ORIGINAL RESEARCH

Personal genomic testing for nutrition and wellness in Australia: A content analysis of online information

Running head: Analysis of nutritional genomics websites

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Abstract

Aim: Personal genomic testing for nutrition and wellness offers a new service delivery model to nutritionists and dietitians. However, research indicates that this type of testing currently lacks sufficient clinical validity and utility to be commercially available. Despite Australian guidelines to the contrary, healthcare professionals are currently offering testing to clients, and promoting these services online. Thus, it is important to understand how personal genomic testing for nutrition and wellness is currently framed online to the public.

Methods: A mixed methods content analysis was conducted to assess the content, quality and marketing approaches of websites offering personal genomic testing for nutrition and wellness to Australians. Websites were identified using popular search engines to mimic the behaviour of a consumer. A novel framework was developed for the purposes of the analysis.

Results: Thirty-nine websites were analysed, comprising four nutritional genomic testing company websites and thirty-five healthcare provider websites. Healthcare providers relied on information from the testing companies. The content was emotive, and little attention was given to the scientific and ethical aspects of personal genomic

testing. Websites appealed to consumer empowerment and framed testing as an essential and superior tool for optimising health.

Conclusions: Websites lacked the transparency necessary for informed consent. A basic checklist of key information was developed to aid healthcare providers when informing potential clients of personal genomic testing for nutrition and wellness online.

Key words: content analysis, nutritional genomics, personal genomic testing.

Introduction

Personal genomic testing for nutrition and wellness (PGT-NG) offers a novel way to tailor dietary advice to an individual. Informed by the evolving study of gene-nutrient interactions, broadly termed nutritional genomics,¹ PGT-NG claims to offer personalised dietary advice that will 'optimise' health.² While promising, in many instances the benefits of PGT-NG have yet to be proven.

Clinical validity refers to the reliability of a test to determine disease-risk based on a specific genetic variation, while clinical utility refers to its ability to inform healthcare decisions; both are key measures of the quality of a genetic test.³ Australian guidelines recommend that healthcare providers should only offer PGT based on nutritional genomics if the test, and related dietary interventions, are sufficiently evidence-based.⁴ To date however, many gene-nutrition relationships lack clinical

validity.⁵⁻⁷ Further, the genetic markers used to determine disease-risk, and the evidence used to provide dietary recommendations, often differ between PGT-NG companies, meaning consumers may receive different test results, and possibly advice, based on the test they take.^{5,8} Many PGT-NG also do not take into consideration the polygenic nature of many non-communicable diseases, nor non-genetic factors contributing to poor health.⁹⁻¹¹ Dietary advice is also rarely cross-culturally validated.^{8,12} As such, Grimaldi *et al.*⁶ recently published a set of guidelines for assessing the clinical validity of gene-nutrition interactions to help ensure only evidence-based information reaches the public. Of further concern, however, the genetic variants included in some PGT-NG also have associations with non-diet related conditions; for example, *APOE-ε4* is related to Alzheimer risk as well as cholesterol regulation.^{13,14} The potential psychosocial, as well as insurance, implications of *APOE-ε4* genotyping may not necessarily be communicated to consumers prior to having the test conducted, or during delivery of results.^{13,15}

The unregulated mass of online promotional content for PGT-NG only perpetuates public misunderstanding of the benefits, limitations and risks of PGT-NG.⁶ Consequently, several key groups, including the Human Genetics Commission in the United Kingdom, have produced recommendations for transparent online advertising for health-related PGT.^{16,17} Nevertheless, content analyses of PGT websites internationally have revealed that these recommendations are frequently ignored.¹⁸⁻²⁰ Instead, website content is solely emotive, particularly appealing to the notion of

consumer empowerment and health transformation.^{21,22} This starkly contrasts with evidence to suggest that even when given gene-based diets, consumers are unlikely to make lasting changes to their lifestyles as a result.^{23,24}

Ultimately, this presents an issue for informed consent. The purpose of informed consent is two-fold: it protects an individual from harm, while also fostering autonomous choice.^{13,25} Internationally, health-related PGT are often sold online, direct-to-consumer, negating the need to involve a healthcare provider. This also eliminates the possibility for pre- and post-test counselling and, given that online information may be inadequate to ensure informed consent, consumers may be at risk of distress, false hope or 'buyer-regret'.^{7,13} In an attempt to minimise this risk, several PGT-NG companies have developed a direct-to-provider model,²⁶ whereby a healthcare provider is trained by the company to facilitate testing for their clients.

Nutritionists and dietitians have been identified as key HPs to offer nutritional genomic advice to clients,²⁷ however, it is unclear how many have incorporated PGT-NG into their practice to date. In Australia, dietitians are considered allied health professionals, and must acquire accreditation with the Dietitians Association of Australia.²⁸ Conversely, the term 'nutritionist', can refer to a variety of nutrition-related HP roles, including those in the field of complementary/alternative medicine (CAM).^{28,29} As such, PGT-NG may also be of interest to a vast array of HPs outside conventional dietetic practice, including naturopaths and homeopaths.

Thus, despite concerns, HPs are offering PGT-NG in Australia and are promoting their services online. In particular, the phrase 'genomic wellness' appears a popular way of advertising testing in Australia. Research into this promotional rhetoric is lacking however, and, internationally, a holistic analysis of the content, quality and marketing approaches of PGT-NG provider websites has yet to be conducted. The aim of this study was therefore to explore how PGT-NG is framed online to the Australian public.

Methods

A mixed-method content analysis was conducted using a framework built in REDCap (Research Electronic Data Capture) version 7.1.2.³⁰

Website searches occurred between February and May 2017. To be eligible, websites needed to offer a PGT-NG service available to Australians, and provide a description of the service (e.g. websites that listed PGT-NG as a service but did not elaborate were excluded). Websites offering PGT covering a broad range of purposes (e.g. ancestry, carrier status), in which NG was not the sole marketing focus, were excluded.

