Evaluating the quality of dietary intake validation studies

Lluis Serra-Majem1,2*, Lene Frost Andersen3, Patricia Henrique-Sanchez1, Jorge Doreste-Alonso1, Almudena Sanchez-Villegas1, Adriana Ortiz-Andrelluchi1, Eva Negri4 and Carlo La Vecchia4,5

1Nutrition Research Group, Department of Clinical Sciences, Centre for Health Sciences, University of Las Palmas de Gran Canaria, PO Box 550, 35080 Las Palmas de Gran Canaria, Spain
2Community Nutrition Research Centre of the Nutrition Research Foundation, University of Barcelona Science Park, Baldiri Reixac 4, 08028 Barcelona, Spain
3Department of Nutrition, Institute of Basic Medical Sciences, University of Oslo, PO Box 1046 Blindern, 0316 Oslo, Norway
4Istituto di Ricerche Farmacologiche ‘Mario Negri’, Via La Masa 19, I-20156 Milan, Italy
5Istituto di Statistica Medica e Biometria, ‘G. A. Maccacaro’, University of Milan, Milan, Italy

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Within the EURopean micronutrient RECommendations Aligned Network of Excellence (EURRECA), a scoring system was developed to assess the quality of dietary intake validation studies. The scoring system included three steps. The first step was to give each study a quality score, which included five components: sample size, statistics used, data collection procedure, consideration of seasonality and supplement use. Scores ranged from 0 to 7, and validation studies classified as very good (≥ 5), good (5–3·5), acceptable/reasonable (3·5–2·5) and poor (< 2·5). The second and third steps included an adjustment/weighting of the correlation coefficient according to the quality score and moreover a rating of the adjusted/weighted correlation. The scoring system was tested in 124 validation studies that included at least one vitamin. Only 5·6% of the 124 studies were judged to be of very good quality according to the quality score, 41·9% of good quality and 16·9% had a poor rating. When adjusting for the study quality scores, crude and adjusted mean correlations of vitamins A, C, D and E intakes were similar, but the percentage of correlation values classified as poor or very good was higher after adjustment. These results show the importance of considering the quality of studies validating dietary assessment methods and the correlations obtained for the micronutrient of interest when interpreting effects observed in epidemiological studies using dietary assessment methods. Without a doubt, this subject constitutes a key topic for research in nutritional epidemiology.

Validation studies: Nutrient intake: Quality: Score

The evaluation of a population’s micronutrient consumption constitutes a true challenge for nutrition research and, in general, has received less attention than the consumption of energy and macronutrients. Food and nutrient intakes are estimated through the administration of dietary assessment methods that usually differ according to study objectives, available resources, the population under study and the design of the epidemiological study(1–3). As such, in cross-sectional studies with the aim of evaluating food consumption and nutritional status for a given population or group of individuals, traditionally daily methods have been utilised, such as a single or multiple 24 h recalls (24HR) or food records. In contrast, epidemiological studies have mostly employed diverse variations of a Food Frequency Questionnaire (FFQ) that has been validated typically by daily methods or biochemical indicators.

Daily methods like 24HR and food records, which are less often validated than FFQ, have both advantages and disadvantages that have been amply described, and given their open-ended nature, by and large their intrinsic value has been accepted if they are administered in adequate conditions(2,3). However, their utility has been challenged due to the increasing knowledge of the problem with misreporting in these methods, which especially affect the selective underreporting of energy and certain food groups among given population groups(5). On the other hand, FFQ used in epidemiological studies have been validated or compared to other methods. Hence, notable validation studies of FFQ can be found in the literature, initiated in a rigorous and thorough manner by the groups of Walter Willett at Harvard University(5,6), and of Rohan and Potter at the University of South Australia(7), among others.

