



## PROJECT DELIVERABLE REPORT

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JOINT PROGRAMMING INITIATIVE – A HEALTHY DIET FOR A HEALTHY LIFE EUROPEAN NUTRITION PHENOTYPE ASSESSMENT AND DATA SHARING INITIATIVE

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## SCOPE

Scope of this deliverable document (D4.5), connected to Task 4.5, was the improve quality of data reporting guidelines for nutritional studies.

## REPORTING GUIDELINES FOR HEALTH STUDIES

Reporting guidelines are publications that providing guidance on what to include in a full and accurate description of a study, differentiating what information would be “nice” to include vs. what must be included. They are not only directed to help the writer of a scientific work in accurately describe what they have done, but can be considered as crucial part of the scientific process itself, being also directed to reviewer, editors, and publishers (O’Connor, 2010). In practical terms, a reporting guideline is a checklist, flow diagram, or explicit texts guiding authors meet certain standards, by providing sets of rules or principles to be followed (Moher et al., 2011; Simera et al., 2010). They usually follow the structure of a research paper, defining rules for every section (i.e. title, abstract, introduction, methods, results, discussion and conclusion). Carefully developed reporting guidelines provide authors with a minimum set of items that need to be addressed (Moher et al., 2011).

Main goals of a reporting guideline can be summarized as follows:

- Report in details how a study was conducted enables repeatability of the results;
- Readers, reviewer, and editors can better assess the impact of bias on the study and its conclusion;
- Saving time in research on big databases (such as PUBMED), facilitating the filtering out of uninteresting results;
- Consequently, improve the capacity of data extraction for reviews and meta-analysis;
- Fulfil an ethical obligation to maximize the utility of research findings

Similarly to what has happened with ontologies in the biomedical field, the growing interest in reporting guidelines has led to the development of a high number of them, threatening the creation of confusion from the multiple standardization efforts (Moher et al., 2011; Simera et al. 2008). For this reason, the EQUATOR Network was created as a central repository and organization for improving the quality of reporting guidelines, with similar intentions of the OBO Foundry in the ontology field (see D4.1 and D4.2). A comprehensive list of reporting guidelines is available at their website (<http://www.equator-network.org/>), together with toolkits and flow chart to choose the most suitable reporting guideline for a researcher’s article. The EQUATOR team collaborates and coordinates with all the all key stakeholders in publication of health research, boosting the quality of publication outcomes.

## EXTENSION OF THE REPORTING GUIDELINES TO THE NUTRITIONAL FIELD

Recently, Carl Lachat, one of the partners of ENPADASI involved in WP2, has developed and published a reporting guideline for nutritional epidemiology and dietary assessment research, by extending the STROBE statement into the STROBE Extension for Nutritional Epidemiology (STROBE-nut) (Lachat et al., 2016). Though not directly developed as an ENPADASI action, the authors clearly refer to a possible application of STROBE-nut for the ENPADASI project, and it adheres to the goals set for this deliverable.



We believe that this work needs little no adjustments and we are thus presenting here a summary of the manuscript, referring the reader to the original publication for further details on the methodology adopted and on the nutritional recommendation developed.

## THE STROBE REPORTING GUIDELINES

The work of Lachat and colleagues represents an extension of already existing reporting guidelines, tailored on the needs of nutritional sciences. Here we will briefly introduce the STROBE statement at the base of their work.

The “Strengthening the Reporting of Observational Studies in Epidemiology” (STROBE) statement (Vandenbroucke et al., 2007) is a checklist of items providing general reporting recommendations for descriptive observational studies and studies that investigate associations between exposures and health outcomes. STROBE addresses the three main types of observational studies: cohort, case-control and cross-sectional studies. Since its release, STROBE was used as a basis for the development of other guidelines; EQUATOR network repository reports a total of 13 extensions (<http://www.equator-network.org/reporting-guidelines/strobe-nut/>).

The STROBE checklist is composed of 22 items, related to title, abstract, introduction, methods, results and discussion sections of articles. As an example, we will report one of the statement part of STROBE, regarding guideline for title and abstract.

