



**COLLEGE OF DIETITIANS
OF ALBERTA**

Nutrigenomics in Dietetic Practice

College of Dietitians of Alberta Position Statement

March 2015

The College has prepared this communication and position statement in follow up to inquiries about the role of Registered Dietitians and nutrigenomics screening. Some of the questions coming forward have been:

- Is using nutrigenomics screening tools within the Dietitian's scope of practice?
- Are there conflicts of interest in using these tests?

We answer these questions, and several relevant others, within the following communication.

Executive Summary:

Nutrigenomics is the study of how the human genome and/or genes interact with diet to influence individuals' and populations' responses to food and disease susceptibility. As a promising emerging field of science and application in dietetic practice, Registered Dietitians considering utilizing nutrigenomics screening tools must be competent to practice in this area and shall review the supporting literature, including attention to the study population sample demographics. Registered Dietitians are required to practice ethically, obtain informed consent, respect the confidentiality and privacy of client information, disclose conflicts of interest, and communicate openly.

What is nutrigenomics?

Within the field of dietetics, nutrigenomics has been summarized as the study of how individual genetic variation may affect a person's response to ingested foods and individual nutrients (1, 2). The interaction between genetics and nutrition traditionally involved both nutrigenetics (how genetic variations modify an individual's response to diet) and nutrigenomics (how nutrients impact gene expression) (2).

The OMICS-ETHICS Research Group out of the University of Montreal indicates that a strict definition of nutrigenomics and nutrigenetics is difficult, as often happens with emerging health technologies and new fields of inquiry. A distinction between nutrigenomics and nutrigenetics is often blurred by various and sometimes conflicting definitions, and despite notable differences, both terms are still commonly used interchangeably. For our purposes the term “nutrigenomics” will be used to describe the overlap between both concepts, as it aims to understand how nutrients and other food components influence genome/gene(s) expression and also how the genome/gene(s) of individuals may impact response to diet (3).

Beyond general understanding of the molecular mechanisms involved in nutrition and health, nutrigenomics research often tends to focus on knowledge that could be used by individuals to customize their diet, which may help to modify disease risk and promote well-being (3). Nutrigenomics may offer a new application context for genomics technologies and research, focusing on this bidirectional study of genetic factors influencing individuals' responses to diet and the effects of bioactive constituents in food on host genome and gene expression (4), however it is not a new concept. In some forms, nutrigenomics has been around for many years (e.g. phenylalanine reduced diet for PKU (2)). The main goal of nutrigenomics research is to examine how the interaction between genes and diet can positively influence human health (5), and therefore as research on the human genome continues, there will continue to be a growing body of evidence and new information on nutrition and the interaction with genetic factors, which may have application to dietetic practice.

Nutrigenomics screening tests or kits, currently available through several companies in Canada, are based on scientific research conducted on specific study populations; these genetic risk assessment tools provide information on how an individual responds to various dietary components, which may impact their risk for chronic disease. Registered Dietitians are using these tools to incorporate a client's genetic profile into nutrition assessment, which allows for more precise dietary advice.

When tailoring a person's nutritional intake to his or her genetic profile, the benefits of nutrition for optimal health may be enhanced when using available nutrigenomics information. The importance of diet to sustain health, prevention and treatment of diseases has been known for a long time. However, the advent of new research tools such as high-throughput “omics” technologies and bioinformatics has recently enabled researchers to go deeper in the analysis of the complex mechanisms that are involved in the way our bodies process and respond to food and thus, ultimately

impact human health and well-being. Notably, the knowledge of the human genome has dramatically broadened the scope of studies in nutrition science (3).

Sample collection processes vary by company, however in general a cheek swab or saliva sample is given by the client and the sample is sent for analysis. A risk assessment is provided in writing to the RD (or client depending on the company's processes).

