RESEARCH PROTOCOL

Development of a Checklist to REport Food INtakE Data "REFINED"

Department of Food Safety and Food Quality
Gent University, Belgium
www.nutrition.ugent.be

Gent, February 10, 2014

Version 2

Prepared by HAWWASH Dana and Dr. LACHAT Carl
Contact carl.lachat@ugent.be

Changes from version 1

- An acronym for the food intake checklist was added
- A section on funding was added
- The template to collect input from the Delphi round participants was revised to be consistent with sections used in the STROBE statement (Annex 1)
- The informed consent procedure was altered to enable informed consent through email
- A section on ethical approval for the modifications to the informed consent procedure was added including approval of this amendment by the Ethical Committee

Contents

Background and objectives

This study aims to improve the quality of reporting food intake studies through developing a checklist that can be used when researchers report a food intake data. Poorly reported food intake studies are unsuccessful in providing accurate description of the methods and findings, and cause heterogeneity that complicates data analysis in systematic reviews (Burrows et al. 2012). Readers of poorly reported studies may reach the erroneous conclusions or implement the results improperly in clinical settings, or in new research projects resulting in ineffective use of resources (Moher et al. 2011).

A research reporting guideline is a simple tool that leads to a better reporting quality and more consistent research literature, without restricting the research creativity. A guideline is mainly a checklist, explicit text, a flow diagram or a combination between these three elements that specifies the items to be reported during a study. Implementing the checklist as a guideline, and improving the quality of reporting by journals and researchers would enable better management of resources and more accurate evidence-based decisions by stakeholders, health professionals and clinicians, leading to increased returns of investments (Simera et al. 2010).

As diet and food intake is an important driver of health, development and use of natural resources, reporting food intake data accurately is a matter of concern. A search identified following checklists for food intake studies:

- A guideline for describing nutritional epidemiological study designs developed for information required for all dietary assessment (Michael Nelson and Margetts 1997),
- A scoring system developed by Serra-Majem *et al.* to evaluate the quality of the dietary intake validation studies (Serra-Majem et al. 2009),
- A checklist developed by Burrows *et al.* for systematic reviews to assess the quality of dietary intake methodology and reporting in child and adolescent obesity intervention trials (Burrows et al. 2012), and
- A checklist called STROFI “Strengthening the Reporting Of Food Intake” developed by Faber *et al.* inspired by the STROBE “Strengthening the Reporting of observational studies in Epidemiology” statement (Faber et al. 2013).

None of the checklists however, were developed following a systematic and acceptable methodology for them to be used widely and endorsed by journals, researchers and other stakeholders internationally. As these checklists lack external validity, there is a recognized need for a checklist to be developed. None of these checklists are registered on the EQUATOR “Enhancing the QUAlity and Transparency of health Research” database of reporting guidelines.

The present study follows a valid recognized method for developing a checklist. The checklist will be pre-tested before it is finalized and will be accompanied with an explanatory document. An expected outcome of this initiative is a new and pre-tested universal checklist that will be recognized, published, and endorsed by multiple journals and used by researchers.

This protocol and checklist will be registered on the EQUATOR Network to increase its recognition, and utilization once developed, also to avoid duplication of efforts with other research groups that might consider developing a similar checklist.

Methods

This study will use “The Guidance for Developers of Health Research Reporting Guidelines” method (Moher et al. 2010) with two types of consensus activities:

1. A formal activity to guide the development process of the checklist. A steering committee composed of researchers from three research institutions will manage the study in the face-to-face (video and Skype conferencing) online meetings.
2. An Informal activity with participants consisting of a large body of international stakeholders of different disciplines (i.e. include methodologists, journal editors, statisticians, epidemiologists, and content experts) will be involved in 3 Delphi rounds. These participants will provide the essential input for the checklist and will be contacted through email.

Design

To develop the checklist eight main activities will be carried out (Figure 1).

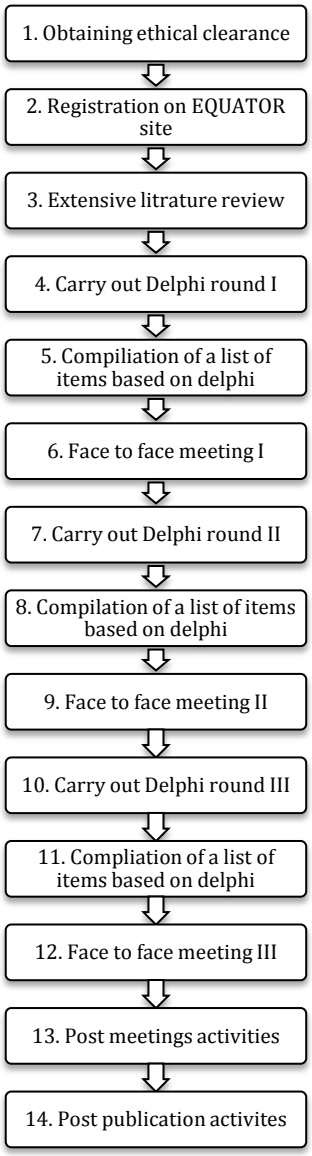

Figure 1: Steps followed for the development of a food intake checklist

Obtaining ethical clearance

This protocol was cleared by the Ethical Committee of Gent University on 10/12/2013 under registration number (nr 2013/1059) (Step 1). A modification to the protocol was

