Biedermann's comments regarding medical manipulation of infants and its apparent safety were included in the results because this was merely commentary and there were no specific cases reported. The RCTs of Wiberg et al,⁵⁹ Klougart et al,⁵¹ Straub et al,⁶⁰ Sandell et al,⁶¹ Balon et al,⁶² Khorshid et al,⁶³ and Olafsdottir et al⁶⁴ were reviewed but excluded from the matrix for this article because there was no mention of whether adverse event data were recorded.

Recommendations

Adverse Event Reporting. More comprehensive methods of adverse event recording across all manual therapy professions are recommended. For example, the Chiropractic Patient Incident Reporting and Learning System launched in the UK in 2005⁶⁵ is now accessible to Australian chiropractors. This adverse event report monitoring service is available for chiropractors to report anonymously. The Chiropractic Patient Incident Reporting and Learning System reporting system is not currently available to all other users of manual therapy so reported events may be overrepresented by chiropractors. We should consider how to include all manual therapists in the collection of this type of data and ensure that practitioners use the service and make changes based on the reports.

Registration boards of all professions involved in this study have the primary role of reducing risk to the community at large from poor practitioner conduct and delivery of care. For example, in Australia, this is through the AHPRA.

A related issue canvassed by Vohra et al⁸ is that not all parents of children treated by a chiropractor will return to the chiropractor if they believe there has been an adverse event. Instead, parents may turn to their medical practitioners or other health care providers such as maternal and child health nurses or hospitals, leading to possible underreporting of adverse events. The regulatory body AHPRA has a role in providing an avenue for reporting of adverse events that is independent and available to everyone in the community.

Undergraduate Education. To enhance the safe application of manual therapy on children, regulatory bodies, and also universities could ensure that undergraduates are exposed to a broad case mix of patients including children and that a range of age appropriate techniques are taught. Further study in this area is required.

In terms of chiropractic training, undergraduate education prepares chiropractors for working with all ages of patients and is part of the worldwide requirements for chiropractic education and accreditation. Likewise, osteopaths, manual medicine practitioners, and physical therapists are trained in the assessment

and application of therapy across all ages of people. A review of the rigor and quality of postgraduate courses available is also needed.

All Manual Therapists Need to Be Diligent in Clinical Practice and Application. Because some of the adverse events reported in the literature may have been avoided if a better history and examination were completed or if there had been a better technique selection or application, it might be appropriate to further investigate both undergraduate and postgraduate training of all types of manual therapy practitioners. Further research is recommended to investigate appropriate technique usage, especially of HVLA, and the range and number of case mix exposures that would deem someone competent to care for children.

CONCLUSION

Published cases of serious adverse events in infants and children receiving chiropractic, osteopathic, physiotherapy, or manual medical therapy are exceedingly rare. There have been no cases of deaths associated with chiropractic care reported in the academic literature to date. Three deaths were reported caused by other types of manual therapists. Performing a thorough history and examination to exclude anatomical or neurologic anomalies before the provision of care, appropriate technique selection and its application may further reduce adverse events across all manual therapy professions.

Practical Applications

- Chiropractic, physiotherapy, osteopathic, and manual medicine practitioners all carry a rare but material risk when applying SMT to infants and children.
- Most events found in this study had an underlying pathology; thus, the presence of an underlying pathology of the bone or nervous system may increase the risk of a serious adverse event occurring in the pediatric population.
- Techniques should be modified to suit the age, anatomy, and unique physiology of the young patient especially for children under 3 months of age.
- The application of modified SMTs by a doctor of chiropractic in a healthy child appears no less safe than SMT applied by a physiotherapist, osteopath, or manual medicine practitioner.

