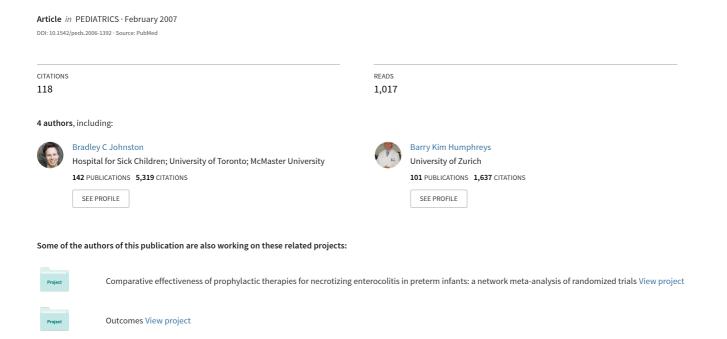
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Adverse Events Associated With Pediatric Spinal **Manipulation: A Systematic Review**

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BACKGROUND. Spinal manipulation is a noninvasive manual procedure applied to specific body tissues with therapeutic intent. Although spinal manipulation is commonly used in children, there is limited understanding of the pediatric risk estimates.

OBJECTIVE. Our goal was to systematically identify and synthesize available data on adverse events associated with pediatric spinal manipulation.

METHODS. A comprehensive search was performed of 8 major electronic databases (eg, Medline, AMED, MANTIS) from inception to June 2004 irrespective of language. Reports were included if they (1) were a primary investigation of spinal manipulation (eg, observation studies, controlled trials, surveys), (2) included a study population of children who were aged 18 years or younger, and (3) reported data on adverse events. Data were summarized to demonstrate the nature and severity of adverse events that may result rather than their incidence.

RESULTS. Thirteen studies (2 randomized trials, 11 observational reports) were identified for inclusion. We identified 14 cases of direct adverse events involving neurologic or musculoskeletal events. Nine cases involved serious adverse events (eg, subarachnoidal hemorrhage, paraplegia), 2 involved moderately adverse events that required medical attention (eg, severe headache), and 3 involved minor adverse events (eg, midback soreness). Another 20 cases of indirect adverse events involved delayed diagnosis (eg, diabetes, neuroblastoma) and/or inappropriate provision of spinal manipulation for serious medical conditions (ie, meningitis, rhabdomyosarcoma).

CONCLUSIONS. Serious adverse events may be associated with pediatric spinal manipulation; neither causation nor incidence rates can be inferred from observational data. Conduct of a prospective population-based active surveillance study is required to properly assess the possibility of rare, yet serious, adverse events as a result of spinal manipulation on pediatric patients.

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Dr Vohra developed the study question, designed the study, oversaw its execution, and participated in data analysis and manuscript preparation: Dr Johnston coordinated the study, lead relevance screening, data extraction, and data analysis, and drafted and revised the manuscript: Ms Cramer contributed to protocol development and study design and participated in relevance screening, data extraction, and manuscript preparation; Dr Humphreys provided expertise in chiropractic practice, spinal manipulation, and chiropractic literature, reviewed the search strategies, and participated in developing the dataextraction form and data analysis; and all the authors read and approved the final manuscript.

Key Words

spinal manipulation, pediatric, adverse

Abbreviations

CAM—complementary and alternative medicine

Cn—cervical vertebra n

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PINAL MANIPULATION IS a noninvasive manual procedure applied to specific body tissues with therapeutic intent. A variety of different care providers (eg, physiotherapists, massage therapists, physicians, osteopaths, naturopaths) may perform manipulation as part of their practice, but it is most frequently performed by chiropractors.1 The procedure is delivered by hand and can vary in velocity, amplitude, duration, frequency, location on the body, and direction of force. According to the American Chiropractic Association, chiropractic procedures specifically include the adjustment and manipulation of the articulations and adjacent tissues of the human body, particularly of the spinal column.² Spinal manipulation, the mainstay of chiropractic care, "emphasizes the inherent recuperative power of the body to heal itself without the use of drugs or surgery."3

