



# Consensus Report of the Academy of Nutrition and Dietetics: Incorporating Genetic Testing into Nutrition Care



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## ABSTRACT

Personalization of nutrition advice is a process already familiar to registered dietitian nutritionists, but it is not yet clear whether incorporating genetic results as an added layer of precision improves nutrition-related outcomes. Therefore, an independent workgroup of experts, supported by the Academy's Evidence Analysis Center staff, conducted a systematic review to examine the level of evidence measuring the effect of incorporating genetic testing results into nutrition counseling and care, compared to an alternative intervention or control group, on nutrition-related outcomes. This systematic review revealed that only weak quality evidence is available in the scientific literature and observed that this field is still maturing. Therefore, at present, there is insufficient scientific evidence to determine whether there are effects of incorporating genetic testing into nutrition practice. The workgroup prepared this Consensus Report based on this systematic review to provide considerations for the practical application of incorporating genetic testing into the nutrition care process.

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## CONSENSUS STATEMENT

There is insufficient evidence from randomized controlled trials regarding the effectiveness of incorporating nutrigenetic testing into nutrition counseling or care and reporting dietary or clinical outcomes at present. However, research on the application of nutritional genomics to practice is in its infancy, and registered dietitian nutritionists should keep abreast of ongoing developments through continuing education. Just as we have with medical nutrition therapy for inborn errors of metabolism, registered dietitian nutritionists are in a position to establish themselves as objective experts in utilizing nutritional genomics to individualize care by remaining transparent about existing evidence, applying clinical expertise and training, and participating in research where possible.

**I** NCREASING KNOWLEDGE OF THE structure and function of the human genome has provided an opportunity to investigate the associations among genetics, nutrition, and health. The use of nutrition-related genetic information to optimize health

outcomes has gained traction among registered dietitian nutritionists (RDNs). RDNs already provide evidence-based nutrition advice that is personalized, such as advice based on existing dietary intake, lifestyle characteristics, phenotypes, client goals, and learning styles.<sup>1,2</sup> Now that genetic testing is more widely available, RDNs need to know whether the incorporation of genetic testing results into the nutrition care process has the potential to improve nutrition-related outcomes beyond usual care.

In 2014, the Academy of Nutrition and Dietetics (Academy) published a Position Statement regarding the use of Nutritional Genomics in Nutrition Practice.<sup>3</sup> At that time, there was little published research examining the clinical effect of incorporating genetic testing results into nutrition practice. This Position Statement has since expired, requiring re-examination of this topic to inform RDNs based on the most current evidence. Current Position Statements provided by the Academy require support from a systematic review with strong or fair quality evidence. On the basis of the heterogeneity and mixed quality of studies

meeting the inclusion criteria of this systematic review on nutritional genomics,<sup>4-6</sup> the workgroup deemed that a Consensus Statement was more appropriate than a Position Statement for this topic. A Consensus Report, which contains the Consensus Statement, may be produced for topics when results are considered preliminary until further evidence is available to confirm or refute these statements.<sup>7</sup> The objective of this Consensus Report is to summarize a recent, relevant systematic review conducted by the Academy's Evidence Analysis Center examining the use of incorporating genetic testing results into nutrition counseling and care and to interpret findings in terms of application to RDN practice.

## CONSENSUS STATEMENT DEVELOPMENT PROCESS

Systematic reviews, in combination with clinical expertise and client values, are the gold standard for

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informing evidence-based practice.<sup>8</sup> The Academy's Evidence Analysis Center Nutritional Genomics workgroup members conducted a systematic review to summarize studies that examined the following research question: In children and adults, what is the effect of incorporating results of genetic testing into nutrition counseling and care, compared to an alternative intervention or control group, on defined outcomes?