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APPENDIX A. STUDIES INCLUDED IN REVIEW

Study	Study Details	Key Findings	Summary
Systematic reviews Vohra et al ⁸	Systematic review of the literature for cases of adverse events involving the use of manipulation on children (Inception-2007)	13 studies included from 13916 identified in initial search (2 RCTs, 11 observational studies); 14 cases of adverse events (9 serious, 2 moderate and 3 minor).	Extensive and very systematic review of the literature; chiropractors found to have caused 5/9 serious events, 4 of these 5 chiropractic cases having preexisting pathologies or neurologic signs and 5 nonserious events included discomfort, pain, or crying. Physical therapist and unknown practitioner caused 1 death each. HVLA was noted in 6 cases; however, the technique/s used in the other 8 cases is unknown. Weakness of this article is that crying and irritability noted as an adverse event
Pistolesse ¹⁷	Systematic review of all survey data (1966-1998; Medline and MANTIS) with quasi-meta-analysis Investigates the recorded complications from chiropractic SMT (only injury data from chiropractic care in the United States)	From 3 major government surveys, estimated pediatric visits of > 5 million and cited only 2 reports of neurologic or vertebrobasilar complication from chiropractic care in the literature. Risk of serious adverse event was extrapolated to be 1 in 250 million pediatric visits.	Weaknesses of this article include that only injury data from chiropractic care in the United States were used so only 2 of 8 known cases were reported. The 32 years of prevalence data is actually an estimate based on the actual data for the first 12 years (1966-1978). The accuracy of this extrapolation is questionable.
Brand et al ¹⁸	Major electronic databases searched for clinical trials on manual therapy applied by chiropractors, osteopaths, and manual medicine practitioners involving infants (1966-2004)	Quotes the following articles (details elsewhere in this table): Includes 1 death Jacobi et al ⁴⁶ and physiological changes following medical manipulation Koch et al ³⁰ Koch et al ³¹	No details of practitioner, type of treatment, or discussion of how apnea and bradycardia was measured. Author repeatedly stating that a lack of RCT studies on effectiveness was evidence as to poor safety, also extensive use of personal communications with experts in the field instead of citing recorded cases and published literature.
Gotlib and Rupert ¹⁹	Systematic review of the literature for cases of adverse events following chiropractic care of children (2004-2007)	No critical analysis of any literature reviewed. Zero cases of adverse events recorded in the timeframe of the review, which included 1275 citations and 57 eligible articles.	Review of literature-based evidence on effectiveness and extrapolated to equal safety. Implies poor-quality research for evidence equals poor safety.
Gleberzon et al ²⁰	Systematic review of clinical trials investigating the effects of SMT on various clinical conditions affecting children (2007-2011); advancing a previous study by Gotlib and Rupert ¹⁹	16 clinical trials met inclusion and exclusion criteria Zero adverse events in any of the clinical trials reviewed, which involved a total of 1809 children. All children received SMT or modified SMT.	Exclusion criteria meant no individual case studies were included; therefore, cases of adverse events already published in the literature were not mentioned in this systematic review.
Narrative literature reviews Humphreys ²¹	Update of clinical research literature on adverse events in children after spinal manipulation (2007-2010)	Only 3 new studies identified. Reports that there were no serious adverse or catastrophic events.	Discusses limitations in previous systematic reviews in classifying adverse events.
Dobson et al ²²	Review of all publications of manipulative therapy providers for effectiveness for colic treatment	Articles reviewing chiropractic, osteopathy, and cranial therapy for colic. Six studies involving 325 infants included. No serious adverse events involving chiropractic or osteopathy. One death caused by craniosacral therapist.	Recognized variability in study quality and discussed low numbers of infants involved in each study; therefore, difficult to draw meaningful conclusions.
Pohlman and Holton-Brown ²³	Review of the literature and summary of the effects and safety of SMT for otitis media	49 articles in English with children under 6 years: 17 commentary; 15 case reports; 5 case series; 8 reviews; and 4 clinical trials. Forty-one chiropractic and 142 osteopathic patients with Otitis Media, with zero serious adverse events.	Grading for quality of articles included; however, 17 commentary articles were included.