approved by the Ethical Committee of 06/02/2014 to enable informed consent through email.

Registration on the EQUATOR website

The protocol of the study and the pre-tested questionnaires will be registered on the EQUATOR website after ethical clearance has been obtained (Step 2).

Literature review

A search for articles concerning food intake studies will be conducted during the development of the checklist to assess the quality of the reporting (Step 3). Information related to sources of bias in these studies will then be identified to have an insight into the items that need to be included in the checklist (Moher et al. 2010). The step will also consider emerging empirical data that reflects current practices.

Delphi rounds

A reporting checklist needs to be developed with a multi-disciplinary set of participants. The Delphi method is a structured group process that is used to collect and understand the opinions of a group of experts in a specific field. It is a practical way to collect information and to reach consensus between experts that are unable to convene physically. The Delphi technique is also flexible as it allows disagreements between participants. Participants are able to express dissenting views, allowing the collection of diverse opinions without causing conflicts. Participants are not influenced by the ideas of others as they are not exposed to them (Cross 1999). For the present study, the Delphi rounds will be constructed according to the recommendation proposed by (Sinha et al. 2011). Although the Delphi process can continue endlessly until there is agreement between all participants, usually three rounds suffice to reach consensus and collect the needed information (Chia-Chien and Brian 2007);(Yousuf 2007). We will conduct a three-stage Delphi process with following specific objectives:

- Delphi round I (Step 4) is a quantitative method and will include open-ended questions, to facilitate getting as many ideas and opinions as possible on the items that need to be included in the checklist. This round is essential as it provides the basic input for the first draft of the checklist. Annex 1 contains the

question of the Delphi round I. Prior to dissemination, the questionnaire will be pre- tested with a sample of ten volunteering researchers.

- Delphi round II (Step 7) will be carried out after the first face-to-face meeting and based on the developed checklist. It will mainly contain dichotomous questions, to check the level of agreement on the items included within the developed checklist. The items will be answered online. The content of the checklist will depend on input from the first Delphi round and information brought up in the first face-to-face meeting. Annex 1 shows how the second round of the Delphi will probe for answers for the various items. An example of similar items that could be included in our checklist is the STROFI checklists (Faber et al. 2013, Vandenbroucke et al. 2007) (Annex 2).

- Delphi round III (step 10) will be the last round and will be carried out after the second face-to-face meeting. This round allows the researchers to reach acceptable consensus and stability of answers within the group, within a considerable timeframe. The questions in this round will be similar to the questions asked during round two, however they will be based on the refined checklist that generates from Delphi round II and face-to-face meeting II. The Delphi round III questions are included as Annex 1.

Invitation letters together with the informed consent will be sent and participants will be given a period of two weeks to reply, they will be sent a reminder once during the data collection period. The invitation letter and informed consent are included as Annex 3 & 4.

Generating a list of items for consideration during the face-to-face meeting

Based on the answers obtained from the first Delphi round and the items considered important from the literature review, a large number of items are expected. A reduction to a concise, more manageable number of items for the checklist will be carried out by the steering committee. Two research groups of the steering committee will carry out the data reduction independently. The third group will serve as moderator and resolve conflicts and disagreements. Using consensus, the steering committee appointed experts of National Institute for Public Health and the environment in the Netherlands

(RIVM) as moderator for the first round, the WHO International Agency for Research on Cancer, France (IARC) for the second round and Gent University, Belgium (UGent) for the last round.

The two checklists prepared from the Delphi rounds will be discussed during the first face-to-face meeting. During this meeting agreement will be reached on a final version as an output of this meeting. Items retrieved during the extensive literature review that were not brought up in the Delphi round might also be added to this version.

Consensus at this stage is pre-defined and will follow the recommendation of (Sinha et al. 2011) and is set to be achieved as agreement of > 70% for each item on the checklist included. In the second and third Delphi round more consensus is expected and a threshold of >80% agreement will be used.

To promote transparency, substantial disagreement, reasons and incorporating the reasons for disagreement will be identified and reported in the minutes of the meeting and exploratory document that complements the checklist.

