Market Analysis of Vitamin Supplementation in Infants and Children: Evidence From the Dietary Supplement Label Database

The Office of Dietary Supplements in concert with the National Library of Medicine recently created the Dietary Supplement Label Database (DSLD) to facilitate the scientific study of dietary supplement labels.1,2 The DSLD allows researchers to extract dietary supplement labels for research purposes. For example, the database may be used to assess label information to ensure that label information is truthful and accurate or to compare and contrast a large number of dietary supplements.

To our knowledge, we report the first analysis of labeled vitamin content for infants and children (<12 months and 12 months to <4 years) through the use of the DSLD. We analyzed whether the content of vitamins as a whole is based on Institute of Medicine (IOM) recommendations.3

Methods | The initial data sets were downloaded July 7, 2013, from the DSLD after using the advanced search option to select for 2 intended user groups, younger than 12 months and 12 months to younger than 4 years. Each dietary supplement label was separated by vitamin into separate spreadsheets and analyzed. In the younger than 12 months group, 21 labels were downloaded and analyzed. Three shown to contain a dietary supplement intended for infants younger than 12 months were excluded. In the 12 months to younger than 4 years group, a total of 172 labels were downloaded and analyzed. Data validation including an electronic mail from the recipient’s perspective. Int J Hum Comput Interact. 2006;21(3):313-332. doi:10.1207/s15327590ijhc2103_3.

Discussion | According to the IOM, infant vitamin supplementation in excess of the RDA/AI for vitamins C, E, K, B₁₂, and B₉ as well as thiamin, riboflavin, niacin, folate, pantothenic acid, biotin, choline, and carotenoids is not recommended. Similarly, in the 12 months to younger than 4 years category, vitamin supplementation in excess of RDA/AI is not recommended for vitamins K and B₉ as well as thiamin, riboflavin, folate, pantothenic acid, and biotin. The recommendation against excess neonatal and pediatric supplementation is because of a “lack of data of adverse effects in this age group and concern with regard to the lack of ability to handle excess amounts. Source intake should be from food only.”5 None of the tolerable upper intake levels have been defined for this reason. However, dietary supplements (Figure) consistently carried out on 10% of vitamin entries in both intended user groups. Vitamin amounts were divided by the IOM5 recommended daily allowance (RDA) or adequate intake (AI) values to reveal a percentage of recommended RDA/AI. The RDA/AI percentages were averaged and standard error of the mean was calculated for each vitamin. Vitamin A concentrations were calculated based on the Office of Dietary Supplements health profession fact sheet6; when the label did not indicate the vitamin A source, preformed units were assumed. The data were then plotted by intended user group (Figure).

Results | Vitamin D was the only vitamin present in the dietary supplements analyzed to contain at or below the RDA value for both pediatric intended user groups (Figure). The remaining vitamins presented in the IOM list contained values in excess of the RDA/AI values or were not present in enough vitamins (n < 3) to complete an appropriate analysis. Vitamin levels varied from a low of 13% of adequate intake for choline to a high of 936% of adequate intake for biotin (Figure, B).

<table>
<thead>
<tr>
<th>Vitamin</th>
<th>Younger than 1 y</th>
<th>Age 1 to 3 y</th>
</tr>
</thead>
<tbody>
<tr>
<td>Vitamin A</td>
<td>100</td>
<td>0</td>
</tr>
<tr>
<td>Vitamin C</td>
<td>200</td>
<td>0</td>
</tr>
<tr>
<td>Vitamin D</td>
<td>300</td>
<td>0</td>
</tr>
<tr>
<td>Vitamin E</td>
<td>400</td>
<td>0</td>
</tr>
<tr>
<td>Thiamin</td>
<td>500</td>
<td>0</td>
</tr>
<tr>
<td>Riboflavin</td>
<td>600</td>
<td>0</td>
</tr>
<tr>
<td>Niacin</td>
<td>700</td>
<td>0</td>
</tr>
<tr>
<td>Folate</td>
<td>800</td>
<td>0</td>
</tr>
<tr>
<td>Biotin</td>
<td>900</td>
<td>0</td>
</tr>
</tbody>
</table>

Percentage of Institute of Medicine recommended daily allowances or adequate intakes of vitamins in dietary supplements marketed to infants (<1 y) (A) and toddlers (1-3 y of age) (B) plotted as the mean percentage (SEM). Mean values were not included when there were insufficient data from the Dietary Supplement Label Database.
tain significant percentages in excess of the RDA/AI recommendations for vitamin supplementation.

