

A LITERATURE REVIEW OF PEDIATRIC SPINAL MANIPULATION AND CHIROPRACTIC MANIPULATIVE THERAPY: EVALUATION OF CONSISTENT USE OF SAFETY TERMINOLOGY

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ABSTRACT

Objective: The purpose of this study was to perform a literature search to identify relevant studies on pediatric spinal manipulation and chiropractic manipulative therapy and to assess if safety terminology was consistent with the International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH).

Methods: A literature search was performed in PubMed using the following terms: *spinal manipulation pediatric*, *chiropractic safety pediatric*, and *manual therapy safety pediatric*. PubMed was searched from inception to April 2012 with no language limitations. The international standards included the terminology of the World Health Organization on side effects, adverse reactions, adverse events and the ICH guideline templates that were adapted for manual therapy for this study.

Results: Of the 9 relevant articles identified in this study, 3 reported methodology for classifying safety incidents, and all 9 used safety terminology (adverse effects or adverse events). However, terminology was not used consistently.

Conclusion: Most of the articles identified in this literature review did not use terminology consistent with the standards established by the ICH when reporting on safety incidents following pediatric spinal manipulation or chiropractic manipulative therapy. More efforts should be taken to include consistent terminology for studies of spinal manipulation and chiropractic manipulative therapy for children. (*J Manipulative Physiol Ther* 2015;38:692-698)

Key Indexing Terms: *Chiropractic; Children; Pediatrics; Manual Therapy; Safety*

Chiropractic care, including spinal manipulation, is commonly used in the management of pediatric spinal, musculoskeletal, and nonmusculoskeletal complaints.¹⁻³ Conditions such as back pain have been shown to be prevalent in the pediatric population and leading to recurrence of episodes in adulthood.^{2,4-6} Pediatric chiropractic research is currently emergent with descriptive studies including few observational studies and clinical trials looking at the effectiveness of chiropractic treatment for specific conditions.² The safety of manual therapy as a treatment approach has also received increased attention in the last decade.^{1,2,7} Several studies providing primary data on the occurrence of safety incidents after pediatric manual therapy have

used inconsistent safety terminology.^{1,7-11} Despite the small amount of information currently available on this topic, 2 systems of classification for safety incidents have been proposed.^{1,12,13}

Lack of consistency in reporting information on adverse reactions/events may lead to confusion regarding the type of safety incident occurring. Investigating and reporting safety incidents will ultimately improve the care provided to patients by allowing appropriate identification and management of known risks.¹⁴ Therefore, understanding international standards in terminology, procedures, and requirements in medical patient safety such as those offered by the International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH) may offer better consistency. The use of internationally agreed terminology and reporting procedures should allow better intra- and interprofessional understanding and sharing of information on the safety of chiropractic pediatric care. Therefore, the purposes of this study were to perform a literature search to identify relevant studies on pediatric spinal manipulation and chiropractic manipulative therapy and to assess if safety terminology was consistent with categories suggested by the ICH.

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Table 1. *The ICH E2B(R2) Guideline Adapted to Chiropractic Care for This Literature Review*

Overall description	Detailed description
Identification information	Identification of patient (country, initials, or reference) Date of report transmission (declared to the collecting system) Type of report (spontaneous, report from study, other, unknown) Seriousness (serious: yes/no choice; if serious which type: death, life-threatening, inpatient hospitalization, persistent, or significant disability/incapacity (as per reporter's opinion); congenital anomaly/birth defect (applicable for treatment during pregnancy); other medically important condition) Date of patient report (when patient reported a side effect) Additional documents held by the chiropractor (of relevance) Report of nullification (report was found to be erroneous; reasons for nullification)
Primary source of information	Identification of reporter (chiropractor's initial, name, or code) Country from which the report is sent Qualification of reporter (chiropractors: BSc, MSc, MChiro, other specialties) Study identification (when appropriate) Information of the sender (collection system of information that would be used by authorities) Information of the receiver (the authorities receiving the report)
Information on the case	Patient initials/patient record number (for suckling infants, parent information includes parent age information—date of birth or age, last menstrual period, weight (kg), height (cm), sex of parent, relevant medical history and concurrent conditions of parents, and relevant drug history of parents) Age information (date of birth, age at time of onset of reaction/event, patient age group [neonate, infant, child, adolescent, adult, or elderly]) Weight (kg)—requirement of weight and height in manual treatments may not be as important as for drug administration Height (cm) Sex Last menstrual period (as appropriate) Relevant medical history and concurrent conditions Relevant drug history In cases of death: date of death, reported causes of death, autopsy: yes/no, autopsy-determined cause(s) of death
Reaction(s)/event(s)	Reaction/event as reported by patient (exact words) Reaction/event in MedDRA terminology (lowest level term) Reaction/event MedDRA term (preferred term) Terms highlighted by the reporter (Highlighted term [patient reported that reaction/event was a major concern or reason for reporting the case]) 1, yes (highlighted by reporter), not serious 2, no (not highlighted by reporter), not serious 3, yes (highlighted by reporter), serious 4, no (not highlighted by reporter), serious Date of start of reaction/event Date of end of reaction/event Duration of reaction/event Time intervals between suspect drug administration (in this case therapy by the chiropractor) and start of reaction/event Outcome of reaction/event at the time of last observation: recovered/resolved, recovering/resolving, not recovered/not resolved, recovered/resolved with sequelae, fatal, unknown Results of test and procedures relevant to the investigation of the patient (both positive and negative results) Results of tests and procedures relevant to the investigation
Drug(s) information—this section has been adapted for manual procedure(s)	Sex of chiropractor Technique used Force, speed, and amplitude of thrust (where applicable) Anatomical area treated (specific joint(s) or tissue(s)) Initial presentation of the patient (indications for treatment) Date of start of treatment Time interval between treatment and start of reaction/event Date of last treatment Duration of treatment Actions taken: stopped treatment, decreased treatment, no change in treatment, modification considered, unknown, not applicable Effect rechallenge for suspected procedure: occurrence of reaction/event after readministration Relatedness of treatment to reaction(s)/event(s)

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