



Serious adverse events associated with paediatric complementary and alternative medicine

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Background

Complementary and alternative medicine (CAM) has been defined as a group of diverse medical and health care systems, practices and products that are not presently considered to be part of “conventional medicine”. Varying rates have been reported, depending on how CAM is defined, but most often, approximately 17–33% of the general paediatric population reports CAM use. In 2004, a survey in a Toronto emergency room showed that 49% of the paediatric population used CAM, with half using natural health products (NHPs) and a third, chiropractic. In general, children with chronic conditions, such as asthma and attention deficit hyperactivity disorder (ADHD), tend to report higher utilization rates, 80% and 68% respectively. Consistently, the most popular CAM therapies in children and adults are NHPs and chiropractic. In 1997, children in the United States made approximately 30 million visits to chiropractors. Despite the frequent paediatric utilization of CAM, few studies have assessed CAM-related adverse events (AEs). Data suggests that AEs do occur and that they are under-reported. A systematic review of paediatric spinal manipulation (SM) identified 14 cases of direct AEs involving neurological or musculo-skeletal events: nine serious (e.g., paraplegia), two moderate (e.g., severe headache), and three minor (e.g., midback soreness). Another 20 cases involved indirect AEs, described as delayed diagnosis (e.g., diabetes) and/or inappropriate provision of SM for serious medical conditions (e.g., meningitis).

In January 2006, the CPSP conducted a one-time survey question on AEs associated with paediatric CAM and obtained a 23% response rate. Seven percent (n=42) of respondents had seen AEs following CAM use in the past year. NHP AEs were the most common (n=41) followed by SMAEs (n=14). In addition, 105 paediatricians reported 488 incidences of patients who had delayed diagnosis/treatment associated with CAM use.

It is important to gather national epidemiological data on serious AEs associated with CAM use in the paediatric population and on indirect AEs associated with delays in diagnosis/treatment secondary to this use.



Methods

The initial reporting form will be sent monthly to clinically active paediatricians and paediatric subspecialists from across Canada who participate in the CPSP. After reporting a case, participants will complete a detailed clinical questionnaire. The study coordinator will review the detailed questionnaires for completeness. Subsequently, the study research team will review AE reports for severity and causality, using definitions adopted by the National Institutes of Health (NIH) and the US Food and Drug Administration (US FDA). In addition to the CPSP participants, a parallel simultaneous independent survey using the same definition and protocol will be conducted with a sample of paediatricians from the American Academy of Pediatrics, Pediatric Research in Office Settings (AAP PROS).

Objectives

- Determine the number of CAM-associated AEs recognized by Canadian paediatricians.
- Generate detailed epidemiological descriptive data about serious AEs (both direct and indirect) associated with CAM use in children in Canada, including their nature and severity.
- Describe the clinical manifestations and risk factors of confirmed cases.

Case definition

Report any patient less than 18 years of age with a serious* direct or indirect[†] adverse event (AE) associated with the use of complementary and alternative medicine (CAM)[§].

* Serious AE is defined as one that results in hospitalization, permanent disability, or death. Classification used by National Institutes of Health.

[†] Indirect AE refers to delays in diagnosis/treatment and/or inappropriate provision for a serious medical condition.

[§] CAM is a broad umbrella term for a variety of practices and products that are not considered part of conventional medicine, such as chiropractic, massage therapy, and natural health products. Natural health products include vitamins and minerals, herbs, homeopathic medicines, traditional medicines, probiotics, and other products like amino acids and essential fatty acids.

Duration

January 2009 to December 2010

Expected number of cases

While serious paediatric CAM AEs appear to be rare, the actual number is unknown. From the CPSP one-time CAM survey question, less than 20 cases per year are estimated.

Ethical approval

University of Alberta Health Research Ethics Board

Analysis and publication

Quarterly reports and an annual report will be distributed to all participants. Study findings will be presented through various media, including relevant conferences nationally and internationally. Data will be published in a peer-reviewed journal when the study is completed.

Bibliography

A bibliography is available from the principal investigator or the CPSP office.