The results of this study question the social responsibility and societal marketing concepts within the dietary supplement industry among those supplements marketed to infants and children younger than 4 years. We contend, based on our analysis, that much of the pediatric vitamin supplementation is not based on IOM recommendations and therefore represents wholesale oversupplementation.

Michael M. Madden, PhD
Danielle DeBias, PharmD, BCPS
G. Elliott Cook, PharmD, BCPS

Author Affiliations: LECOM School of Pharmacy, Erie, Pennsylvania (Madden, DeBias); Provider Resources Inc, Erie, Pennsylvania (Cook).

Corresponding Author: Michael M. Madden, PhD, LECOM School of Pharmacy, 1858 W Grandview Blvd, Erie, PA 16509 (mmadden@lecom.edu).


Author Contributions: Drs Madden and Cook had full access to all of the data in the study and take responsibility for the integrity of the data and the accuracy of the data analysis.

Study concept and design: All authors.

Acquisition of data: All authors.

Analysis and interpretation of data: All authors.

Drafting of the manuscript: All authors.

Critical revision of the manuscript for important intellectual content: All authors.

Administrative, technical, and material support: Madden, DeBias.

Study supervision: Madden.

Conflict of Interest Disclosures: None reported.


COMMENT & RESPONSE

Reducing Neonatal Mortality: Are High-Coverage Women’s Participatory Groups the Cost-effective Solution We Have Been Searching for?

To the Editor As a Gates grant recipient working on a technology to improve birth outcomes in low-resource environments, I welcome cost-effectiveness in community-based interventions. Unfortunately, after reading Fottrell et al,1 I am left with several thoughts. First, the claim that women’s group participation is a cost-effective intervention is exciting; however, the cost analysis is not explained, even minimally. One has to read the eAppendix even for basic information. Readers recognize that women’s groups focusing on the dissemination of information on maternal and child health to others have a great potential to save lives and money. There was no clear indication as to how and why this conclusion was drawn within the article. Fottrell et al should explain if the cost-effectiveness is inclusive of the health system—strengthening costs and what that entails financially, which indicates a significant improvement in itself.

Second, with my own interest in effective ways to spread maternal and child health information, I am left wondering about the details of the intervention. These were not given—even going back to the previous articles, they did not address the issue for me. Was there intracluster variation? Were there unequal numbers of previously consummated groups formed in the previous study dispersed in the intervention and the control groups? How would I replicate the intervention?

As mentioned in the protocol,2 2 factors influence the impact of women’s group interventions on newborn mortality: intensity and coverage. But, it is impossible to know from the methods which other factors influenced the outcome of this intervention. Strategic planning, community commitment, level of exposure to the intervention, and identifying the early adopters are all important factors in determining success of the intervention; nevertheless, this information was not discussed.

Lastly, readers need a fuller description of the strategy for choosing facilitators and how women were recruited into the groups. This makes a big difference in the dissemination, internalization, and diffusion of the information to communities on maternal and neonatal health, which, after all, should be a major area of emphasis for behavioral change in low-resource environments. I look forward to the response from Fottrell et al to help guide the field and my current work.

Margo Klar, MPH

Author Affiliations: Department of Epidemiology, College of Medicine, University of Florida, Gainesville; College of Public Health and Health Professions, University of Florida, Gainesville.

Corresponding Author: Margo Klar, MPH, University of Florida, 2004 Mowry Rd, PO Box 100231, Gainesville, FL 32611 (mklar@ufl.edu).

Conflict of Interest Disclosures: None reported.


In Reply We thank Dr Klar for her comments. The presentation of cost-effectiveness in our article follows the concise norm for similar trial articles. The account in the eAppendix provides the essential details of the cost-effectiveness analysis. Further analysis of costs, including sensitivity analysis, will be submitted for publication to add to the growing evidence base for women’s groups interventions.3 We would like to correct