Studies were included in the systematic review supporting this Consensus Statement if they were controlled trials published in peer-reviewed journals between 2008 and 2018 and answered the research question. Although crucial to delivering personalized or precision nutrition, examination of inborn errors of metabolism, the microbiome and allergies/sensitivities were outside of the scope of this review. Studies investigating genomics were included if relevant to the inclusion criteria. The workgroup chose to focus on controlled trials because this study design is currently considered the gold standard for evaluating the efficacy of an intervention,<sup>9</sup> although in the future, other designs, such as "N of 1" studies; stepped wedge trials; and meta-analyses of findings, may be expanded and validated to examine nutritional genomics and achieve adequate statistical power.<sup>10</sup> Observational studies give valuable insight into how nutritional genomics can be implemented in the real world, but without a control group it is difficult to ascertain which aspect of care is effective. For example, in the Food4Me randomized controlled trial (RCT),<sup>11</sup> inclusion of multiple comparisons allowed for elucidation that individualized counseling from a dietitian generally improved nutrition outcomes, but adding nutritional genomic information to this standard of care generally did not further improve outcomes. Although studies examining associations between genes and outcomes are important for determining potential clinical utility, these studies are not adequate for determining whether using information related to specific genes in practice would be beneficial to a client.

The workgroup intended to include as many controlled trials as possible, while still addressing the question at hand. The workgroup selected studies

based on eligibility criteria determined before the literature search, summarized results of these trials according to the nutrition outcomes that the studies reported, and conducted meta-analyses when possible. Outcomes of interest included mortality, quality of life, disease incidence or prevention of disease progression, anthropometric measures and body composition, relevant laboratory measures routinely collected in practice, dietary intake, and adverse events. The intent was to capture any nutrition-relevant and clinically important health outcomes. Outcomes such as motivation to change behavior are useful, but unless studies demonstrate an actual change in dietary intake or a change in another clinically relevant nutrition outcome, the outcome was not included in this systematic review. Similarly, the systematic review broadly included any scientifically reasonable comparison groups and did not restrict to only interventions tested using, or compared to, those delivered by RDNs.

The systematic review process was conducted according to international best standards to minimize bias.<sup>12</sup> Despite being a robust process, any systematic review is reductionist by design, but it is presently the best approach for pooling appropriate evidence and avoiding bias. For each outcome, evidence was summarized and graded to describe the strength of evidence as well as the direction and statistical significance of the findings. Grading of strength of evidence was based on the number and designs of the studies included, sample sizes, risk of bias demonstrated in the studies, consistency in findings between studies, precision of the findings, as well as directness in answering the research question of interest.<sup>13,14</sup> Results of the systematic review were used to form this Consensus Report. The full methodology of the systematic review can be found elsewhere.<sup>4-6,13</sup>

### BRIEF SUMMARY OF SYSTEMATIC REVIEW RESULTS

The systematic review underpinning the current Consensus Report identified 15 publications representing 12 RCTs that met the broad inclusion criteria but were heterogeneous in terms of genes/single nucleotide polymorphisms (SNPs) examined, intervention procedure, and outcome

measures.<sup>4-6,11,15-28</sup> Very few nutrition interventions used the skills of RDNs when delivering nutrition counseling and care. Researchers measured very few clinically relevant health outcomes, such as disease incidence, prevention, or progression. Of the reported outcomes, few were significantly different when genetic information was incorporated. Fatty liver Hamaguchi score, anxiety and depression scores, and heart risk score were reported in 1 study each, yielding weak/limited quality evidence that there was no difference in outcomes observed when incorporating genetic testing results compared to not incorporating genetic testing results.<sup>4,5</sup>

There were also no significant differences in intermediate outcomes of cholesterol (total, low-density, or high-density lipoproteins) or triglyceride levels, weight, body mass index (calculated as kg/m<sup>2</sup>), waist circumference, fasting blood glucose, insulin levels, or Homeostatic Model Assessment of Insulin Resistance observed when results of genetic testing were incorporated into nutrition care compared to the control group. However, percent body fat, but not lean mass, was significantly decreased when individuals with nonalcoholic fatty liver disease were given gene-specific dietary counseling based on SNPs related to glucose and fat metabolism. Quality of evidence was rated as weak/limited for all outcome measures except cholesterol and triglyceride levels and anthropometric measures, which had fair quality evidence.<sup>4,5</sup>

