A FOUNDATION FOR EVIDENCE-BASED MANAGEMENT OF NUTRIGENOMICS EXPECTATIONS AND ELSIS

A project by the OMICS-ETHICS research group aiming at laying an empirical foundation that could discern and anticipate the socio-ethical issues associated with NGx research and its potential applications. For more details and contacts, please visit our website at http://www.omics-ethics.org/en/research-projects-nutrigenomics.

Methodology of the first phase: literature review, data extraction and analysis

A. Sample and analysis

We performed a systematic review of clinical studies in nutrigenetics and nutrigenomics published since 1998 until 2007 inclusively. Studies for potential inclusion were identified through a PubMed search. As nutrigenomics is a recent word that was indexed and introduced as a MeSH category encompassing nutrigenetics in PubMed only as of 2008, we completed our search with different combinations of the following key words: ‘food’, ‘nutrient’, ‘diet’, ‘gene’, ‘interaction’, and ‘association’. The search was limited to titles and abstracts of original articles and reviews; commentaries and letters were excluded. Based on the NIH definition [1], all intervention and/or observational studies that involved human beings as participants were considered as clinical studies, while studies limited to the analysis of human cells or tissues only, with no other active human participation than tissue or cell donation, were excluded. Moreover, to be included in our sample, studies had to meet the following criteria: (1) having a specific gene component (e.g. candidate gene or polymorphism); (2) having a dietary component: nutrient (from...
the diet or as a supplement), food, dietary pattern (e.g. Mediterranean diet), etc., and (3) describing an interaction between (1) and (2) that may impact health, disease onset, or nutritional biological pathways. A total of 173 studies met these criteria. These publications constituted the sample upon which we performed a detailed content analysis. The data extracted from these publications for this first phase of this project were: (a) the authors’ geographical location; (b) the participants’ geographical location; (c) the participants’ particulars, such as race, ethnicity, origin, nationality, ancestry, age, sex, comorbidities, and any other available data linked to participants’ description, as well as any exclusion and inclusion criteria reported by the authors. The description of participants was completed in many cases with the tables provided by the authors to present their results. The following elements were also extracted from the publications of our sample: (d) all authors’ statements or comments about the potential or actual impact of genetic variations linked to ethnicity, and (e) all limitations of the study results explicitly acknowledged and reported by the authors. It has to be noted that in 120 of the 173 publications of our sample (hereafter ‘referring publications’), the authors referred to previous publications and/or previous or ongoing studies (hereafter ‘referred publications’) for the description of the methodology of their study, and/or of their participants or of their selection. Consequently, we consulted all referred publications (190 publications) to gather as much information as possible about the participants’ location, age, and ethnic origin.

As the goal of this first phase of our study was also to investigate whether scientific articles could be a source of biohype, we used a method that involves the study of the context in which claims, especially interpretative claims, are made in the scientific literature. An interpretative claim occurs when authors “refer to the broader implications of research findings . . .” [2, p. 11]. Ours goals were to examine i) whether such claims could be found in the articles reporting nutrigenetics study results, and ii) whether
articles containing such claims reported the methodological limitations of the study and explicitly acknowledged the impact of these limitations when extrapolating the results to clinical applications. In order to identify any claims that could make scientific journal articles a potential source of biohype and document their prevalence, the “main statements about the utility and scope of the study results” were extracted from each article. These statements were usually found either in the discussion or in the conclusion section of the articles. The “main statements about the utility or the scope of the results of the study” such as reported in the 173 articles were assessed to identify interpretative claims, i.e. explicit statements about potential clinical applications that were extrapolated from the study results. In order to evaluate the extent of the gap between extrapolated clinical applications and their actual achievability given the methodological limitations involved in any given study, the following data were extracted from the articles: a) the gene and polymorphism under study; b) the food component under study; c) the study design; d) the tools used for the assessment of dietary intakes; e) the size of the studied population; f) the impact of genetic variations under study; g) the main statements about utility and scope of the study results; and h) all limitations of the study results explicitly reported and, if it is the case, acknowledged by the authors. A detailed content analysis was subsequently performed.

B. Limitations

Given the recent use of the terms ‘nutrigenomics’ and ‘nutrigenetics’, the results of our search for clinical studies in this field is likely limited by the key words (and combinations) that we chose. Nutrigenetics and nutrigenomics cover disparate fields and complex mechanisms that can be described in many different ways. Thus, our sample might not include all clinical studies that could have been identified with other key words and that could have met the three selection criteria mentioned above.
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Studies that only measured gene expression, without pointing out and referring to a particular polymorphism or specific DNA sequence(s) or variation were also excluded.

We could only identify the participant exclusion or inclusion criteria that were explicitly reported by the authors in their publications or that could be inferred from population sample descriptions such as provided in the publications. Yet, only a full review of research protocols could give a real picture of the explicit exclusion or inclusion criteria used in nutrigenetics research. As mentioned above, 120 ‘referring’ publications referred those readers interested in getting more information about the participants or the methodology of the study to one or several previously published papers (‘referred publications’). Yet, 30 of referring publications provided us with one or more references which we could not access (e.g. papers or books not accessible on the Internet or not accessible without fees from the electronic journals and library databases of our university). Moreover, 14 referring publications referred to an ongoing or previous study from which participants were recruited or in which participants took part but for which they did not provide any explicit reference in their bibliography. In 4 of these referring 120 publications, the references given for the description of the methodology, the participants and/or their selection were inaccurate (e.g. reference to the abstract of a poster at a symposium, an incomplete reference, a reference to a theoretical paper that contributed no useful information about the participants of the referring study, etc.). Finally, instead of providing the expected full description of the methodology of the study and/or of the participants, several referred papers turned to other previous publications for the same purpose (and in turn, some of the latter publications referred the readers to even earlier papers for the same descriptions). We did not extend our analysis of
references beyond the references provided by referring\(^1\) publications.

Finally, we cannot demonstrate that the articles in which we identified interpretative claims were actually read or used by the media – or the general public, or policymakers – and that they were therefore an actual source of biohype. Nevertheless, it is worth noting that these articles contributed to the development of the field of nutrigenetics in a manner similar to all the articles of our initial sample, if we refer to the number of times each article has been cited in the published literature and to the impact factor of the journals.

**References**


\(^1\) Please note that the October 2012 version of this document stated that “We did not extend our analysis of references beyond the references provided by referred publications” instead of “[...] by referring publications”. We apologize for this error, which did not affect the validity of our results.