The face-to-face consensus meetings

Steering committee meetings will be organized through a videoconference. A conference room with the needed resources for every meeting, and a suitable time to allow maximum participation will be foreseen. No meals will be provided and participants will not need to travel.

In each meeting, there will be an introductory phase, and an overall summary of the agenda. The Delphi round results, results of the data reduction, empirical evidence from literature, background topics and some glossary such as what could be considered as an item on the list will be presented in the meeting. An alternating moderator will be assigned.

The discussions will revolve around the items and information in the checklist and the rational, evidence and consensus behind it. In order to reach consensus, a classification scheme for selecting items to include in the checklist will be used, similar to the one used in developing the Consort checklist (Moher et al. 2010). Each meeting has specific objectives to achieve:

- Face-to-face meeting I (step 6):
    - Developing the first food intake checklist, based on the items received from Delphi round I and the items found from the literature, through discussions to reach consensus.
    - This meeting will be chaired and moderated by RIVM.
- Face to face meeting II (Step 9):
    - Discussing the findings of Delphi round II, and using these findings to improve the developed checklist, where items with consensus below 70% on valid responses will be excluded from the refined version of the checklist.
    - Discussing whether it is advisable to develop a flow diagram together with the checklist or not.
    - This meeting will be chaired and moderated by IARC.
- Face to face meeting III (Step 12):
    - Discussing the findings of Delphi round III, where items with consensus below 80% on valid responses will be excluded from the first draft of the checklist that will be pre-tested.
    - Discussing the development of the explanation and elaboration document, and authorship model that needs to be adapted.
    - Discussing the dissemination plan including, publication strategies and journals endorsement.
    - This meeting will be chaired and moderated by UGent.

Post-meeting activities

After drafting and finalizing the checklist, strategies to implement the dissemination plan will be considered by the steering committee.

Developing the guidance statement

In this step, the focus will be on drafting the checklist with several attempts to come out with the best version. Notes from the face-to-face meeting will be taken into account when developing and organizing concisely worded checklist items. The checklist will be supported by a document that explains the rationale and the development process.

Pilot test the checklist

The checklist will be tested through developing a scoring system to assess the quality of reporting of food intake studies. Items on the list will be given a certain weight of the final score depending on the importance of inclusion during reporting, based on consensus of the checklist developers.

The aim of this test is to check measurement agreement and the reliability of the checklist. Two food intake studies will be selected for scoring by two different groups: the checklist developers and 30 external participants from the nutrition field. The score of the checklist developers will serve as a basis for comparison with the results obtained by the second group of participants to assess the checklist inter-rater validity and reliability.

An information letter and informed consent will be distributed before the test (Annex 4 and 5). The scoring checklist together with two chosen studies will be sent and participants will be asked to submit the scores for the two papers back in a week. In case of unwillingness of many invitees to participate in this exercise, a list of additional participants will be developed and they will be contacted to join this part of the research.

Developing the explanation and elaboration document

An explanatory and elaboration document will be developed and signed by the steering committee. This document will explain the rationale and evidence for the inclusion of each item together with an elaboration on the details of each item. The document will also contain anonymous critical comments and dissenting views on particular items on the checklist to trigger feedback from users and facilitate future efforts in this area.

Developing a publication strategy

To support the use and dissemination of the checklist and for it to be more influential, publishing it in as many journals as possible will be of high priority. The first step will be to contact the editors who took part in the Delphi round to discuss the publication strategy, as well as implementing the publication strategies discussed during the last meeting.

Post-publication activities

Seeking and dealing with feedback and criticism

Criticism and feedback will be encouraged from all stakeholders as a way to improve and update the checklist. Contact details and relevant information will be provided in the manuscripts and online.

Encouraging endorsement of the checklist

The support of journals to endorse and use the developed checklist will be sought. The journal editors that were involved in the checklist development will be first contacted, followed by as many journals as we can contact. Strategies discussed during the last meeting concerning endorsement will be implemented.

Supporting adherence to the checklist

To ensure that the checklist will have its intended impact, issues concerning adherence to the checklist will be addressed. A clear statement of how authors should use the checklist and what level of adherence is required will be developed, together with some recommendations to the journals that will be endorsing the checklist.

Evaluating the impact of reporting checklist

An evaluation round will take place five years after successful endorsement and publication with a review paper.

Developing a web site

Putting the checklist on a Gent University website as well as IARC and RIVM will be negotiated, together with issuing a copyright of both the checklist and the explanation and elaboration document.

Translating the checklist

If the checklist proves to be successful after publications, and other researchers ask to translate it, active involvement in the translation phase will be sought to make sure translation is carried out appropriately.

Updating the checklist

The checklist will be updated on a needs basis after a few years, to make sure it reflects current practices of journals and researchers.