APPENDIX A (continued)

Study	Study Details	Key Findings	Summary
Posadzki and Ernst ²⁴	Summary and critical evaluation of the data from systematic review of spinal manipulation for any pediatric condition (Inception-2011)	5 articles relating to effectiveness of spinal manipulation in children. RCTs involving SMT, chiropractic or osteopathic therapy. Makes anecdotal reference to several hundred severe and life-threatening adverse events	Reported adverse events are in relation to adult patients and not pediatric cases. Uses lack of effectiveness data found in the review of literature to conclude that spinal manipulation and chiropractic is not recommended.
Alcantara et al ²⁵	An integrative review of the literature to summarize the breadth and depth of chiropractic in the care of children with constipation.	17 articles with 15 case reports, involving children from 3 weeks to 8 years of age. Zero cases of adverse events reported. Treatment applied from low force SMT to HVLA SMT.	This is not a systematic review of the literature, but an integrative review as non-peer-reviewed articles were included.
Randomized controlled trials			
Sawyer et al ²⁹	A prospective pilot study with parallel-group, observer-blinded, randomized feasibility study of 22 patients with chronic otitis media with effusion. Children, 6 months to 6 years, received active or placebo SMT and results were measured using tympanometry, otoscopy, and parent diaries.	20 patients aged 6 months to 6 years randomized to chiropractic HVLA-SMT (n = 9) or placebo SMT (n = 11); a total of 200 chiropractic SMT visits, zero serious adverse events resulted.	Weakness: Low number of participants in each group. Practitioners not qualified or experienced in using measuring devices for effusion associated with chronic otitis media
Koch et al ³⁰	Prospective clinical trial of 199 infants to investigate vegetative reactions after mechanical irritation of suboccipital region	199 infants received upper cervical manual therapy from a medical manipulator. Thrusts estimated to be 50 N applied to all children with asymmetry and muscle tension disorders. Apnea and flushing of skin observed in 50 infants given the medically induced impulse.	Changes in observed physiology only and not assessed with breathing monitor or skin sensors. Equally, force of thrust estimated and not measured in the study, so unsure if this is accurate. Clinical trial not blinded nor randomized to control for bias
Bronfort et al ³⁴	Pilot randomized controlled trial to determine if chiropractic SMT in addition to optimal medical management resulted in clinically important changes in asthma-related outcomes, and secondly to assess the feasibility of conducting a full scale RCT	Total of 36 children 6-17 years 22 children had an estimated 19 SMT sessions in the chiropractic SMT group. 12 sham treatments Adverse events reported as none in either group.	Two less patients than what was required to be statistically significant completed the trial. Did not state the existence of adverse events or not, so it is assumed that none occurred.
Koch et al ³¹	Prospective clinical trial to measure heart rate changes in infants with KISS receiving manual therapy from medical manipulators.	695 infants 1-12 months with no underlying pathology. Radiographs taken of all infants prior to medical manipulation applied between 30 and 70 N. No rotation applied only lateral flexion and extension Severe short lasting bradycardia observed in almost 50% of all infants less than 3 months receiving medical manipulation of upper cervical spine. Bradycardia was mild in children older than 4 months; 87 cases of severe, short lasting bradycardia following medical manipulation.	All infants were monitored with ECG only. Breathing changes (apnea), flushing of skin and blood pressure were excluded due to movement artifacts. However, the measure of 30-70 N was not assessed in every case, so unclear if a higher force was applied to those infants experiencing severe bradycardia. The target of 50 N and never more than 70 N is an estimation only. Term <i>chiropractic</i> used throughout document even though the therapy applied was by medical mechanical manipulation
Philippi et al ³²	Randomized controlled trial with blinding to assess improvement of asymmetry in infants receiving osteopathic care	32 infants with postural asymmetry age 6-12 weeks with at least 36 weeks gestational age. 16 in sham condition and 16 given OMT. One visit a week for 4 weeks. Follow-up over 10 months. No serious adverse events resulted. 4 mild adverse events (increased vomiting, excessive crying)	There were only a small number of participants in treatment group.
Rowe et al ³³	Pilot randomized controlled trial to explore issues of safety, patient recruitment and compliance,	6 cases of scoliosis treated with HVLA and 2 minor transient soreness. 2 chiropractic patients	Very small number of cases so difficult to draw efficacy conclusions. Also, 120 chiropractic interventions