When incorporating genetic testing results into nutrition care, there were no significant differences in energy intake, percent total energy from mono- or polyunsaturated fatty acids, including long-chain omega-3 fatty acids, macronutrient distribution, fiber, vitamin C, folate, fruit and vegetable intake, whole grains/oily fish/red meat or low-fat dairy products, deep-fried food, added sugar, caffeine, Healthy Eating Index, or the Mediterranean Diet score observed compared to participants who did not have genetic testing results incorporated. The quality of evidence for saturated fat, fiber, vitamin C, folate, sodium, fruit and vegetable intake, deep-fried food, and snacks were weak/limited. The dietary outcome measures of total energy, total energy from fat, Omega-3 Index, whole

grain/oily fish/red meat or low-fat dairy and the Mediterranean Diet where considered fair quality evidence. For 3 dietary intake outcomes (saturated fat, salt/sodium, and alcohol intake), results varied according to genetic risk. For example, in 1 RCT with healthy Asian-American young adults, incorporating genetic testing results related to risk of alcohol-dependent cancers into nutrition care decreased amount and frequency of alcohol consumption for those with at-risk genotypes compared to the control group.<sup>4,6</sup>

Overall, it was the assessment of this workgroup that it was premature to make a clinical recommendation on the effects of incorporating genetic testing into nutrition care due to the nascent but growing nature of the literature at present.

## IMPLICATION FOR PRACTITIONERS

### What Can RDNs Do to Support Greater Evidence for Nutritional Genomics?

In general, RDNs are well equipped to engage with research and advise researchers, industry groups, and health care providers on the delivery of nutrition assessment and interventions in nutrigenetic studies. Very few studies included in the systematic review specifically mentioned the involvement of RDNs in their research design or implementation. It is possible that the lack of RDN involvement in the research design and analysis may have influenced the effectiveness of the nutrition interventions assessed. The Academy of Nutrition and Dietetics' Nutrition Research Network provides support for RDNs wishing to engage with research and the systematic review supporting this Consensus Statement identifies gaps in the literature, which may be useful to inform future, high-quality studies in this area.

As in all new advances, there will be clients who are early adopters and who lead, rather than chase, the science. Current RDN practitioners using nutrition-related genetic information in their practice should be encouraged to record and document clinical cases in the Academy of Nutrition and Dietetics Health Informatics Infrastructure (ANDHII).<sup>29</sup> The analysis of ANDHII data may assist future

workgroups in proving an accurate picture of the effectiveness of nutritional genomics, which will only be possible with timely, accurate, and multiple case inputs.

### Should RDNs Advise Clients to Use Genetic Testing to Improve Outcomes?

While many envisage the potential of genetic testing, there is still an incomplete picture of the genetic influence on diet and health. Although most of the studies in the systematic review examined 1 or a handful of genes/SNPs and found no significant effect on outcomes, this may be explained by what we now understand is the polygenic nature of many chronic diseases. For example, many gene variants can each contribute a small effect to an overall increased risk of obesity.<sup>30</sup> Beyond genotype, we should acknowledge that complex phenotypes are multifactorial, and are influenced by factors other than genetics. When clients express interest in incorporating genetic testing information into nutrition care, RDNs should discuss the balance between potential benefits and risks or harms, including the financial cost of the genetic test and the level of science supporting the use of genetic testing in nutrition care.

### What if a Client Has Ordered a Direct-to-Consumer Test and Wants the RDN to Interpret/Translate the Test?

Much of the nutritional genomics evidence arose from genome-wide association studies that examine associations among genes, diet, and health in large population samples. Gene–diet interactions reported in association studies may or may not be causal and consequently have not demonstrated an impact in follow-up RCT investigations yet. RDNs can have increased confidence in using specific genetic information in practice if positive gene–diet interactions are reported in both association studies and RCTs. The recent systematic review<sup>4-6</sup> demonstrated that even highly replicated gene–diet interactions rarely translated to improved nutrition outcomes when examined in the context of an RCT. In addition to the concerns of basing personalized nutrition advice on genome-wide association studies, some genetic tests offer information

about carrier status or disease risk alleles for conditions such as cancer, Alzheimer disease, or Parkinson disease. However, having a particular SNP related to such complex, multifactorial conditions does not necessarily indicate that the individual will develop the disease. Similarly, a negative result for a risk allele does not mean that the individual is free of disease risk. Likewise, genetic variation typically has only a small influence on phenotypes, such as obesity and fitness. Although tens of thousands of SNPs have been associated with complex traits, each one generally has only a small influence on overall heritability. Moreover, many genetic testing companies examine only a few select SNPs, and genetic markers used to define disease risk and the associated dietary advice provided differs between companies providing genetic test results. RDNs need to be aware of the shortcomings of limited testing scope of genetic tests and some genetic testing companies.