Generally speaking, FFQ have usually been validated for the consumption of energy, macronutrients, fatty acids, fibre and a given micronutrient. In fact, the first validation studies of these types of questionnaires addressed only a few vitamins and minerals such as vitamin C, vitamin A, Ca and Fe(1,5–7). For the most part, correlations for micronutrients were usually lower than those for macronutrients, especially for those on behalf of EURRECA’s RA 1.1 ‘Intake Methods’ members: Serra-Majem L (Coordinator), Cavelaars A, Dhonoukse-Rutten R, Doreste JL, Frost Andersen L, García-Alvarez A, Glibetic M, De Groot L, De Vries J, Gurinovic M, Henrique-Sanchez P, Naska A, Ngo J, Novakovic R, Ortiz-Andrelluchi A, Øverby NC, Pijs L, Ranic M, Ribas-Barba L, Ristic-Medic D, Román-Viñas B, Ruprich J, Saavedra-Santana P, Sánchez-Villegas A, Tabucci G, Tepsic J, Trichopoulou A, van’t Veer P, Vucic V, Wijnhoven TMA.

* Corresponding author: Lluis Serra-Majem, fax +34 928 453475, email lserra@dcc.ulpgc.es
micronutrients whose intake level depended on the consumption of a great number of foods\(^{(1,5,6)}\). Since the initial validation studies conducted in the 1980s to the present, hundreds of these types of studies have been published and, despite the fact that consensus-based criteria for how they should be administered are lacking, in most cases, the experience of Willett & Lenart\(^{(1)}\) and the Nurse’s Health Study has been followed.

Within the context of the EUROpean micronutrient REComendations Aligned Network of Excellence\(^{(8)}\) (EURRECA), we have conducted an in-depth review of all validation studies\(^{(9–14)}\) with the aim of analysing the utility of distinct dietary questionnaires, and particularly FFQ, for evaluating micronutrient intake. To achieve this, systematic reviews of all published validation articles that evaluated micronutrients or \(n\)-3 fatty acids were realised so as to assess the degree of validity of these questionnaires. In general, the questionnaires under study evaluated a set of various micronutrients, and occasionally, the focus was to assess a specific micronutrient such as Ca or vitamin A. Given the EURRECA project’s objective of subsequently conducting distinct meta-analyses for each of the micronutrients, it was deemed necessary to make a tool available that could be used to estimate the quality of validation studies that evaluated dietary questionnaires. To our knowledge, the development of such a quality criteria tool has not been carried out to date.

The objective of the present study was to provide a tool for evaluating the quality of studies validating FFQ and to explore its applicability in a sample of validation studies. This would allow for weighting-observed correlations with obtained quality estimations when combining a given number of studies for the evaluation of a specific micronutrient in different population groups\(^{(9–14)}\).

**Material and methods**

In order to identify the most accurate method for assessing the different micronutrient and \(n\)-3 intakes in the adult population and among specific population groups, a scoring system was needed to assess the quality of the different validation studies.

Based on tasks for the present research activity on intake methods, which consisted of conducting systematic reviews of validation papers, for all reviews, the papers were classified into three different categories, according to the reference method or gold standard applied in the validation study:

1. The reference method was another dietary assessment method evaluating short-term intake, including both 24HR, estimated and weighed records of less than 7 d.
2. The reference method was another dietary assessment method of long-term intake, including more than 7 d of dietary collection and
3. The reference method was a biomarker. In this case, a discussion on the selected/available biomarker and its characteristics as a recovery or concentration biomarker was needed.

The studies included in categories (1) and (2) may be called correlation or misclassification were utilised.

Scores could range from 0 (poorest quality) to a maximum of 7 (highest quality). This allowed for the classification of validation studies according to their methodological quality (Table 1 step 1):

1. Very good/excellent, score \(\geq 5\).
2. Good, \(3.5 \leq \text{score} < 5\).
3. Acceptable/reasonable, \(2.5 \leq \text{score} < 3.5\).
4. Poor, \(\text{score} < 2.5\).

For the simultaneous analysis of several validation papers with the aim of estimating a mean combined correlation of various studies per micronutrient for a given diet assessment method, the correlation coefficient value of each study was multiplied by its quality score. Then, the sum of the weighted correlations was divided by the sum of the validation studies’ quality scores. This provided us with a correlation coefficient adjusted for the study’s methodological quality (see Table 1 step 2).