The allure of nutrigenetics/omics is strong, and although the College is not discouraging Registered Dietitians from considering the use of nutrigenomics screening tools in practice, the College cautions regulated members that because this is a relatively new field, with the potential for ethical-legal-social considerations related to the research methodologies utilized in this field (3), Registered Dietitians wishing to practice in this area must be: well-informed on the research supporting the various tools available, including the research methodologies employed and the limitations in study design; remain current on the ongoing changes to the perspectives of experts in the field; and practice ethically and safely in the client's best interest.

What are some of the professional practice considerations for RDs related to nutrigenomics screening?

1. Is nutrigenomics within my "scope of practice"?

The Practice Statement for Registered Dietitians and Registered Nutritionists is found in Schedule 23 of the *Health Professions Act* in Alberta and includes in this statement (6):

“in their practice Registered Dietitians and Registered Nutritionist do one or more of the following:

- (a) assess nutritional status and develop, implement and evaluate food and nutrition strategies and interventions to promote health and treat illness.”

Assessment of nutritional status generally includes a comprehensive evaluation consisting of a diet and/or relevant medical history, physical examination, laboratory assessment, anthropometric assessment, and at times body composition analysis, and/or functional data assessment. In regards to nutrigenomics, these same factors would be taken into consideration during nutritional assessment and evaluation, with the additional risk assessment data provided from a nutrigenomics screening tool to guide the implementation of strategies and interventions to promote health. Despite this supplemental information, it is still necessary to understand fully the client's nutritional needs, and ultimately to assist him or her in making behavior changes in order to achieve optimal health.

Registered Dietitians are required to maintain professional competence in their area of specialty (see *Standards of Practice*, Standard 6. Competence) (7). As with any area of practice within dietetics, Dietitians may consider the use of innovative tools in their practice (such as nutrigenomics screening tools) so long as they understand the field of study, its limitations and benefits to individual clients based on current and up to date

knowledge in the field, and feel competent in their knowledge and skill in the area. It is essential that all regulated health professionals practice only within their area of competence. Each has the obligation to provide safe, ethical best practice.

2. *Scientific evidence for nutrigenomics screening tools:*

Scientific evidence in support of nutrigenomics screening is strong in several areas (5) impacting nutrition recommendations. When undertaking any new skill in your practice, it is always important that the Registered Dietitian do his / her homework and practice from an evidence-informed perspective. Examine the scientific literature and conduct a critical appraisal of the evidence behind the screening tools, including an analysis of research methodologies and population sample selection to determine appropriate application of various companies' products and tools to individual clients. Utilize professional judgment to support (or refute) the use of nutrigenomics screening with appropriate clients in your practice.

Specifically, one of the identified ethical-legal-social considerations in this area of research relates to the fact that ethnicity matters (3). It has been noted that research subjects are often adults of "caucasian" ethnicity, or more troublesome, that the ethnicity of research subjects has not been noted at all. Translation of research findings to all ethnicities and population demographics, including the elderly, infants, children and pregnant woman may be limited due to the scarcity of research conducted in these specific sub groups (3). Because there may be challenges in applying research findings broadly to every person in a population, the College suggests Registered Dietitians take this point into consideration when reviewing the applicability of research and its methodologies/design to the general population and when translating this information to assist clients in modification of chronic disease.

3. *What are the patient health information concerns with nutrigenomics screening and data management?*

It should be made clear to all clients who may be in the position to request nutrigenomics screening that this testing is a risk assessment tool only, and is in no way diagnostic (5). It is meant to provide the regulated health professional and/or client with information on *the risk* of altered response to dietary components which may affect nutritional status (5). These tools do not identify deficiencies or specific chronic disease, but identify potential for disease risk, which may be modulated by altering nutritional intake. As noted above, it should also be made clear that research methodologies used in the original science may limit the applicability of results to individual clients (for example, related to ethnicity and age of study group participants) in some cases (3).