Participants

Participants in the face-to-face meetings

An executive group consisting of international multidisciplinary experts from (i) Gent University in Belgium, (ii) the nutrition and metabolism sector at IARC, and (iii) RIVM will constitute the steering committee. They will guide the development of the checklist and prepare a separate explanatory report that will serve as a new reporting guidance for all study designs that use food intake tools in their data collection.

Meetings will be organized in advance to ensure the presence of everyone. Researchers will be asked to confirm their attendance two weeks before each meeting. Two reminders will be sent, one, a week before and one a day before.

Moreover, in order for all participants in the meeting to have current knowledge about the progress of the study, background information will be sent to them at least one week prior to the meeting to enable informed discussions.

Participants in the Delphi rounds

According to the Delphi technique by (Chia-Chien and Brian 2007) there are no specific criteria to select the participants for the Delphi round. However, participants should be the most appropriate and could be chosen through nomination of the respected and well-known individuals. We aim for least 20 international stakeholders of different disciplines involved in the Delphi rounds and at least three methodologists, three journal editors, three statisticians, three epidemiologists, and three content experts. To account for no reply and dropouts, the invitation will be circulated widely to a larger number of experts. Snowballing will be encouraged and invitees will be asked to suggest additional names of participants. To minimize selection bias, a systematical procedure is used to select participants. Two different approaches will be used:

1- Journal editors

   The criteria of selection are based on journals ranked under the in nutrition and dietetics category of the web of knowledge. The top twenty-five journals in this category were listed and grouped them by publisher. Each group of editors per

one publisher will be contacted with one email and invited to take part of the Delphi rounds. One reminder will be sent.

2- The methodologists, statisticians, epidemiologists and the content experts A systematic approach will be used to select these participants. First, corresponding authors that have been publishing relevant papers on these matters will be invited (see introduction for examples). If they are unwilling to participate, then the last author will be contacted. Second, work package leaders and principal investigators of large and well-known international dietary assessments projects will be invited. Specifically, the principal investigators of following projects will be contacted: EFCOVAL, EFCOSUM, OPEN STUDY, EU MENU, PANCAKE, ASPADAM.

Participants in the checklist piloting

Testing the checklist would be done through asking a sample of 30 researchers within the nutrition field to assess two different food intake studies using the scoring checklist developed by the researchers, and comparing their results with the results of the checklist developers obtained when doing the same exercise. These participants will be identified through convenience sampling using personal contacts.

Rigor, validity and reliability

The Delphi method is repetitive in nature, and the risk of dropouts during the second and third round usually increases (Cross 1999). This will be taken under consideration in this study. The invitation letter will highlight the importance of participating in all Delphi rounds. Dropout rate will be calculated after each round and unresponsive participants will be contacted to understand the reason behind their dropout of the study. The dropouts for pilot testing the checklist will be managed in the same manner.

Timeline

The milestones for all steps within this research as following (Table 1).

Table 1: Milestones for the development of a Checklist to report food intake data

DATE	MILESTONE
1/10/2013	Project Started
15/11/2013	Proposal submission for ethical clearance
10/2//2014	Staring Delphi round I
10/3/2014	Face-to-face meeting number one to be completed
15/2/2014	Starting Delphi round II
10/3/2014	Face-to-face meeting number two to be completed
15/3/2014	Starting Delphi round III
30/3/2014	Face-to-face meeting number three completed
10/4/2014	Starting pilot testing the checklist
30/6/2014	Completion of explanation and elaboration document
1/7/2014	Developing a publication strategy
30/7/2014	Post publication activities

Ethical considerations

Participants' confidentiality will be ensured, since only the researcher and principal investigator will have access to aspects like the origin of the feedback opinions, responses during the Delphi rounds and checklist piloting. All participants will remain anonymous, as none of their statements will be attributed to them by name even after the completion of the final report. Each participant will receive an invitation letter with information about the study and an informed consent form. Participation and informed consent will be filled and sent back by email to the researchers.

Funding

There was no outside funding for this study

Details of the research team

Member of the steering committee are listed in table 2.

