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**TITLE:**

**YEAR:**

**Publisher citation:**

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(ISSN \_\_\_\_\_; eISSN \_\_\_\_\_).

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# 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.