Chiropractic medicine is the most common complementary and alternative medicine (CAM) practice used by children.^{4,5} Children made an estimated 30 million visits to US chiropractors in 1997.6 In Canada, a recent survey of 1804 participants in a university hospital pediatric emergency department in Toronto, Ontario, indicated that 31% of children sought chiropractic care.7 In addition, a cross-sectional survey of a random sample of 140 Canadian chiropractors (57% response rate) revealed that all the respondents also treated children (0−18 years old), and 13% of all visits over the preceding month involved children and youth.8 Although, chiropractors are trained to treat neuromuscular problems that stem from a mechanical disability within the body,9 children have been found to visit chiropractors for a variety of reasons including health promotion, musculoskeletal problems, asthma, otitis media, allergies, infantile colic, tonsillitis, attention-deficit/hyperactivity disorder, and enuresis.6,9-14

Spinal manipulation has been suggested as a potential cause of cerebrovascular accidents (eg, stroke) through mechanical injury to the vertebral artery. In adults, concerns regarding serious adverse events related to spinal manipulation have led to a series of studies examining risk.15-17 For example, a review of the literature on complications of spinal manipulation, which evaluated case reports, surveys, and review articles, identified 295 complications, yielding estimates of vertebrobasilar accidents from 1 in 20 000 patients to 1 per 1 million cervical manipulations, and cauda equina syndrome to be <1 per 1 million treatments. 17-19 Data from 4 prospective investigations of 2058 adults who received chiropractic spinal manipulation indicated that 30% to 55% reported a minor adverse event (eg, local discomfort, additional pain, stiffness, headache, fatigue, fainting).20-23

Despite the fact that spinal manipulation is widely used on children, pediatric safety data are virtually non-existent. Consequently, some pediatricians believe that the use of spinal manipulation on children is dangerous and advise against its use,^{24–26} whereas other health care

practitioners and many parents continue with this practice. There is an urgent need to quantify the risk associated with spinal manipulation in children.

METHODS

Data Sources

A comprehensive search was developed by a clinical librarian in collaboration with content experts to identify all relevant reports regardless of publication status. The following electronic databases were searched: Central (second quarter, 2004), Medline (1966–2004), PubMed (1966–2004), Embase (1988–2004), CINAHL (1982–2004), AltHealthWatch (1990–2004), MANTIS (1900–2005), and ICL (1985–2004) from inception to June 2004 irrespective of language. For a copy of our search strategy, please contact the corresponding author. The primary authors of relevant articles and experts in the area of spinal manipulation were contacted for information on additional studies. In addition, reference lists of relevant articles were examined.

Study Selection

Two reviewers (Dr Johnston and Ashish Mahajan, BSc) independently reviewed the titles and abstracts (where available) of all articles generated from the electronic and grayliterature search. The full manuscripts of reports relevant to adverse events associated with spinal-manipulation criteria were retrieved. Independent reviewers (Dr Johnston, Ms Cramer, and Denise Adams, BSc) assessed the full articles of each potentially relevant study by applying the following predetermined set of eligibility criteria: (1) the study was a primary investigation/report (ie, case reports, case series, case control, randomized, controlled trials, and survey or surveillance studies); (2) part or all of the study population was 18 years or younger and; (3) adverse events were reported. We searched for adverse events related to delivery of spinal manipulation (eg, pain, weakness, disability), and noted adverse events related to delayed or missed diagnoses when they were described. Inclusion was not limited by the condition studied, provider of the spinal-manipulation intervention (eg, chiropractor, osteopath, physiotherapist, physician), or the comparison intervention.

Data Extraction

Independent reviewers (Dr Johnston, Ms Cramer, and Denise Adams, BSc) used a structured data-extraction form to independently extract data. The key data extracted were type of publication/report (eg, case report, randomized, controlled trial), participant characteristics (eg, age and gender), previous medical diagnosis/diagnoses, type of manipulation (eg, light fingertip pressure, mobilization, flexion, rotation, high-velocity/low-amplitude), location of manipulation (eg, cervical), schedule of manipulation, outcome, and timing of the adverse

event in relation to therapy. Any discrepancies between reviewers were discussed and resolved by referring to the original report and, if necessary, consultation with a third reviewer.

Data Synthesis

Adverse events were classified by using the following categories: severe (indicating hospitalization, permanent disability, mortality), moderate (transient disability, involving seeking medical care but not hospitalization), minor (self-limited, did not require additional medical care), and delayed diagnosis or treatment (moderate to severe adverse event [as defined above] not directly related to the administration of a spinal manipulation but as a result of delayed diagnosis or treatment of a medical condition [eg, meningitis]). Adverse events were tabulated by using descriptive statistics. A priori, we planned to summarize adverse events derived from randomized, controlled trials using risk differences (with corresponding 95% confidence intervals) because events were considered rare; we planned to summarize data (and conduct subgroup analyses if possible) according to severity and type of adverse event, timing of the adverse event, age group (birth to 5 years, 6-13 years, 14-18 years), type and schedule of manipulation, location of manipulation, and type of practitioner.