Table 2: Members of the steering committee

Name	Field of expertise	Research group
Carl Lachat (PI)*	Content	Gent University
Patrick Kolsteren	Epidemiology	Gent University
John Van Camp	Content	Gent University
Willem De Keyzer	Dietitian & nutritionist	Gent University (associated)
Danna Hawwash	Thesis student	Gent University
Marga Ocke*	Epidemiology/methodologist	RIVM
Hendriek Boshuizen	Statistician	RIVM
Inge Huybrechts*	Nutritionist	IARC
Nadia Slimani	Nutritionist	IARC
Graham Byrnes	Statistician	IARC

PI: Principal Investigator; * coordinator for each institution

The principal Investigator of this study is

Dr. Carl lachat

Department of Food Safety and Food Quality, Faculty of Bioscience Engineering Gent University (www.nutrition.ugent.be)

Coupure links 653, 9000 Gent, Belgium

+32 9 264 9377

Carl.lachat@ugent.be

References

T. Burrows, R. K. Golley, A. Khambalia, S. A. McNaughton, A. Magarey, R. R. Rosenkranz, M. Alllman-Farinelli, A. M. Rangan, H. Truby, and C. Collins. 2012. The quality of dietary intake methodology and reporting in child and adolescent obesity intervention trials: A systematic review. *Obes Rev* 13, no. 12: 1125-38.

Hsu Chia-Chien and A. Sandford Brian. 2007. The delphi technique…making sense of sonsensus. *Practical Assessment, Research & Evaluation* 12.

Vinette Cross. 1999. The same but different a delphi study of clinicians' and academics' perceptions of physiotherapy undergraduates. *Physiotherapy* 85, no. 1: 28-39.

M. Faber, F. A. Wenhold, U. E. Macintyre, E. Wentzel-Viljoen, N. P. Steyn, and W. H. Oldewage-Theron. 2013. Presentation and interpretation of food intake data: Factors affecting comparability across studies. *Nutrition* 29, no. 11-12: 1286-92.

Michael Nelson and Barrie M. Margetts. 1997. *Design conepts in nutritional epidmiology*. Ed second edition. New York: oxford university press.

D. Moher, K. F. Schulz, I. Simera, and D. G. Altman. 2010. Guidance for developers of health research reporting guidelines. *PLoS Med* 7, no. 2: e1000217.

D. Moher, L. Weeks, M. Ocampo, D. Seely, M. Sampson, D. G. Altman, K. F. Schulz, D. Miller, I. Simera, J. Grimshaw, and J. Hoey. 2011. Describing reporting guidelines for health research: A systematic review. *J Clin Epidemiol* 64, no. 7: 718-42.

L. Serra-Majem, L. Frost Andersen, P. Henrique-Sanchez, J. Doreste-Alonso, A. Sanchez-Villegas, A. Ortiz-Andrelluchi, E. Negri, and C. La Vecchia. 2009. Evaluating the quality of dietary intake validation studies. *Br J Nutr* 102 Suppl 1: S3-9.

I. Simera, D. Moher, J. Hoey, K. F. Schulz, and D. G. Altman. 2010. A catalogue of reporting guidelines for health research. *Eur J Clin Invest* 40, no. 1: 35-53.

I. P. Sinha, R. L. Smyth, and P. R. Williamso. 2011. Using the delphi technique to determine which outcomes to measure in clinical trials: Recommendations for the future based on a systematic review of existing studies. *PLoS Med* 8, no. 1.

J. P. Vandenbroucke, E. von Elm, D. G. Altman, P. C. Gotzsche, C. D. Mulrow, S. J. Pocock, C. Poole, J. J. Schlesselman, M. Egger, and Strobe Initiative. 2007. Strengthening the reporting of observational studies in epidemiology (strobe): Explanation and elaboration. *Epidemiology* 18, no. 6: 805-35.

Muhammad Imran Yousuf. 2007. Using experts' opinions through delphi technique. *Practical Assessment, Research & Evaluation.* 12.

Annex 1: Delphi round data collection instruments

Checklist to REport Food INtake Data "REFINED"

Round I Delphi

Please describe what should be reported under the different sections of a study that reports food intake data. You can add additional sections or elements if necessary.

Sections*	Item No	Describe what you recommend should be reported
Title and abstract	1	
Introduction		
Background / rationale	2	
Objectives	3	
Methods		
Study design	4	
Setting	5	
Participants	6	
Variables	7	
Data sources / measurements	8	
Bias	9	
Study size	10	
Quantitative variables	11	
Statistical methods	12	
Results		
Participants	13	
Descriptive data	14	
Outcome data	15	
Main results	16	
Other analysis	17	

Sections*	Item No	Describe what you recommend should be reported
Discussion		
Key results	*18*	
Limitations	*19*	
Interpretation	*20*	
Generalisability	*21*	
Other information		
Funding	22	
Supplementary material	23	
Other	24	

Sections are consistent with those of the Strobe statement for cross-sectional, case-control, cohort and observational studies http://www.strobe-statement.org . We added “supplementary material” and “other”.