In order to analyse the implications of using the scoring system, a systematic review of the validation studies addressing the intake of at least one vitamin was performed, and the average of correlations was calculated without (crude) and with (adjusted) the scoring system. As explained in the paper from Henríquez-Sánchez et al.\(^{(9)}\), the following number of studies addressing each vitamin was included: 76 articles

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**Table 1**

<table>
<thead>
<tr>
<th>Category</th>
<th>Description</th>
<th>Score</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Very good/excellent</td>
<td>(\geq 5)</td>
</tr>
<tr>
<td>2</td>
<td>Good</td>
<td>(3.5 \leq \text{score} &lt; 5)</td>
</tr>
<tr>
<td>3</td>
<td>Acceptable/reasonable</td>
<td>(2.5 \leq \text{score} &lt; 3.5)</td>
</tr>
<tr>
<td>4</td>
<td>Poor</td>
<td>(\text{score} &lt; 2.5)</td>
</tr>
</tbody>
</table>
for vitamin A, 108 for vitamin C, 21 for vitamin D, 75 for vitamin
E, 47 for folic acid, 19 for vitamin B12, 21 for vitamin B6, 49 for
thiamine, 49 for riboflavin and 30 for niacin, extracted from a
total of 124 different studies. The correlation values obtained
for every vitamin in each of the studies were summed up, first
without consideration of the quality of the study or scoring
system, and second taking this factor into account. Sub-
sequently, the proportion of correlations for vitamins A, C, D
and E were classified into four categories: very good ($\geq 0.7$),
good (0.5–0.69), acceptable (0.3–0.49) and poor (<0.3; Table
step 3), and comparisons between crude and adjusted figures
were made using a McNemar $\chi^2$ test in SPSS-PC (15).

Results
Table 1 presents the scoring system administered to evaluate
the quality of the validation studies. Among the 124 validation
studies analysed, the quality scores ranged from 0.5 to 6
(highest score obtained by Sudha et al. (16)). The average
was 3.19 and median 3.0 (Table 2). Table 2 shows the
classification of the validation studies, with 47.5% of the
studies rating as good (41-9%) or very good (5-6%) quality,
and 16-9% having a poor quality rating. Table 3 shows the
mean and classification of crude and quality-adjusted
correlation coefficients obtained for vitamins A, C, D and
E. Although no significant differences were found, correlation
averages were similar, and the percentages of correlations
below 0.3 (poor) were considerably higher after adjusting
for the quality of the validation study. Additionally and in
contrast, for vitamins A and D, the percentages of correlations
$\geq$0.7 (very good) were substantially higher after adjustment
for quality.

Discussion
It is quite surprising that to date a systematic review has not
been conducted, which evaluates validation studies of FFQ.
Over the last few decades, nutritional epidemiology has
developed and increased in an exponential fashion, due in
part to the innovation of simplified, properly validated ques-
tionnaires for evaluating the consumption of food and
nutrients. The development of these types of instruments
accommodates the inherent needs of epidemiological studies
in which larger population samples make it a necessity to
utilise data collection methods that are valid, accessible,
reproducible and less costly. In general, the validation of
FFQ has been achieved by comparing with various records/
registers, which adequately distributed over a long period of
time, typically 1 year, reflect usual intake. Multiple 24HR
and biomarkers have also been utilised.

When developing the quality scoring system, five principal
variables were taken into account: sample and sample size,
statistics, data collection, seasonality and supplements.
Sample size is an aspect that has been given minimal