RESULTS

Electronic database searches identified a total of 13 916 articles for consideration. After screening, 164 potentially relevant articles were identified for full review. An additional 68 potentially relevant articles were identified from review of the reference lists and by contacting authors of included reports and experts in field. Thirteen studies met inclusion criteria (10 English, 2 French, 1 German): 2 randomized, controlled trials, 4 case series, and 7 case reports (Fig 1). There were 212 articles that were excluded: 77 were not primary studies, 70 did not involve pediatric patients, 29 did not involve spinal manipulation, 32 did not report an adverse event, and 4 were irretrievable. A full list of excluded articles is available from the corresponding author.

We identified 14 cases of direct adverse events (Table 1),27-36 9 of which were classified as serious and resulted in hospitalization, permanent disability, or death.^{27–33} In 10 of 14 cases, the adverse events occurred within 24 hours of spinal manipulation. 27,29,31-33,35-37 Each case involved a chiropractor and was reported in the United States. We identified an additional 20 cases of delayed diagnosis and/or inappropriate provision of chiropractic care (type of spinal manipulation unspecified in all cases) that resulted in indirect adverse events.^{37–41} Seven cases involved delayed treatment of cancer (eg, diabetes, aggressive osteosarcoma, metastatic neuroblastoma). 40,41 Two cases involved delayed treatment for meningitis, and 1 case involved delayed treatment for embryonal rhabdomyosarcoma.37,38 Each of the latter 3 cases resulted in death^{37,38} (Table 2).

We were unable to combine data or conduct a priori subgroups analyses because of methodologic heteroge-

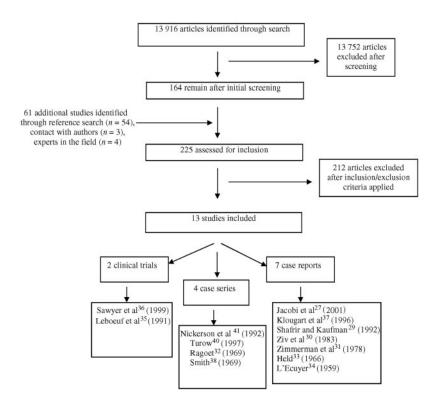


FIGURE 1 Flow of studies considered for review.

Type of Adverse Event	Adverse Event	Time to Adverse Event	Gender and Age	Type/Schedule of Spinal Manipulation	Location of Spinal Manipulation	Practitioner	Relevant Medical Diagnosis
Serious Jacobi et al ^{27,28} (2001), Germany	Subarachnoidal hemorrhage and death	Immediate	NS, 3 mo	Vojta technique ^a /1 treatment involving several "strong rotation and reclination" movements	Cervical spine, arm, thigh	Physiotherapist	NS
Shafrir and Kaufman ²⁹ (1992), US	Quadriplegia secondary to spinal cord astrocytoma and SM; regressed to paraplegia (18 mo postnoneratively)	Immediately after second SM	Male, 4 mo	Flexion, extension, axial loading and unloading/at least 3 SMs over 2 d	Neck	Chiropractor	Congenital torticollis; spinal cord astrocytoma
Ziv et al³º (1983), Canada	Progressive no representation of the representation of the rest, in legs, donus at rest, urinary urgency and feetinency parapleptia	2 wk	Female, 12 y	NS/NS	NS	Chiropractor	Osteogenesis imperfecta, head, neck, and low-back pain
Zimmerman et al³¹ (1978), US	Severe occipital and bifrontal headache, vomiting, left facial weakness, diplopia, araxia.	Several hours posttreatment	Male, 7 y	Rapid manual rotations of the head with flexion and hyperextension/at least 3 SMs	Head	Chiropractor	Intermittent headaches
Ragoet ³² (1969), France	Anterior dislocation of atlas and fracture of odontoid axis at C2	Immediate	Female, 18 y	NS/NS	C1–C2	Chiropractor	Spinal-thoracic pain
	Dislocation of atlas	Immediate	NS, 6 y	NS/NS	C1-C2	NS	Dorsolumbar injury as a result of a fall
	Death, preceded by possible fracture and/or dislocation of axis (unclear)	Immediate	NS, 5 y	NS/NS	C1-C2	SX	Pneumonia
Held³³ (1966), France	Acute respiratory decompensation, tracheotomy, neurologic deficits at C6 and C7 vertebrae	Immediate	Male, 12 y	Assisted (passive) range of motion of cervical spine examination/performed once	Cervical spine examination	Medical doctor	Minor head trauma; presented with persistent headaches, neck pain
L'Ecuyer³⁴ (1959), US	Neck pain and progression to unsteady gait, poor coordination, drowsiness, and hospitalization; delayed diagnosis of congenital occipitalization	6 d post-SM	Female, 12 y	NS/4 SMs over 1 mo	Head and neck	Chiropractor	Neck pain resulting from congenital torticollis