When presented with a specific genetic test, RDNs may wish to follow up with the testing organization and/or published literature about the accuracy, validity, and applicability of the genetic test being considered.<sup>31</sup> An additional role for the RDN is to educate clients to become discerning consumers and to critically evaluate the claims of the company providing the genetic test as well as the test results. Genetic testing companies may be able to provide evidence regarding the strength of the gene–nutrition association and efficacy when utilized in practice. In addition, RDNs can rely on systematic reviews and high-quality research studies to determine whether the genes/genetic test in question has demonstrated efficacy in practice. In response to the rise in genetic testing, groups such as the Human Genetics Commission in the United Kingdom, have produced recommendations for transparent online advertising for health-related gene testing<sup>32</sup> and an ongoing need for the education of health care providers. Although US Food and Drug Administration oversight of direct-to-consumer (DTC) testing companies is minimal at present, regulation of DTC genetic tests is evolving. Among several DTC services currently available, only 1 is regulated by the US Food and Drug Administration.<sup>33,34</sup> However, the

National Institutes of Health recently published a guide about DTC testing to help the consumer critically evaluate companies and results that may be useful for RDNs in practice.<sup>35</sup> In particular, RDNs may wish to consider the following issues when evaluating a DTC genetic testing company<sup>36</sup>:

- Is the laboratory that analyzes saliva or buccal cell samples certified by either the Clinical Laboratory Improvement Amendment or the College of American Pathologists?
- Does the company have a strong advisory board of qualified scientists, health professionals, and RDNs?
- Does the company provide access to a certified genetic counselor for questions or clarification?

Despite the lower predictive power of DTC genetic tests for many multifactorial diseases, several guidelines outline an opportunity for the possible prevention of disease through early, targeted interventions.<sup>31</sup> As such, discussions of a hybrid approach to the use of genetic tests by consumers have commenced and would allow for successful coexistence of genetic testing in the nutrition health care space. The following recommendations have been proposed<sup>37</sup>:

- Improve pretest education to consumers to facilitate informed consent. Informed consent should align with what a patient might expect in a medical setting.
- Separating the informed consent of the genetic test to the storage; use and sale of the samples for research.
- Partnering of DTC companies with RDNs and appropriate health care providers for the purpose of seamless referral for consumers who receive high-risk genotype results.

Therefore, when presented with a genetic test from a client, RDNs should apply basic, evidence-based principles. Specifically, RDNs should rely on the best available evidence, interpreted through the lens of clinical experience and client values, with referral to genetic counselors as appropriate. RDNs who choose to partner with companies to offer nutrigenetic testing as part of their practice can use these same

criteria to evaluate companies. As with any partnership with private industry, the individual RDN's clinical judgment is imperative.

### What if a Client Has a Genetic Test that Has Been Ordered by a Health Care Professional?

Health care professionals may order genetic tests for clients for a variety of reasons, including predicting or detecting adverse health conditions in order to implement appropriate prevention, diagnosis, or treatment strategies. When these genetic tests are nutrition-related (eg, coronary heart disease or certain cancers), RDNs can work as members of interdisciplinary teams to determine how to optimally utilize these results as part of the standard nutrition care process.

Medical nutrition therapy requires multifaceted nutrition assessment, with consequent interventions individualized to the multifaceted client being served. In this context, genetic information can be used as a tool that is one piece of the nutrition assessment puzzle, with intervention decisions that result from several considerations including, for example, a nutrition-focused physical examination, laboratory measures, or food security status. For some clients, genetic information may be a motivating factor for change.<sup>38</sup> However, this systematic review could not find strong evidence of an effect of genetic information on nutrition-related outcomes as of yet. The methods by which RDNs utilize genetic information that has been provided by the medical team will need to be individualized to the specific client, including their goals and motivations, nutrition status, priority of nutrition concerns, value of genetic testing, and other factors. Examining the effects of genetic testing data ordered for a non-nutrition reason on nutrition-related outcomes is an area ripe for more research and RDN reporting via ANDHII.