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APPENDIX A (continued)

Study	Study Details	Key Findings	Summary
	treatment standardization, sham treatment refinement, interprofessional cooperation, quality assurance, outcome measure selection, and statistical analysis.	120 chiropractic interventions Serious adverse events reported as nil.	were with combined medical care, so this may be different to the usual chiropractic intervention experience.
Observational surveys Hayden et al ²⁸	Prospective cohort study to describe current chiropractic practices in the management of low back pain in children and adolescents, including treatment outcomes, and factors associated with those outcomes	Random selection of chiropractors in Canada who treated patients in the 4-18 years age range. Practitioners must have had 5-year experience as a chiropractor, 2+ pediatric patients per week minimum. A total of 53 patients and 310 visits with SMT used in 95% of child visits Complications were reported as none.	39/54 practitioners dropped out of study; therefore, the 53 pediatric patients visits were taken from only 15 practitioners.
Hayes and Bezilla ²⁷	Retrospective review of medical records of children under 19 years in the care of osteopathic physicians in 2 US states	File notes of 346 pediatric patients in 2 US states reviewed for adverse events and treatment aggravations following osteopathic treatment Zero serious adverse events reported. 31 treatment-associated aggravations (1 dizziness, 2 headache, 7 worsening symptoms, 21 mild soreness and pain related issues)	156 pediatric files were excluded from analysis due to only one visit occurring and it was not noted if adverse events were the reason for cessation of care.
Miller and Benfield ²⁶	Literature review and a retrospective study of survey data to review the number of adverse events reported at a chiropractic teaching clinic in the UK for children under 3 years of age, so that risks of potential adverse events could be put into context	Three-year study (2002-2004) 5242 treatments from 697 Anglo-European Chiropractic College (AECC) files (nil excluded who had treatment)— serious adverse events reported as nil. 4 mild events (crying <24 hours) Quotes the following articles (details elsewhere in this table): Vohra et al ⁸ Pistolese ¹⁷	Study relies only on data written by practitioner in file post treatment. Potential for practitioner bias in recording of any minor adverse event. Study does not include type of treatment
Miller et al ³⁹	Case series: Prospective data collection from patient files and discharge surveys completed by mothers to describe features and outcomes of infant cases presenting for chiropractic care due to breastfeeding difficulties	144 infants under 3 months all referred by a medical practitioner to a chiropractic teaching clinic for suboptimal breast feeding. Estimated average of 576 chiropractic manual treatments (average of 4 visits per infant) Adverse effects reported as nil.	Infants sent to chiropractor from medical practitioner and screened for underlying health pathologies prior to care. This may have reduced the incidence of undetected pathology, since the group also had a higher than normal incidence of birth intervention.
Marchand ¹⁶	Cross-sectional Internet survey to determine the number of pediatric visits to a cohort of European chiropractors over a 1-month period, noting conditions treated and adverse events	93% of the 956 chiropractors surveyed treated children with a total of 19821 per month child visits. Zero severe adverse events 23 moderate adverse events (soreness, headache), 534 mild adverse events (crying, not sleeping) Birth—23 months and adolescents were 63% of child the reported visits	High number of practitioners and patient numbers and discussed the limitations of using recall survey information.
Cross-sectional surveys Alcantara and Ohm ³⁵	Review of the files of 53 chiropractors participating in a PBRN for cases of adverse events in pediatric patients	53 chiropractors, 1161 pediatric patients, 10249 treatments. 17 mild reactions (soreness)	Data collected from information in files, no treatment types listed. Selection bias in all data used in survey because practitioner selected the files included for the PBRN themselves.
Alcantara et al ³⁸	Survey of parents with children under chiropractic care	389 pediatric cases, (parents surveyed), 3048 treatments, 2 mild reactions (soreness)	No data on total number of files available for review, date of collection, exclusion/inclusion criteria for chiropractic centers, or pediatric cases,

APPENDIX A (continued)