Round II Delphi

The checklist will be developed based on the responses from Delphi round I and the face-to-face meeting after the Delphi, therefore the questions in this round will be based on the checklist and they will mainly assess whether the participant agree on each item on the list, therefore **agreement on the item, its description and ranking will be assessed using the following format**

Item	Description	Do you agree on the item *		Do you agree on its description		Do you agree on its ranking	
		Y/N	If not, motivate why	Y/N*	If not, motivate why	Y/N?	If not, motivate why
1							
2							
3							
4							

Round III Delphi

The checklist will be further improved based on the responses from Delphi round II and the face-to-face meeting that will follow, therefore the questions in this round will be based on the refined checklist and they will mainly assess whether the participant agree on each item on the list, therefore **agreement on the item, its description and ranking will be assessed using the same format used in Delphi round 2**

Item	Description	Do you agree on the item		Do you agree on its description		Do you agree on its ranking	
		Y/N	If not, motivate why	Y/N	If not, motivate why	Y/N?	If not, motivate why
1							
2							
3							
4							

Annex 2: Examples of existing checklist

STROBE Statement—checklist of items that should be included in reports of observational studies (http://www.strobe-statement.org)

Item	No	Recommendation
Title and abstract	1	(*a*) Indicate the study's design with a commonly used term in the title or the abstract
		(*b*) Provide in the abstract an informative and balanced summary of what was done and what was found
Introduction		
Background/rationale	2	Explain the scientific background and rationale for the investigation being reported
Objectives	3	State specific objectives, including any prespecified hypotheses
Methods		
Study design	4	Present key elements of study design early in the paper
Setting	5	Describe the setting, locations, and relevant dates, including periods of recruitment, exposure, follow-up, and data collection
Participants	6	(*a*) *Cohort study*—Give the eligibility criteria, and the sources and methods of selection of participants. Describe methods of follow-up *Case-control study*—Give the eligibility criteria, and the sources and methods of case ascertainment and control selection. Give the rationale for the choice of cases and controls *Cross-sectional study*—Give the eligibility criteria, and the sources and methods of selection of participants
		(*b*) *Cohort study*—For matched studies, give matching criteria and number of exposed and unexposed *Case-control study*—For matched studies, give matching criteria and the number of controls per case
Variables	7	Clearly define all outcomes, exposures, predictors, potential confounders, and effect modifiers. Give diagnostic criteria, if applicable
Data sources/ measurement	8*	For each variable of interest, give sources of data and details of methods of assessment (measurement). Describe comparability of assessment methods if there is more than one group
Bias	9	Describe any efforts to address potential sources of bias
Study size	10	Explain how the study size was arrived at
Quantitative variables	11	Explain how quantitative variables were handled in the analyses. If applicable, describe which groupings were chosen and why
Statistical methods	12	(*a*) Describe all statistical methods, including those used to control for confounding
		(*b*) Describe any methods used to examine subgroups and interactions
		(*c*) Explain how missing data were addressed
		(*d*) *Cohort study*—If applicable, explain how loss to follow-up was addressed *Case-control study*—If applicable, explain how matching of cases and controls was addressed *Cross-sectional study*—If applicable, describe analytical methods taking account of sampling strategy
		Cross-sectional study—Report numbers of outcome events or summary measures
		(e) Report any senstivitiy analysis

Item	No	Recommendation
Results		
Participants	13*	(a) Report numbers of individuals at each stage of study—eg numbers potentially eligible, examined for eligibility, confirmed eligible, included in the study, completing follow-up, and analysed
		(b) Give reasons for non-participation at each stage
		(c) Consider use of a flow diagram
Descriptive data	14*	(a) Give characteristics of study participants (eg demographic, clinical, social) and information on exposures and potential confounders
		(b) Indicate number of participants with missing data for each variable of interest
		(c) *Cohort study*—Summarise follow-up time (eg, average and total amount)
Outcome data	15*	*Cohort study*—Report numbers of outcome events or summary measures over time
		Case-control study—Report numbers in each exposure category, or summary measures of exposure
		Cross-sectional study—Report numbers of outcome events or summary measures
Main results	16	(*a*) Give unadjusted estimates and, if applicable, confounder-adjusted estimates and their precision (eg, 95% confidence interval). Make clear which confounders were adjusted for and why they were included
		(*b*) Report category boundaries when continuous variables were categorized
		(*c*) If relevant, consider translating estimates of relative risk into absolute risk for a meaningful time period
Other analyses	17	Report other analyses done—eg analyses of subgroups and interactions, and sensitivity analyses
Discussion		
Key results	18	Summarise key results with reference to study objectives
Limitations	19	Discuss limitations of the study, taking into account sources of potential bias or imprecision. Discuss both direction and magnitude of any potential bias
Interpretation	20	Give a cautious overall interpretation of results considering objectives, limitations, multiplicity of analyses, results from similar studies, and other relevant evidence
Generalisability	21	Discuss the generalisability (external validity) of the study results
Other information		
Funding	22	Give the source of funding and the role of the funders for the present study and, if applicable, for the original study on which the present article is based

*Give information separately for cases and controls in case-control studies and, if applicable, for exposed and unexposed groups in cohort and cross-sectional studies.