### What Does an RDN Need to Know About Ethics, Informed Consent, and Data Privacy?

RDNs should be aware of the ethics around informed consent as they pertain to genetic testing companies. This is an opportunity for RDNs to offer

clients support and independent advice regarding nutrition-related genetic test results. There is no requirement for precounseling from a health professional when ordering a DTC test. Instead, consumers typically review the written consent information on the website or contact the online support person. Some DTC companies offer customers the ability to contribute their test results to research databases. The use of group data to support better health outcomes and research initiatives should be supported. However, the use of personalized genetic information could be a profitable commodity for some DTC companies and the usage and privacy of that genetic data requires careful consideration.

RDNs and other health professionals have undertaken an oath to protect the best interest of clients,<sup>39</sup> so genetic testing results ordered by a health professional should include a pre-counseling session with the client by that health professional on the potential outcomes and risks. Similarly, the results should be delivered by a health professional along with an understandable interpretation and a clear discussion on the level of evidence supporting the interpretation. For example, health professionals will need to use communication and counseling skills to ensure that any information provided about genotype does not cause either undo anxiety or a false sense of security. Few studies have evaluated health literacy as it pertains to genetic information, so health professionals should ensure that clients understand the limitations of genetic testing. RDNs may be involved in all of the above conversations and are responsible for making sure their clients understand genetic results that are being used in nutrition care.

Due to the rapid development of this field, regulation lags behind product availability, and RDNs must be conscious of privacy risks. The RDNs' Code of Ethics can guide practitioners with questions about client and practitioner rights and responsibilities.<sup>39</sup> In addition, only 1 study in the systematic review reported on adverse events, so there is, in general, a lack of information about the risks associated with incorporating genetic testing into nutrition care. This is another opportunity for more research and reporting via ANDHII.

## How Can an RDN Become Trained and Competent in Nutritional Genomics?

In 2017, the Accreditation Council for Education in Nutrition and Dietetics revised its standards to include nutritional genomics as a required competency for accredited Didactic Programs in Dietetics.<sup>40</sup> Resources from the Dietitians in Integrative and Functional Medicine Dietetic Practice Group may be useful to RDNs already in clinical practice. For instance, Dietitians in Integrative and Functional Medicine's Best Available Evidence Decision Tool can aid RDNs in evidence-based practice<sup>41</sup> and newly published Standards of Practice and Standards of Professional Performance outline competent, proficient, and expert levels of practice in nutrition in integrative and functional medicine.<sup>42</sup> RDNs can also anticipate continuing education opportunities from the Academy to provide guidance for the clinical utility and ethical aspects of nutritional genomics. There is a need for evidence-based RDN and client education materials on nutritional genomics in order to provide high-quality and applicable information in clinical, research, and academic settings.

The knowledge and confidence of RDNs in using genetic testing to inform the nutrition care process is considered low and recommendations to provide additional training have been proposed.<sup>43,44</sup> By obtaining training in nutritional genomics, RDNs can be prepared for honest and transparent conversations with clients about the evolving nature of the field. Targeted learning opportunities embracing a participatory model of investigation will assist RDNs to be adequately prepared to advise clients.<sup>45</sup>

## Resources and Information for RDNs

Resources to guide utilization of nutritional genomics in practice are being developed regularly. The following are a selection of resources that may be particularly pertinent to RDNs.

- In 2019, the Dietitians in Integrative and Functional Medicine Dietetic Practice Group published Standards of Practice and Standards of Professional Performance that can guide

practitioners in incorporating personalized nutrition technologies into nutrition care.<sup>42</sup> The Integrative and Functional Medicine Dietetic Practice Group highlight the importance of providing nutrition care and services by performing a systems assessment (biological, clinical, and lifestyle) to develop a nutrition care plan.