Study	Study Details	Key Findings	Summary
			no treatment type listed. Main researcher employed by funding body. Selection bias in all data used in review.
Alcantara et al ³⁷	Random data collection from chiropractors participating in a PBRN to review adverse events after treatment in pediatric population.	812 pediatric patients, 7346 treatments with 9 mild reactions (soreness)	Data collected from information in files, no treatment types listed. Selection bias in all data used in review.
Alcantara et al ³⁶	Survey of parents and chiropractors of patients under 18 years under care during a 1-year period of time.	Chiropractic survey of 577 patients receiving a total of 5,438 visits. 3 treatment aggravations, 0 treatment complications. Patient parent surveys for 239 patients, 2 treatment-related aggravations, 0 treatment complications.	Most data collected from practices and parents affiliated with research organization. Selection bias in all data used in review.
Case reports			
Simonian and Staheli ⁴³	Report on cause of leg fractures in 2 children receiving physiotherapy manipulation	4 leg fractures in 2 children after physiotherapy manipulation of leg contractures. 1 child amyoplasia congenital disorder	Study of only 2 cases
Holla et al ⁴²	Review of infant death after craniosacral therapy	3-month-old infant Forced, held, flexion of entire vertebral column by craniosacral therapist. Infant died of asphyxiation from obstruction to upper airway in prolonged forced neck position	Does not reveal if technique was applied correctly or if therapist was qualified
Wilson et al ⁴¹	Report of an infant presenting with rib fractures after chiropractic care	3-week-old infant held upside down around rib cage by chiropractor in assessment. Activator instrument applied to the thoracic spine of infant. 7th and 8th posterior rib fractures noted on presentation at hospital emergency department 5 days after chiropractic visit	No discussion of whether the Activator Instrument was placed on the rib cage where the fractures were located. No discussion of whether the fractures may have occurred from being held upside down around the waist/ribs. No description of the setting used on the Activator Instrument, which varies the force applied.
Struewer et al ⁴⁰	Review of a 17 year old with hemothorax after osteopathic thoracic spinal manipulation	Osteopathic physician applied seated rotational and extension high-velocity thrust manipulation to 17 years old with thoracic spinal pain. Massive hemothorax caused as a result of therapy by osteopathic HVLA thrust	Discussion throughout the article refers to chiropractic technique and dangers of chiropractic, when the therapist involved was an osteopathic physician.
Discussion papers			
Spigelblatt ⁴⁵	Position statement based on review of literature and ad hoc survey collection, including discussion of cases of adverse events relating to spinal manipulation of children	Nonspecific data collection. Survey, literature review, opinions. No inclusion or exclusion criteria and no sample sizes. Quotes the following articles (details elsewhere in this table): Jacobi et al ⁴⁶ Zimmerman et al ⁵²	Position paper, selection, inclusion/exclusion bias, data collection, ad hoc, extrapolated data leads to author bias in results. Confuses efficacy with safety to bias paper. Uses adult data and applies findings to children.
Doyle ⁴⁴	Review of the literature regarding the safety of pediatric care	12 articles reviewed referred to adverse events. Biedermann ¹³ No serious adverse events reported in more than 30000 treatments by medical manipulators Leboeuf et al ⁵⁰ 2 mild adverse events (discomfort), from 171 pediatric patients interactions Quotes the following articles (details elsewhere in this table): Pistolese ¹⁷	Few diagrams or tables in the article to follow the flow of data from the reviewed articles. Uses Biedermann commentary as part of justification of SMT. Conclusion of safety of chiropractic care based on the results of the 12 articles. No recommendation to collect adverse event reporting data in a more comprehensive way.

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APPENDIX A (continued)

Study	Study Details	Key Findings	Summary
		Shafir and Kaufman ⁵³ Miller and Benfield ²⁶ Vohra et al ⁸ Held ⁶⁶ Jacobi et al ⁴⁶ Koch et al ³¹ Sawyer et al ²⁹ Klougart et al ⁵¹	

ECG, electrocardiogram; *HVLA*, high-velocity low-amplitude; *OMT*, osteopathic manipulative therapy; *PBRN*, practice-based research networks; *RCT*, randomized controlled trial; *SMT*, spinal manipulation therapy.