Management of Natural Health Products in Pediatrics: A Provider-Focused Quality Improvement Project

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ABSTRACT

Introduction: The use of natural health products by pediatric patients is common, yet health care providers often do not provide management guidance. The purpose of this project was to improve management of natural health products by pediatric nurse practitioners.

Method: Pediatric nurse practitioners from large metropolitan city were recruited (n = 32). A paired pretest-posttest design was used. Study participants were engaged to improve knowledge of natural health products, and a management toolkit was created and tested.

Results: Mean knowledge scores increased from 59.19 to 76.3 ($p < .01$). Management practices improved with regard to patient guidance ($p < .01$) and resource utilization ($p < .01$). Assessments of product use ($p = .51$) and drug/herb interactions ($p = .35$) were not significant.

Discussion: This investigation is the first known study to improve knowledge and management of natural health products in pediatric clinical practice. J Pediatr Health Care. (2015) *29*, 137-144.

KEY WORDS

Natural health products, management, U.S. regulation, knowledge, toolkit

Approximately one third of pediatric patients use natural health products (NHPs) to treat or maintain their health, yet health care providers (HCPs) often omit management guidance related to NHPs (Bailey, Gahche, Thomas, & Dwyer, 2013). Through their lack of guidance to patients and their families who use these medicinal therapies, HCPs could be perpetuating the false ideal that if a product is "natural," it is therefore innocuous and "safe." HCPs should routinely inquire about all therapies used for health

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BACKGROUND

NHP is a Canadian term that refers to medicinal products that include vitamin and mineral supplements, herbal preparations, traditional and homeopathic medicines, probiotics, and enzymes (Health Canada, 2014). In the United States, these same products are considered "food products" and federal law binds them to the term, "dietary supplement" (U.S. Food and Drug Administration [FDA], 2014). Despite the label assigned to these products, they are commonly used to treat medical conditions or optimize health outcomes. For the purposes of this study, dietary supplements are considered medicinal, rather than nutritional; therefore, the term NHP will be used.

The limited regulatory oversight of NHPs by the FDA poses a disadvantage for HCPs in providing adequate guidance on the use of the products in pediatric patients. The FDA regulates NHPs by requiring manufacturers to follow good manufacturing practices, although no demonstration of safety, quality, or effectiveness is required before a product is marketed (U.S. FDA, 2014). Only once a product has been reported to cause adverse health consequences will the FDA conduct a full investigation and take necessary action. This delayed response may have life-threatening consequences to consumers, because adverse events from NHPs are significantly underreported (Cohen, 2014; Fabricant, 2013). Since 2008, the FDA has conducted inspections to assess compliance with the new regulations, and unfortunately, one out of four manufacturers failed to meet quality standards (Tsouderos, 2012).

CLINICAL PROBLEM

Patient use of NHPs is common, although HCPs frequently do not attempt to manage or discuss them with their patients because of their limited knowledge and lack of confidence (Gilmour, Harrison, Asadi, Cohen, & Vohra, 2011; Kemper, Vohra, & Walls, 2008). Data from the National Health And Nutrition Examination Survey (2007-2010) revealed that 85% of children who use NHPs do so without guidance from their HCP (Bailey et al., 2013). Even though HCPs may not have initiated NHP therapy, they are still expected to provide patients/families with guidance (Gilmour, Harrison, Asadi, et al., 2011). For example, if a parent is giving a toddler elderberry for treatment of influenza, the parent should be advised that studies do not support its use for children younger than 18 years, and preparations containing glycoside sambunigrin can be potentially toxic and lead to cyanide and lead poisoning (Natural Standard, 2014).

HCPs infrequently ask about the use of NHPs as a part of their patient assessments, even though the literature frequently laments this omission (Robinson & McGrail, 2004; Sawni & Thomas, 2007). The National Institutes of Health (NIH) has launched initiatives with their "Time to Talk" campaign for better communication between HCPs and caregivers/patients (National Center for Complementary and Alternative Medicine [NCCAM], 2014). Communication is essential to identify which products are being taken, why, and to prevent potential drug-herb interactions. Depending on its pharmacodynamic interaction, an NHP can alter the function of CYP450 liver enzymes, rendering a prescription drug more toxic or ineffective (Goldman, Rogovik, Lai, & Vohra, 2008). For example, the use of 5-hydroxytryptophan (commonly found in St Johns wort) with concurrent use of antidepressants is contradicted because of the increased risk for serotonin syndrome (Natural Standard, 2013).

INTENDED IMPROVEMENT

Approximately 14,000 pediatric nurse practitioners (PNPs) in the United States are serving as HCPs for children (National Association for Pediatric Nurse Practitioners, 2014). The primary goal of this project was to improve PNP knowledge and management of NHPs in clinical practice. With more than 85,000 NHPs on the market, understanding the content, safety, and health implications for each product may be considered an insurmountable task (Fabricant, 2013). Fewer than 5% of HCPs report feeling very knowledgeable about NHPs or having sufficient education to answer questions or give advice on the safety or efficacy of NHPs (Kemper & O'Conner, 2004).

STUDY QUESTION AND AIMS

This study was designed to answer the question: Will the provision of evidence-based management support—in the form of a toolkit and education specific to use and pharmacovigilance of NHPs—improve PNPs management practices of these products?

Project aims were twofold. The first aim was to increase PNP knowledge of NHP management, which was measured by comparing mean knowledge test scores in four areas: (a) patterns of use; (b) drug/herb interactions; (c) regulation/safety; and (d) availability of management resources. The second aim was to develop and disseminate resources that aid in the decision making and management of NHPs. The second aim had four measures; (a) increased PNP assessment of the use of NHPs; (b) increased PNP assessment of potential drug/herb interactions; (c) increased attempts of PNPs giving patient guidance with NHPs; and (d) increased PNP utilization of resources to manage NHPs.

METHODS

Ethical Considerations

The project received expedited Institutional Review Board approval from Johns Hopkins University. Participant information was de-identified and data were