TABLE 1 Continued.	.pa						
Type of Adverse Event	Adverse Event	Time to Adverse Event	Gender and Age	Type/Schedule of Spinal Manipulation	Location of Spinal Manipulation	Practitioner	Relevant Medical Diagnosis
Moderate Leboeuf ⁸⁵ (1991), Australia	Severe headache and stiff neck	Immediate	4-15 y	NS/SM every 2 wk for up to 8 treatments (both groups received the same treatment)	NS (areas of aberrant spinal movement detected through observation and	Five 5th-year chiropractic students	Nocturnal enuresis
Missississississississississississississ	Acute lumbar pain	Immediate	As stated above	As stated above	As stated above	As stated above	As stated above
Sawyer et al³6 (1999), US	Midback soreness	SN	6 mo to 6 y	High-velocity, low-amplitude (motion palpation and light touch of specific spinal segments)/~10	Full spine, emphasis on cervical spine	Academic chiropractors	Chronic otitis media
Klougart³ ⁷ (1996),	Irritability Loss of consciousness	Immediate Immediate	6 mo to 6 y Female, 10 y	adjustments over 4 wk As stated above Gonstead technique ^b /at least	As stated above C7 and T1	As stated above Chiropractor	As stated above Headache and nausea

SM indicates spinal manipulation; NS, not specified; T1, thoracic vertebra 1.

^a Vojta therapy; used to "modify the reflex activity of the child and orient the neuromotor development toward a more physiological track." It involves body work "based on reflex locomotion and pathing (forcing a neuronal way)." This is often done via spinal adjustments, referred to as "spinal automatisms" to correct "lesions" of the spinal cord.²³

2 treatments

e Gonstead technique: a common type of manipulation in which the forces applied to the vertebrae are in the sagittal plane (posterior to anterior) rather than twisted in rotation.

TABLE 2 Summary of Indirect Adverse Events in Case Series

Author (Year)	Adverse Event	Gender and Age	Type of SM	Schedule of SM
Turow ⁴⁰ (1997)	Delayed treatment for choriocarcinoma	Male, 18 y	NS	3 times per wk for 2 mo
	Delayed treatment for aggressive osteosarcoma	Male, 13 y	NS	NS, over a 6-wk period
Nickerson et al ⁴¹ (1992)	Delayed treatment for posterior fossa ependymoma	NS	NS	NS
	Delayed treatment for acute lymphocytic leukemia	NS	NS	NS
	Delayed treatment for testicular carcinoma	NS	NS	NS
	Delayed treatment for metastatic neuroblastoma	NS	NS	NS
	Delayed treatment for metastatic neuroblastoma	NS	NS	NS
	Delayed treatment for reactive cervical adenitis	NS	NS	NS
	Delayed treatment for encopresis with learning disability	NS	NS	NS
	Delayed treatment for otitis media	NS	NS	NS
	Delayed treatment for Crohn disease	NS	NS	NS
	Delayed treatment for complex partial seizures	NS	NS	NS
	Delayed treatment for hypertension with unilateral kidney disease	NS	NS	NS
	Delayed treatment for iron-deficiency anemia	NS	NS	NS
	Delayed treatment for severe rheumatoid arthritis	NS	NS	NS
	Delayed treatment for slipped femoral epiphysis	NS	NS	NS
Smith ³⁸ (1969) (from a 1940 case)	SAE involving delayed medical treatment for meningitis and death after 4 mo of care	Male, 6 y	NS	Every 3 d over 4 mo
	SAE involving delayed medical treatment for embryonal rhabdomyosarcoma and death after 5 mo of care	Female, 8 y	Chiropractic adjustment	22 d (consecutive) of adjustments
	SAE involving delayed medical treatment for meningitis and death	NS	NS	NS

For all cases shown, the practitioner involved was a chiropractor, and the studies were all performed in the United States. NS indicates not specified; SM, spinal manipulation; SAE, serious adverse event.

neity between trials.^{35,36} Below, we describe the 2 clinical trials and the nature and severity of adverse events related to pediatric spinal manipulation. The remaining direct and indirect adverse events are described in Tables 1 and 2.