### Table 1. Scoring system to assess the quality of the nutrient intake validation studies

<table>
<thead>
<tr>
<th>Step 1</th>
<th>Quality of the validation study</th>
<th>Variables in general</th>
<th>Specific variable</th>
<th>Points</th>
<th>Score</th>
</tr>
</thead>
<tbody>
<tr>
<td>Score the studies according to:</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>1. Sample and sample size</td>
<td>Non-homogeneous sample (sex, SES, smoking and obesity) n &gt; 100 (n &gt; 50 for biomarkers)</td>
<td></td>
<td></td>
<td>0.5</td>
<td>0.5</td>
</tr>
<tr>
<td>2. Statistics:</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Group level</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Correlations: (select only one of the three types, choosing type with the highest score)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Agreement</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Data collection</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Seasonality</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Supplements</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Total score (S) may range from a minimum of 0 (for all studies) to a maximum of 7</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Step 2</td>
<td>Correlation reporting</td>
<td></td>
<td><strong>Formula</strong></td>
<td><strong>Step 3</strong></td>
<td><strong>Correlation rating</strong></td>
</tr>
<tr>
<td></td>
<td>Weight the correlation coefficient of the study by the score obtained in step 1 (quality of the validation study) and calculate the average for all the studies for the nutrient under study:</td>
<td></td>
<td>$X_n = \frac{\sum (Rn \times Sn)}{\sum Sn}$</td>
<td></td>
<td>$X_n &lt; 0.3$ Poor</td>
</tr>
<tr>
<td></td>
<td>Where, $R_n =$ correlation coefficient; $S_n =$ quality score of validation study; $X_n =$ weighted correlation average per reference method category</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>$0.3 \leq X_n &lt; 0.5$ Acceptable</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>$0.5 \leq X_n &lt; 0.7$ Reasonable/good</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>$X_n \geq 0.7$ Very good</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>SES, Socioeconomic status.</td>
<td><strong>Footnote</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

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consideration in validation studies. According to Willett & Lenart\(^1\), selecting an appropriate number of subjects for a validation study is less than straightforward as correlations for many nutrients are likely to be examined and the precision required remains arbitrary. These authors have estimated that a reasonable sample size for a validation study should comprise between 100 and 200 people. We chose the sample of 100 individuals as a study quality criterion when using other dietary assessment methods as a gold standard; a sample of 100 individuals as a study quality criterion when using biochemical markers as the reference methods, a reasonable sample size for a validation study should comprise between 100 and 200 people. We chose the sample size of just fifty individuals could be considered available\(^{(18)}\). However, as only a limited number of recovery markers are available, adjustment for energy intake could be an alternative, since it may diminish the problem of correlated random errors. For this reason, energy adjustment and the deattenuating of the correlation are critical points in the statistical methods used in the validation studies of dietary intake. Bland & Altman\(^{(19,20)}\) recommended not to use the correlation analysis in these types of studies, but rather to analyse the standard deviation of the difference between the two methods, since this is not influenced by between-person variation. Additionally, classification within the same tertiles of consumption may be useful as well. Statistical procedures account for 3 out of 7 points of the quality score as they are critical to a sound analysis. Moreover, since there is no single method to relate a surrogate measure to a measure of truth that conveys all the available information, it is probably best to analyse and present the data in several ways\(^{(21,22)}\).

As for data collection procedures, FFQ and food records can be administered by personal interview or by telephone or can be self-administered, using electronic means or postal mailings. In general, the accuracy and quality of data

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### Table 2. Quality score of the validation studies of FFQ including any vitamin

<table>
<thead>
<tr>
<th>Quality score</th>
<th>n</th>
<th>%</th>
<th>n</th>
<th>%</th>
<th>n</th>
<th>%</th>
<th>n</th>
<th>%</th>
<th>n</th>
<th>%</th>
<th>n</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Very good (≥5.00)</td>
<td>5</td>
<td>9.4</td>
<td>0</td>
<td>0.0</td>
<td>1</td>
<td>5.3</td>
<td>1</td>
<td>5.3</td>
<td>1</td>
<td>3.0</td>
<td>7</td>
<td>5.6</td>
</tr>
<tr>
<td>Good (3.5 ≤ score &lt; 5)</td>
<td>22</td>
<td>41.5</td>
<td>6</td>
<td>30.0</td>
<td>8</td>
<td>42.1</td>
<td>7</td>
<td>36.8</td>
<td>15</td>
<td>45.5</td>
<td>52</td>
<td>41.9</td>
</tr>
<tr>
<td>Acceptable (2.5 ≤ score &lt; 3.5)</td>
<td>15</td>
<td>28.3</td>
<td>7</td>
<td>35.0</td>
<td>8</td>
<td>42.1</td>
<td>9</td>
<td>47.4</td>
<td>12</td>
<td>36.4</td>
<td>44</td>
<td>35.5</td>
</tr>
<tr>
<td>Poor (&lt;2.5)</td>
<td>11</td>
<td>20.8</td>
<td>7</td>
<td>35.0</td>
<td>2</td>
<td>10.5</td>
<td>2</td>
<td>10.5</td>
<td>5</td>
<td>15.2</td>
<td>21</td>
<td>16.9</td>
</tr>
</tbody>
</table>

Mean 3.19

Median 3.00

24HR, 24 h recall.