Example 2: STROFI (STrengthening the Reporting Of Food Intake)*: checklist of items that can be addressed in reports of food intake

	Item number	Recommendations
TITLE and ABSTRACT	1	Indicate in the title and/or abstract that *food intake* was assessed
INTRODUCTION		
Background/rationale	2	Explain the scientific background and rationale for assessing and reporting *food intake*
Objectives	3	State the aim or research question of the main study (if the reporting of food intake was a secondary objective)
	4	State the objective(s) of the reporting of *food intake*
METHODS (related to dietary assessment)		
Setting	5	Describe the context, location (*where*)
Time	6	Describe relevant dates (year) and time of year (season) when *food intake* data were collected (*when*)
Study population and sample	7	Describe study population and inclusion/exclusion criteria (*who*)
	8	Describe the sampling design, recruitment protocol, response rate and final sample size
Data source	9	State from whom/where data were obtained (unit of assessment)
	10	Indicate if secondary data analysis was done
Data collection related to dietary methodology	11	Specify dietary assessment technique using standard or clearly defined terminology; describe development of assessment tool (where needed). (If possible, provide access to assessment tool)
	12	Describe method(s) of food intake quantification (portion size estimation aids)
	13	Define reference period for dietary assessment
Data management	14	Describe how foods reported in household measures were converted to weights (if done)/coding principles/measures for quality assurance/data cleaning
	15	State assumptions made
	16	Provide the name, edition and date of food database used
	17	Specify how food grouping was done, including rationale for grouping
Statistical methods	18	Specify which statistical techniques were used
	19	Where relevant, provide formulae for calculations either in the text or as an addendum
	20	Check that the techniques used meet the study objectives
RESULTS		
Participants	21	Report sample numbers at each stage of study and for each assessment (missing data/withdrawals/ reasons for non-participation)
Food intake	22	Tabulate findings with very clear headings as to the nature of the content • if more than one dietary assessment methodology was used, clearly indicate the methodology • define what is meant by % consumers or per capita • define how foods were ranked (if done) • define foods grouped together • if not all foods are reported: define cut-off value for reporting foods • state denominator (for percentages and average intakes)
	23	Use footnotes to explain local food names/items
	24	Ensure that the results relate to the study objectives/questions
DISCUSSION		
Key results	25	Summarize in relation to objectives
Limitations	26	Specify potential bias, confounding or other shortcomings
Interpretation	27	Give a careful interpretation in terms of objectives, shortcomings, results from similar studies
Generalizability	28	Discuss external validity of study (representativeness/applicability to other people and settings)
OTHER INFORMATION		
Funding	29	Give sources of funding and the role of the funders for the present study. If applicable, also state funders of original work on which present publication is based.

* An adapted extension of STROBE [75].

Faber, M., et al. (2013). "Presentation and interpretation of food intake data: Factors affecting comparability across studies." Nutrition.

Annex 3: Invitation letter for Delphi participants

Dear Sir/Madam,

We contact you as an expert in dietary assessment methods to participate in the development of a food intake checklist to improve the quality of reporting food intake data. We aim to develop a checklist that is endorsed by journals and helpful to researchers internationally. The study is coordinated by Dr. Carl Lachat (Ugent, Belgium), Dr Inge Huybrechts (IARC, France) and Dr. Marga Ocké (RIVM, Netherlands).

The checklist will be developed with a multi-disciplinary group of people including methodologists, journal editors, statisticians, epidemiologists, and content experts. For this purpose, we organize a Delphi consultation by e-mail. A steering committee will discuss and summarize the input from the different participants to develop the checklist.

This mail initiates the first of three Delphi round. It includes open-ended questions to facilitate getting as many ideas and opinions as possible about items needed to be included in the checklist. This round is essential, as it will serve as the basic input for a first draft of the checklist. If you provide input, we will consider your suggestions during the update of the checklist and disseminate an updated draft of the checklist until consensus is reached.

We propose a deadline of two weeks for each of the Delphi rounds to receive your input and will send one reminder.

This study obtained Ethical clearance from Gent University on 10/12/2013 (B670201319178) and did not receive outside funding. The full protocol is available from the EQUATOR website.

Your privacy and anonymity will be guaranteed. Only the project promoter assisting in the review of the data and a researcher) will have access to raw information gathered.

Therefore, if you choose to participate in this study please return the informed consent signed by e-mail.

