



AUTHOR(S):

TITLE:

YEAR:

Publisher citation:

OpenAIR citation:

Publisher copyright statement:

This is the _____ version of an article originally published by _____
in _____
(ISSN _____; eISSN _____).

OpenAIR takedown statement:

Section 6 of the "Repository policy for OpenAIR @ RGU" (available from <http://www.rgu.ac.uk/staff-and-current-students/library/library-policies/repository-policies>) provides guidance on the criteria under which RGU will consider withdrawing material from OpenAIR. If you believe that this item is subject to any of these criteria, or for any other reason should not be held on OpenAIR, then please contact openair-help@rgu.ac.uk with the details of the item and the nature of your complaint.

This publication is distributed under a CC _____ license.

Yellow Card Reports Associated with Use of Natural Health Products in Children -An Exploratory Analysis

Robert Gordon University, Aberdeen

Okechukwu Ndu, Alison Strath, Lesley Diack

o.o.ndu@rgu.ac.uk

Introduction: The safety of paediatric Natural Health Product (NHP) use has not been studied for the Yellow Card Scheme (YCS). This study explored the reports of suspected adverse reactions (ADRs) received on the YCS from 1963 until July 2012 in connection with the use of NHPs in children.

Methods: The YCS data was mined to estimate the frequency and seriousness of the ADR reports for subjects aged 0-17 years in terms of patient demography, NHP type and mode of use, and outcome.

Results: NHPs generated 2,167 reports (0.03 %) within the period, of which 192 (8.6 %) concerned paediatric subjects. 186 valid paediatric reports were uniformly distributed by sex ($p=0.059$) and age category ($p=0.991$). 52 reports (28.0 %) were classified as serious, more than half of which (28; 53.8 %) were for non-emergency medical events. While most cases (137; 73.7 %) were described as resolving/resolved at the time of report, 6 fatalities (3.2 %) were reported, mostly for infants (5; 83.3 %). Herbal preparations yielded the most reports (116; 62.4 %), and dietary supplements the least (20; 10.8 %). However, dietary supplement use resulted in a much higher proportion of serious reports (70 % vs. 19 %; $p<0.001$). Compared to single product use, NHP use in combination generated more reports ($p=0.001$), a much higher frequency of resolving/resolved cases ($p<0.001$), and less fatal cases (2 vs. 4).

Conclusions: Yellow Card reports associated with paediatric use of NHPs are few, uniformly distributed and mostly non-serious. Dietary supplements and infants are most associated with serious reports and fatality, respectively. NHP use in combination is associated with more reports, but also much better outcomes, than single product use.