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### Table 3. Comparison between crude and quality adjusted correlation coefficients obtained for vitamins A, C, D and E

<table>
<thead>
<tr>
<th>Vitamin</th>
<th>Range</th>
<th>(R_{crude})</th>
<th>(R_{adjusted})</th>
<th>(P)</th>
<th>(R_{crude})</th>
<th>(R_{adjusted})</th>
<th>(P)</th>
<th>(R_{crude})</th>
<th>(R_{adjusted})</th>
<th>(P)</th>
<th>(R_{crude})</th>
<th>(R_{adjusted})</th>
<th>(P)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Vitamin A</td>
<td>&lt;0.3</td>
<td>16.3</td>
<td>16</td>
<td>24.6</td>
<td>24</td>
<td>ns</td>
<td>8.8</td>
<td>9</td>
<td>15.7</td>
<td>16</td>
<td>ns</td>
<td>9.5</td>
<td>2</td>
</tr>
<tr>
<td>0.3–0.49</td>
<td>46.9</td>
<td>46</td>
<td>42.9</td>
<td>42</td>
<td>ns</td>
<td>40.2</td>
<td>41</td>
<td>38.2</td>
<td>39</td>
<td>ns</td>
<td>33.3</td>
<td>7</td>
<td>33.9</td>
</tr>
<tr>
<td>0.5–0.69</td>
<td>32.7</td>
<td>32</td>
<td>23.5</td>
<td>23</td>
<td>ns</td>
<td>35.3</td>
<td>36</td>
<td>30.4</td>
<td>31</td>
<td>ns</td>
<td>42.9</td>
<td>9</td>
<td>19.0</td>
</tr>
<tr>
<td>≥0.7</td>
<td>4.1</td>
<td>4</td>
<td>9.2</td>
<td>9</td>
<td>ns</td>
<td>15.7</td>
<td>16</td>
<td>15.7</td>
<td>16</td>
<td>ns</td>
<td>14.3</td>
<td>3</td>
<td>28.6</td>
</tr>
<tr>
<td>Total</td>
<td>100</td>
<td>98</td>
<td>100</td>
<td>98</td>
<td>100</td>
<td>102</td>
<td>102</td>
<td>102</td>
<td>102</td>
<td>100</td>
<td>19</td>
<td>100</td>
<td>19</td>
</tr>
</tbody>
</table>

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\(S6\)
collection are greater when using personal interviews, particularly in cross-sectional studies\(^{(25)}\). In addition, self-administered questionnaires are generally less reliable in low income populations and those with less education\(^{(24,25)}\). Taking the afore-mentioned into account, in our opinion, collecting dietary information for the gold standard or reference method by personal interview, independently if the validated questionnaire is self-administered or not, may provide better comparisons with less possibility of correlating errors among the two estimated methods. A score of 1 was included for those validation studies using information gathered by face to face interview. The qualification of the person administering the interview was a variable not taken into specific consideration for scoring, but is also a factor that impacts on quality data collection i.e. previous training, being a diettian, or bilingual or cross-cultural interviewer\(^{(26)}\).

Seasonality is an important issue in nutrition epidemiology, particularly as it is directly related to the intake of certain vitamins. For this reason, it is important to take it into consideration when validating a questionnaire; usually, authors tend to distribute the food records over different time periods throughout the year\(^{(27)}\). As such, we have included seasonal variation as a quality criterion, with the addition of 0.5 points for studies taking this factor into account.