Thank you for your time

Kind regards,

Contact of the researcher:

Dana Hawwash

dana.hawwash@UGent.be

Principal Investigator:

Dr. Carl Lachat

Department of Food Safety and Food Quality

Coupure Links 653, 9000 Gent, Belgium

Tel: 00 32 9 264 61 63,

carl.lachat@UGent.be

Annex 4: Informed consent form

Checklist to REport Food INtake Data "REFINED"

Informed consent form

Before you agree to participate in this study, you need to be aware that:

- This study was cleared by the Ethical Review Board of the Ghent University.
- This clearance is not to be taken as an obligation to take part in this study.
- Your participation is only voluntary. If you wish, you can withdraw from this study at any point, even after providing consent. You can withdraw by contacting the researchers through email or telephone. You do not have to motivate or explain the decision of withdrawal.
- You can revise your answers to the questions if you wish so.
- Your input will be stored anonymously; researchers not involved in the data collection will not have access to your personal data and name.
- You can contact the researcher or the coordinator of the project at any time if you wish to obtain more information regarding this study.
- There are no risks related to your participation in this study. However, in accordance to the Directive concerning experiments on humans (07/05/2004), an insurance with faultless responsibility has been foreseen for the unlikely event that you receive any injury or damage due to the participation in this study.

I declare that I have been informed about the purpose of this study and understand that I can refuse to answer a particular question and withdraw when I like. My name won't be associated in any publication with the collected information. I accept that there is neither remuneration nor direct benefit for me.

My consent will be confirmed by returning following statement by email:

"*I hereby consent to participate in the Delphi round consultation for the development of a food intake checklist and understand that my views and opinions will be treated confidentially*."

Researcher
Dana Hawwash

dana.hawwash@UGent.be

Project coordinator
Dr. Carl Lachat

carl.lachat@UGent.be

Annex 5: Invitation letter for a validation study of a food intake guideline

Dear Sir, Madam,

We like to invite to participate in the validation of a checklist for reporting food intake studies. The development of the checklist is aims to improve the quality of reporting food intake studies through developing a guideline statement that can be used when researchers report a food intake study.

This study is a collaboration project between researchers from: Gent University in Belgium, the nutrition and metabolism section at the WHO International Agency for Research on Cancer (IARC) in France, and the National Institute for Public Health and the environment (RIVM) in the Netherlands. A valid recognized method was used to develop a guideline report for food intake studies, using consensus activities. Agreement regarding the checklist was reached in both formal and informal consensus. Formal included face-to-face meetings while informal was limited to Delphi rounds through web communications. The study is already registered on the EQUATOR network. An expected outcome of this initiative is the development of a universal checklist that will be published and endorsed by multiple journals.

At this stage of the research, the newly developed checklist must be tested before its dissemination. The aim of the testing is to check measurement agreement and the reliability of the checklist. One valid method to verify this is by developing a scoring system for the checklist to assess the quality of already reported food intake studies. Items on the list are given a certain weight of the final score depending on the importance of inclusion during reporting. This scoring system will be used to score two selected food intake studies.

You have been identified as a potential participant to take part in the checklist pre-testing activity and therefore the present letter seeks to provide information about the research so that you become well aware of its implication in the case you decide to participate in it.

Two selected food intake studies will be emailed to you together with the scoring checklist as soon as you sign the informed consent. You will be given duration of two weeks to read the studies, and assess the quality of their reporting, through giving a certain score for items mentioned on the checklist depending on whether they are reported and if so, the quality of the reporting. Then you have to send the two-scored checklists back with a score for each study.

The length of scoring the studies depends on the effort and time you put into it, and your willingness to reply.

The piloting of the checklist will start on the 10th of April, and we would appreciate if you could submit your answers before the 25th of April 2014.

You are not obligated to participate in this study and you may withdraw at any time. Nevertheless, it is very important to participate to have representative data for analysis, and for you to contribute to the development of a better checklist that will be endorsed and published where you can also benefit from it as this guideline should assist in improving the quality of reporting food intake data. The results will be given at the end of the study and we will still be able to discuss it at that time if you wish.

In accordance to the Directive concerning experiments on humans (07/05/2004), insurance with faultless responsibility has been foreseen for the unlikely event that you receive any injury or damage due to the participation in this study.

It is important to note that privacy and anonymity will be guaranteed. Only the project promoter assisting in the review of the data and myself will have access to raw information gathered.

Therefore, if you choose to participate in this please fill in the informed consent, and send it back to me

Thank you for your time

Kind regards,

Dana Hawwash

Contacts

Researcher
Dana Hawwash
dana.hawwash@UGent.be

Principal Investigator
Dr. Carl Lachat
Department of Food Safety and Food Quality
Coupure Links 653, 9000 Gent, Belgium
Tel: 00 32 9 264 61 63,
carl.lachat@UGent.be