Two trials were included.35,36 The first trial randomly assigned 171 children to 1 of 2 active treatment groups: both groups received spinal manipulation (the only discernable difference was that 1 group waited 2 weeks to start therapy).35 Two adverse events were reported, both of moderate severity (ie, required medical attention). One case involved the onset of severe headaches and stiff neck after cervical manipulation, which improved gradually over the next 2 weeks with additional soft tissue therapy. Neither the parent nor the child could recall any previous symptoms involving serious headaches or stiff neck. A second case involved the onset of acute lumbar pain postmanipulation, which also resolved.35 The second study was a randomized, controlled trial of 20 children (9 received treatment and 11 served as controls) that reported 2 minor adverse events involving 1 case of midback soreness that resolved after a few days and 1 case of irritability for a short period posttreatment.36 The authors concluded that the patients tolerated the treatments well with only minimal, self-limiting adverse effects.36

DISCUSSION

To our knowledge, we report the first systematic review of adverse events related to pediatric spinal manipulation irrespective of language. We identified 14 adverse events in 10 reports, 9 of which were serious and resulted in hospitalization, permanent disability, or death.^{27,29–34} An additional 20 cases of delayed diagnosis and/or inappropriate provision of spinal manipulation resulted in indirect adverse events.^{37,38,40,41} Case reports and case series can be interpreted as spontaneous reporting or "passive" surveillance. Although they are useful to demonstrate the type and nature of adverse events, these reports do not provide information on the incidence of adverse events because of the lack of data regarding the total number of manipulations provided (ie, denominator data).

Spontaneous reporting of adverse events is well known to underestimate risk. An example of the limitations of passive surveillance was documented by a British survey of neurologists that was meant to ascertain cases of serious neurologic complications occurring 24 hours post–cervical manipulation, in which 24 respondents identified 35 such cases over the previous year; none of these had been reported previously.⁴² Lessons from spontaneous reports of adverse drug reactions suggest that <10% of serious adverse events are reported.⁴³

The serious concerns regarding both the quantity and quality of these spontaneous reports limit assessment of causation. Given the large numbers of children who have received spinal manipulation during the decades assessed by our search strategy, adverse events resulting from spinal manipulation are either remarkably rare or underreported.

A number of risk factors may predispose a child to an adverse event as a result of spinal manipulative procedures, including immaturity of the spine, rotational manipulation of the cervical spine, and high-velocity spinal manipulations.44-47 We found that all 9 serious adverse events (eg, death resulting from subarachnoid hemorrhage, paraplegia, etc) occurred in children under 13 years of age.30,32,34 In a case series, Ragoet32 presented 3 cases of dislocated atlas as a result of pediatric spinal manipulation. Evidence suggests that there is a strong correlation between severity of injury to the spinal cord and the immaturity of the spine44 and that the atlas (cervical vertebra 1 [C1]) and dens of the axis (C2) of children are more vulnerable to trauma than those of adults. 45 Although 5 of our serious adverse-event reports did not specify the type of spinal manipulation used, 2 of the 4 that reported serious adverse events specified that the practitioner used rapid and/or strong rotational maneuvers.^{27,31} The majority of complications attributed to spinal manipulative therapy have occurred as a result of rotational manipulation of the cervical spine.46 In addition, high-velocity manipulations of the spine have the potential for serious complications resulting from diagnostic error/inadequate patient assessment.47 Although the authors did not clearly specify the type of spinal manipulation provided, 2 of the severe adverse-event reports identified underlying risk factors (spinal cord astrocytoma, congenital occipitalization) that may have predisposed the child to the subsequent serious adverse event (ie, quadriplegia, unsteady gait).29,34 An error in the diagnosis of any number of preexisting conditions such as arteritis, arthritic and cardiac conditions, clotting abnormalities, meningitis, or vertebrobasilar insufficiency may predispose children to neurologic and/or vertebrobasilar complications.45,48-50