- Beyond the United States, a European consortium of personalized nutrition experts recently proposed a framework to help clinicians evaluate the evidence for published gene–diet interactions, titled “Nutrition Gene Cards.” The Nutrition Gene Cards are in the process of being developed and will be short publications that evaluate gene–diet interactions based on the proposed framework.<sup>46</sup>
- Other efforts are also underway to catalog the clinical utility of genetic variants associated with health and disease. For example, ClinGen is a database that curates evidence for the clinical utility of genes and associated variants.<sup>47</sup>
- The Centers for Disease Control and Prevention and the National Institutes of Health websites already have a plethora of useful information for both clinicians and the public.<sup>48-50</sup>
- Nutritional genomics courses are becoming increasingly available in the academic setting,<sup>45</sup> including short-courses that can improve skills for RDNs who are already practicing.<sup>51</sup>
- The Academy is currently in the process of creating a certificate of training in Nutritional genomics.<sup>52</sup>

## Future Opportunities

For emerging technologies such as nutritional genomics, peer-reviewed research will always lag behind practice. Due to the paucity of peer-reviewed research available on the effectiveness of utilizing nutritional genomics in practice, it is essential that RDNs formally document their experiences using this technology. RDNs who are early adopters of this technology can collect and store data using the

ANDHII,<sup>29</sup> which can ultimately allow for data sharing and synthesis of many “N of 1” cases to evaluate the efficacy of multifaceted, individualized care. In addition, practicing RDNs can collaborate with the Academy's Nutrition Research Network and, potentially, genetic testing companies in order to formally examine how nutritional genomics can be effectively utilized in real-world settings.<sup>53</sup> RDNs' background in biochemistry, commitment to evidence-based practice, and expertise in delivering individualized nutrition care provides a foundation to serve as objective leaders at the forefront of applying nutritional genomics to practice.

## CONCLUSIONS

Genetic information is increasingly available to clients, and the application of genetic information to nutrition care is continually being developed and refined. It will be crucial to update this Consensus Report as more research becomes available. Based on results from a systematic review, other supporting research, member feedback, and considerations of opportunities and potential concerns of incorporating genetic testing into practice, practitioners should consider the following:

1. There is a paucity of evidence related to the effectiveness of integrating genetic information into the nutrition care process. More high-quality studies are needed. RDNs should continue to stay abreast of the results from on-going, high-quality research that examines the clinical efficacy of utilizing genetic information in nutrition practice.
2. RDNs should use critical thinking skills to interpret the best available and emerging evidence through the lens of clinical experience and client values when deciding whether and how to translate genetic tests into personalized interventions.
3. When a client brings genetic testing results purchased on their own from a company (DTC test), RDNs should request that genetic test companies provide all relevant, peer-reviewed, scientific information regarding

supporting evidence behind the gene–nutrition and gene–disease risk associations, as well as for efficacy when used in nutrition practice.

4. Diet recommendations based solely on DNA do not accurately represent personalized or precision nutrition. Rather, tailoring diets for precision nutrition requires a holistic approach that considers lifestyle, preferences, concomitant health conditions, and all other domains of the Nutrition Care Process. As such, when clients provide RDNs with genetic test results, the RDN can approach nutritional genomics as one piece of a typical nutrition assessment and consequent intervention.
5. RDNs should use appropriate communication and counseling skills to ensure that any information provided about genotype is transparent, realistic, and applicable to the individual client. RDNs should honestly and clearly inform clients that any information is based on what is known from the science at the present time, and new information may become available.
6. More high-quality RCTs are needed. When possible, RDNs should participate in nutrition research that incorporates genetic testing into nutrition practice in order to determine whether this nutrition assessment/intervention method contributes additional value beyond traditional, personalized nutrition assessment methods. The Academy's AND-HII and Nutrition Research Network can aid in collecting and sharing relevant experiences in nutritional genomics.
7. RDNs have a responsibility to be aware of potential privacy concerns and to protect client data. RDNs must bear in mind the ethical considerations associated with nutrition-related genetic testing, such as economic cost of unnecessary health care follow-up, protection of patient information, patient anxiety, or

false sense of security regarding future health status.

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A. Braakhuis, A. Ellis, C. R. Monnard, and M. Rozga participated in all steps of designing the systematic review, screening studies, and reviewing, editing, grading, and voting on evidence synthesis. A. Braakhuis, A. Ellis, and M. Rozga wrote the first draft of this Consensus Report. All authors thoroughly reviewed, edited, and approved of the final manuscript.