Privacy and confidentiality:

The privacy and confidentiality of client information is paramount. Details of Registered Dietitian conduct, related to the confidentiality of client/patient information, is found in the College's *Code of Ethics* (8). The client must consent to the collection, use and/or

disclosure of their health information by a Registered Dietitian, and it is the Registered Dietitian's obligation to protect that information once collected.

Informed consent:

The client must also provide informed consent related to nutrigenomics screening, therefore it is the obligation of the Registered Dietitian to provide sufficient information to enable clients to make decisions about recommended services including information about expected benefits, risks, options and alternatives to nutrigenomics screening (8, 9).

Prior to obtaining consent to nutrigenomics testing, the Registered Dietitian should address the rationale and nature of the test with the client; the cost of the test; how the sample will be obtained; who will analyze the results; what will happen to the data following collection; alternatives to nutrigenomics testing; advantages and disadvantages, benefits and risks of nutrigenomics testing; and answer any questions or concerns of the client.

It should also be noted that any reputable company selling screening kits will have their own consent forms, identifying all of the points noted above. The Registered Dietitian is encouraged to review consent forms carefully and be comfortable with the content and/or address any concerns with the company directly before utilizing the kit.

Client consent to disclosure:

Clients must also provide consent to disclosure of any personal health information to third parties such as insurance companies and employers, including the results of any genetics screening; the client has the right to refuse disclosure if requested (9).

Please refer to the Chapters on Confidentiality and Consent to Treatment found in the *Professional Practice Handbook for Dietitians in Alberta* (9) available on the College website for more information on these topics.

4. Are there any conflicts of interest to consider when using nutrigenomics screening tools?

A conflict of interest occurs when a professional has an obligation to promote one interest, but promotes another instead, for example when the professional stands to profit or benefit personally by promoting the competing interest (9). Conflicts of interest can negatively influence professional judgment.

In the case of nutrigenomics or any emerging area of practice, the RD has a professional responsibility to recommend approaches to nutrition care that are client-centered and meet the client's needs, not those of the professional. The Dietitian can not be seen to benefit personally or professionally, for example for monetary gain or research opportunity, outside of the consultation fee and reimbursement for screening kit costs. For example, if the Registered Dietitian purchases a screening kit to use as part of his/her practice with the client, it should be explained what the Dietitian's fees include related to the assessment the client is undertaking.

It is also the Dietitian's responsibility to ensure that the company chosen to use for screening is credible, practices professionally, has good science behind its tools and is not further benefiting from client naiveté in this new area, for example, by selling costly vitamin and mineral supplements as an adjunct to the results.

When discussing nutrigenomics screening with clients, RDs must manage any real or perceived conflicts of interest by identifying and/or disclosing any potential conflicts of interest (9). They must indicate all options the client has related to the test, including declining consent to the test, and reassuring clients that their care will not be compromised regardless of decision to proceed or not. The client should be reminded of the cost of the test and the cost of the time for counseling related to the results.

5. Are there any other ethical issues to consider?

Nutrigenomics testing may lead to preventive measures, but there are concerns that only the individuals who can afford to pay for these services may be able to benefit from them (2).

Registered Dietitians should inform clients that recommendations made by some testing companies may be aimed at encouraging clients to purchase nutrient products that may not be significantly different from readily available products. Dietitians should be aware of which companies make these recommendations. RDs should inform their clients about the availability of comparable products, including readily available foods, which would meet nutritional recommendations made by a given company (2).

6. Communication

Excellent communication skills are paramount to the successful practice of Registered Dietitians. The Registered Dietitian should be transparent and clear with clients that nutrigenomics is a screening tool, which may have limitations in its broad application, and is not meant for diagnostic purposes. It should be made clear that the screening kits may identify potential for chronic disease and therefore recommendations may modify the risk.

The RD should clearly discuss the pros and cons, the risks and benefits, and the alternatives to nutrigenomics screening so the client can provide informed consent should they decide to move forward with screening assessment.

If you have questions or require more information on Nutrigenomics in practice, please contact the College office.

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