- ✓ **Recommendation n° 1a: Indicate the study's design with a commonly used term in the title or the abstract.**

A research article should clearly, and with defined/standardized words, report the study design adopted in title and/or abstract section. Fulfilling this recommendation has a twofold advantage:

- Title and abstract are the first and main part a researcher/editor will read while deciding whether or not to consider a publication (i.e. while deciding whether or not to continue in reading). Clearly state the study design facilitate this operation, and boost manuscript visibility.
- Moreover, explicitly state the study design also help a correct indexing of the manuscript in electronic databases, increasing the probability to be included in query results, and with a high position

## STROBE-NUT REPORTING GUIDELINE

Figure 1 reports the original table from the manuscript. As it is visible, both the original STROBE recommendation and, if present, the relative extension(s) for nutritional sciences are indicated. Extension are highlighted by the prefix nut- and a number, indicating to which STROBE recommendation the extension is referred.

As an example, we will report one of the extension part of STROBE-nut, extending recommendation n° 1 of STROBE, and regarding guideline for title and abstract.

- ✓ **Recommendation n° nut-1: State the dietary/nutritional assessment method(s) used in the title, abstract or keywords.**



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The same motivation previously indicated for recommendation 1 of STROBE, can be applied to recommendation nut-1 of STROBE-nut. Nevertheless, STROBE-nut also introduce the possibility of specifying the dietary/nutritional assessment method(s) used in keywords section of the manuscript, as also keywords are important for indexing in electronic databases.



Item	Item Number	STROBE Recommendations	Extension for Nutritional Epidemiology Studies (STROBE-nut)
<b>Title and Abstract</b>	1	(a) Indicate the study's design with a commonly used term in the title or the abstract.	<b>nut-1.</b> State the dietary/nutritional assessment method(s) used in the title, abstract, or keywords.
		(b) Provide in the abstract an informative and balanced summary of what was done and what was found.	
<b>Introduction</b>			
Background Rationale	2	Explain the scientific background and rationale for the investigation being reported.	
Objectives	3	State specific objectives, including any prespecified hypotheses.	
<b>Methods</b>			
Study Design	4	Present key elements of study design early in the paper.	
Settings	5	Describe the setting, locations, and relevant dates, including periods of recruitment, exposure, follow-up, and data collection.	<b>nut-5.</b> Describe any characteristics of the study settings that might affect the dietary intake or nutritional status of the participants, if applicable.
Participants	6	(a) Cohort study—give the eligibility criteria and the sources and methods of selection of participants. Describe methods of follow-up.	<b>nut-6.</b> Report particular dietary, physiological, or nutritional characteristics that were considered when selecting the target population.
		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.	
Variables	7	(b) Cohort study—for matched studies, give matching criteria and number of exposed and unexposed.	<b>nut-7.1.</b> Clearly define foods, food groups, nutrients, or other food components.  <b>nut-7.2.</b> When using dietary patterns or indices, describe the methods to obtain them and their nutritional properties.
		Case-control study—for matched studies, give matching criteria and the number of controls per case.	
		Clearly define all outcomes, exposures, predictors, potential confounders, and effect modifiers. Give diagnostic criteria, if applicable.	
Data Sources—Measurements	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.	<b>nut-8.1.</b> Describe the dietary assessment method(s), e.g., portion size estimation, number of days and items recorded, how it was developed and administered, and how quality was assured. Report if and how supplement intake was assessed.
			<b>nut-8.2.</b> Describe and justify food composition data used. Explain the procedure to match food composition with consumption data. Describe the use of conversion factors, if applicable.
			<b>nut-8.3.</b> Describe the nutrient requirements, recommendations, or dietary guidelines and the evaluation approach used to compare intake with the dietary reference values, if applicable.
			<b>nut-8.4.</b> When using nutritional biomarkers, additionally use the STROBE Extension for Molecular Epidemiology (STROBE-ME). Report the type of biomarkers used and their usefulness as dietary exposure markers.
			<b>nut-8.5.</b> Describe the assessment of nondietary data (e.g., nutritional status and influencing factors) and timing of the assessment of these variables in relation to dietary assessment.
			<b>nut-8.6.</b> Report on the validity of the dietary or nutritional assessment methods and any internal or external validation used in the study, if applicable.
Bias	9	Describe any efforts to address potential sources of bias.	<b>nut-9.</b> Report how bias in dietary or nutritional assessment was addressed, e.g., misreporting, changes in habits as a result of being measured, or data imputation from other sources.
Study Size	10	Explain how the study size was arrived at.	