A major challenge in proving or refuting causation between pediatric spinal manipulation and serious adverse events is the lack of sufficient randomized trials. Unfortunately, like randomized trials of conventional treatment, many randomized trials of CAM fail to adequately evaluate for potential adverse events.51,52 In particular, the 2 trials included in this review failed to adequately describe most of the 10 recommendations on reporting harms-related issues suggested by the Consolidated Standards of Reporting Trials (CONSORT) statement.35,36,53 Moreover, developing risk estimates for rare events requires population-based sampling. For this reason, our review was not limited to randomized, controlled trials but assessed all reported primary medical

literature including observational studies and reports. It is concerning that modeling from reports of adverse drug reactions suggests that more than 1 to 3 spontaneous case reports of rare or uncommon adverse events is unlikely to be coincidental.54,55

The only other previous review of this topic was narrative, not systematic.56 The authors neglected to include a number of potentially important databases (eg, Central, Embase, ICL) and did not search for non-English reports.^{57–59} Although they concluded that the risk of neurologic and/or vertebrobasilar complications from chiropractic manipulation was 1 in 250 million pediatric visits,56 we feel that this estimate is inaccurate and likely underestimates risk. Numerator data were derived from incomplete assessment of cases identified in the medical literature, and denominator data were based on an estimated number of chiropractic visits made by children in the United States. Although our search strategy was more comprehensive, we did not feel comfortable creating risk estimates with an uncertain denominator. We urge the development of an active surveillance model to prospectively gather data about the quantity and quality of adverse events so that risk estimates can be made with greater precision.

It is difficult to know the cause for the identified indirect adverse events (eg, delayed diagnosis and/or inappropriate provision of spinal manipulation). We postulate that this is related to lack of sufficient pediatric training for CAM providers. We have recently collected survey data on the knowledge, attitudes, and behavior of chiropractors and osteopaths with regards to children in their practice. Of 287 respondents, 71% graduated between 1992 and 2002, 78% of the respondents identified 1 semester or less of formal pediatric education during their training, 72% received minimal or no pediatric clinical training, and 93% recommended increased pediatric training in their schools.60 Collaborating with experts in pediatric education toward developing a standardized pediatric curriculum for CAM providers may offer a way forward. Such collaboration should involve the development of guidelines for medical referrals, joint integrative care between physicians and CAM providers,61 and the development of a scope of practice for pediatric chiropractic and osteopathic care. Despite what some have advised,24,26 many children continue to visit chiropractors, and many chiropractors continue to treat children.8 We believe collaboration of this nature would result in improved patient safety.

Our study has several limitations. First, we uncovered mostly case reports. Many of the cases contained limited data, and assessment of the validity of case reports is generally insufficient to reach conclusions regarding causality.52,54 However, to exclude the case reports would have severely biased our results because it would not have allowed for the identification of potentially uncommon and unexpected adverse events,54,62,63 which

may differ from those detected in clinical trials.64 Second, our search strategy did not allow for systematic identification of indirect adverse events (eg, delayed or missed diagnoses); therefore, these indirect adverse events are likely underestimated. Concerns regarding chiropractic care have been raised about advice given regarding childhood immunizations, frequency of radiographs, recommendations regarding dietary supplements, and lack of familiarity with serious childhood conditions resulting in delayed diagnosis of a serious medical condition.6 These concerns were incompletely captured by our review. Finally, we excluded cases that were only identified in medicolegal proceedings or the lay press.^{65–67} Our search strategy was not designed to identify such reports, and to include these cases would create a false impression that they were the only ones reported in the potentially vast non-health-specific, non-peer-reviewed resources.

CONCLUSIONS

Spinal manipulation is common among children, and although serious adverse events have been identified, their true incidence remains unknown. Randomized. controlled trials will likely reveal common minor adverse events, 20,35,36 and these events must be better reported. Prospective population-based studies are needed to identify the incidence of serious rare adverse events associated with spinal manipulation. Patient safety demands a greater collaboration between the medical community and other health care professionals, particularly chiropractors, such that we can investigate and report harms related to spinal manipulation together. In the interim, clinicians should query parents and children about CAM usage and caution families that although serious adverse events may be rare, a range of adverse events or delay in appropriate treatment may be associated with the use of spinal manipulation in children.

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