Finally, the inclusion of supplements was considered an important characteristic in validation studies for micronutrients, unless the questionnaire was intentionally designated for non-supplement users only. With the exception of certain vitamins from the B complex group, for the majority of micronutrients, validation study correlations improved when supplement intake was taken into consideration\(^{(28)}\), which seems evident for those populations whose intake of supplements is qualitatively and quantitatively important. In fact, in a systematic review on vitamins\(^{(29)}\), correlations were higher when supplements were taken into account in the validation studies, especially for vitamins D, E, B\(_6\), and folic acid, but less for vitamin B\(_{12}\) or vitamin A.

Some authors have developed scoring systems for evaluating dietary methodology (quality) in epidemiological studies\(^{(30)}\), and the quality criteria included, among others, the number of FFQ items, the form of administration and the application of feasibility testing or pre-testing. It is often difficult to come across these quality parameters in epidemiological studies, and particularly so in the abstract of the article. Nevertheless, our objective in the present analysis was not so much to judge the quality of nutrition information in epidemiological studies applying \textit{a priori} defined criteria, but rather to assess the quality of validation and calibration studies of FFQ, with the aim of including, excluding or weighting the study or studies that utilise a given questionnaire in possible reviews or meta-analyses for a specific micronutrient. To our knowledge, this factor has not been taken into consideration in systematic reviews or meta-analyses of nutrition epidemiological studies before.

In the present study, we found that less than half of FFQ validation studies, evaluating any given vitamin, were of ‘good’ or ‘very good’ quality and that 17% were of ‘poor’ quality. Quality scores were lower in those validation studies where FFQ was compared to dietary records reflecting short-term intake. When applying the quality score to adjust the correlation obtained in these validation studies for vitamins, the mean correlations were nearly the same, but the percentage of studies with correlations falling to the lowest category (poor) increased for all vitamins included in this analysis. Moreover, after adjusting for the study quality score, an increase in the percentage of studies whose correlations shifted to the highest category (very good) was seen for vitamins A and D. This information should be considered when interpreting results from studies using FFQ to evaluate vitamin intake.

The impact of measurement errors in dietary assessment instruments in the design, analysis and interpretation of nutrition studies may be much greater than previously estimated, particularly in prospective cohort studies\(^{(31)}\). Recently, discussions about FFQ limitations compared to food records or recalls have been pointed out, particularly due to results emerging from the EPIC and other studies\(^{(32–38)}\). Without a doubt, this has led to the erroneous utilisation of some FFQ, not necessarily due to the nature of the instrument in and of itself, but rather to its inappropriate application (i.e. FFQ validated in a population or for dietary components different from that in the epidemiological study); albeit, a considerable percentage of these tools may also be of low-quality design. As such, and especially when considering micronutrients, it is critical to utilise high-quality instruments in which we have obtained an adequate estimation of intake for a given micronutrient (drawn from the correlation coefficient of the validation study). The issue should not be limited to the validation of a questionnaire, but rather it should address the utility of the instrument for measuring intakes of a given micronutrient and whether the design and analysis are adequate\(^{(39)}\).

As pointed out by Block & Hartman\(^{(40)}\), negative outcomes may often be the result of poor instruments and faulty data impede the progress of research, which may all be particularly relevant when studying micronutrients. According to those authors, the factors that may affect the validity of a diet questionnaire are: (1) respondent characteristics, (2) questionnaire design and quantification, (3) adequacy of the reference data and (4) quality control of data management.

Judging the quality of dietary exposure assessment in epidemiological studies is a crucial element. The scoring system proposed in the present paper or other tools that may follow can contribute to increasing the quality of the evidence in nutrition research, due to its capacity to serve as guidance for validation studies of diet questionnaires as well as for its utility in the selection and weighting of results from already conducted nutritional epidemiological studies.

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L. S.-M. developed the initial validation instrument, coordinated the discussion and consensus, designed the study and wrote the paper. L. F. A. took part in the discussions of the
initial validation instrument and contributed to the discussion, consensus and manuscript content. P. H. conducted some statistical analysis and contributed to the discussion and consensus. J. D.-A. conducted some analysis, contributed to the discussion, consensus and manuscript content. A. S.-V. contributed to the discussion, consensus and manuscript content. C. L. V. contributed to the discussion, consensus and manuscript content. The authors have no conflict of interests to report.

References