Figure 1- continue: STROBE recommendation and STROBE-nut extension. From: Lachat C, Hawwash D, Ocké MC, Berg C, Forsum E, et al. (2016) Strengthening the Reporting of Observational Studies in Epidemiology—Nutritional Epidemiology (STROBE-nut): An Extension of the STROBE Statement. PLOS Medicine 13(6): e1002036. <https://doi.org/10.1371/journal.pmed.1002036>



Quantitative Variables	11	Explain how quantitative variables were handled in the analyses. If applicable, describe which groupings were chosen and why.	<b>nut-11.</b> Explain the categorization of dietary/nutritional data (e.g., use of N-tiles and handling of nonconsumers) and the choice of reference category, if applicable.
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. (e) Describe any sensitivity analyses.	<b>nut-12.1.</b> Describe any statistical method used to combine dietary or nutritional data, if applicable.  <b>nut-12.2.</b> Describe and justify the method for energy adjustments, intake modeling, and use of weighting factors, if applicable.  <b>nut-12.3.</b> Report any adjustments for measurement error, i.e., from a validity or calibration study.
<b>Results</b>			
Participants	13	(a) Report the numbers of individuals at each stage of the study—e.g., numbers potentially eligible, examined for eligibility, confirmed eligible, included in the study, completing follow-up, and analyzed. (b) Give reasons for nonparticipation at each stage. (c) Consider use of a flow diagram.	<b>nut-13.</b> Report the number of individuals excluded based on missing, incomplete, or implausible dietary/nutritional data.
Descriptive Data	14	(a) Give characteristics of study participants (e.g., demographic, clinical, and social) and information on exposures and potential confounders. (b) Indicate the number of participants with missing data for each variable of interest. (c) Cohort study—summarize follow-up time (e.g., average and total amount).	<b>nut-14.</b> Give the distribution of participant characteristics across the exposure variables if applicable. Specify if food consumption of total population or consumers only were used to obtain results.
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 (e.g., 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.	<b>nut-16.</b> Specify if nutrient intakes are reported with or without inclusion of dietary supplement intake, if applicable.
Other Analyses	17	Report other analyses done—e.g., analyses of subgroups and interactions and sensitivity analyses.	<b>nut-17.</b> Report any sensitivity analysis (e.g., exclusion of misreporters or outliers) and data imputation, if applicable.
<b>Discussion</b>			
Key Results	18	Summarize key results with reference to study objectives.	
Limitation	19	Discuss limitations of the study, taking into account sources of potential bias or imprecision. Discuss both direction and magnitude of any potential bias.	<b>nut-19.</b> Describe the main limitations of the data sources and assessment methods used and implications for the interpretation of the findings.
Interpretation	20	Give a cautious overall interpretation of results considering objectives, limitations, multiplicity of analyses, results from similar studies, and other relevant evidence.	<b>nut-20.</b> Report the nutritional relevance of the findings, given the complexity of diet or nutrition as an exposure.
Generalizability	21	Discuss the generalizability (external validity) of the study results.	
<b>Other Information</b>			
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.	
Ethics			<b>nut-22.1.</b> Describe the procedure for consent and study approval from ethics committee(s).
Supplementary Material			<b>nut-22.2.</b> Provide data collection tools and data as online material or explain how they can be accessed.

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Figure 1- continued: STROBE recommendation and STROBE-nut extension. From: Lachat C, Hawwash D, Ocké MC, Berg C, Forsum E, et al. (2016) Strengthening the Reporting of Observational Studies in Epidemiology—Nutritional Epidemiology (STROBE-nut): An Extension of the STROBE Statement. *PLOS Medicine* 13(6): e1002036. <https://doi.org/10.1371/journal.pmed.1002036>



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