The aim was to mimic the behaviour of a potential consumer, and as such, the search terms and search strategy was designed with this in mind.³¹ Popular testing companies were identified as a result of the search strategy and subsequently included

in the search terms. Thirteen simple terms (genomic wellness, personalised wellness test, MTHFR test, DNA wellness test, MTHFR wellness test, nutritional genomics testing, nutritional genomics Australia, nutrition and wellness test, personal genomic diet, personal genomics nutrition, [Company 1 name] practitioner, [Company 2 name] practitioner, [Company 3 name] practitioner) were entered into Google and Bing, two popular search engines. Internet users rarely look beyond the top 30 search links,³¹ however, to ensure nothing was missed, unique links were collected from the first five pages of each search (ten links per page).

A novel framework was developed to meet the aims of the analysis (see Figure 1). The framework, particularly the 'content' domain, was informed by items proposed in published guidelines^{4,16,17} and similar content analyses,^{19,20,32} which were modified for relevance to nutritional genomics. The Flesch Reading Ease³³ formula was used to aid an assessment of website understandability, whereby a 'lay-level' was considered a score between 60 and 100. This is a freely available online scoring program which the website text was copied into. The framework was piloted using international websites collected during website searching. This prompted minor changes to aid clarity and usability.

As with the search strategy, the websites were analysed from the perspective of the consumer. To be analysed, the information needed to be immediately and easily accessible. For example, links to 'terms and conditions' pages located in website footers were not included in the analysis.

Websites were de-identified and assigned ID numbers. Microsoft Excel 2013 and REDCap were used to generate descriptive statistics, and NVivo 11 (QSR International) was used to collate website text. The text was analysed thematically, using a constant comparative approach.³⁴ Ten percent of the websites were co-analysed by one of the co-authors, with the percentage of inter-rater agreement calculated.

Results

Thirty-nine websites were analysed; four PGT-NG testing company websites (three Australian-owned and one operating internationally) and 35 HP websites (Table 1). Three testing companies were known to the research team at the time of study commencement, however, also appeared during website searching. The final testing company was found using the selected search terms. No other testing companies meeting the inclusion criteria were found using the search strategy. All HP websites belonged to complementary/alternative medicine (CAM) practitioners (such as naturopaths) or clinics. Three naturopaths also referred to themselves as nutritionists, while two of the CAM clinic websites stated that a dietitian would facilitate testing. Only one HP website indicated that a genetic counsellor was available. Interrater agreement was 98%.

While website content varied (Table 2), most provided rationale for testing and a description of the service (e.g. 100% stated who would interpret results and 92%

explained how results would be returned). Only two studies cited specific evidence to support the rationale, and the technical and scientific aspects of PGT-NG were rarely touched upon (e.g. 20% explained the multifactorial nature of health). None of the websites provided information about data storage, data sharing or the use of DNA samples for research.

Three of the PGT-NG websites of testing companies required a HP to facilitate testing and provided consumer-orientated sections and information for prospective HPs. Company 2 provided a list of accredited HPs across Australia for the consumer to choose from, and while the majority came from the field of CAM, several HPs were medically trained (e.g. general practitioners). Company 4 offered testing direct-to-consumer and provided the least amount of information (4/17 framework items, 24%), meaning an assessment of quality could not be conducted. Company 1 provided the most detailed information, covering 65% of the framework items, however, the information was riddled with scientific errors, particularly in the section aimed at practitioners. Regarding copy number variants, Company 1 wrote, '*These are genes where you can have more or less copies, so there is not just two copies like your SNP genes.*' Company 1 was also the only website overall to explain how a genetic variant is considered clinically valid, however again, quality was poor (depth = *average*, accuracy = *somewhat*, exaggeration = *average*, understandability = *average*, credibility = *somewhat*).

Much of the information that presented on HP websites appeared to have been copied directly from the testing company websites. When HPs attempted to provide information in their own words, quality varied (see Figure 2). In particular, credibility scores dropped due to poor grammar and typographical errors. HP1 wrote, *'Simply by providing your body with the nutrients it genetically needs, you could see these symptoms vanish.'* Even for HP websites targeting consumers, language was not at a lay-level ($M=46.27$ for the Flesch Reading Ease Formula).

Information was also highly skewed in favour of testing. Only 2/39 websites mentioned risks; HP34 warned against overestimating the predictive power of PGT and stressed the importance of working with the healthcare provider. HP33 was the only website to address the potential to find out unwanted results. The website stated, *'The information it provides is substantial, and not for the weak hearted.'* Eight websites acknowledged at least one limitation. Issues of clinical validity were not mentioned, however, consumers were guaranteed that the tests are of a *'gold standard'* (HP39). HP6 stated, *'This type of testing has proven scientific accuracy and takes away the guessing.'* Instead, limitations were framed in regards to test scope, with statements indicating what the test would not cover, such as paternity testing.

Overall, the tone of the information was positive and motivational, with the most common emotional appeals being empowerment (only 2/39 websites scored *'none'* on the empowerment scale) and transformation (5/39 websites scored *'none'*). HP22

wrote, *'Knowing your genetic blue-print can empower you to make the best lifestyle choices to optimise your genetic expression for optimal health.'*

The most common images used on websites were DNA (n=19), people (n=14), laboratory equipment (n=9) and food (n=9). These images were used to complement the textual material, for example, healthy, smiling individuals implied the benefits of testing, while scientific imagery portrayed the legitimacy of the test.

The textual material was synthesised into major themes:

PGT-NG is a superior tool for facilitating wellness: Websites emphasised this by using the metaphor of PGT-NG being able to 'unlock' health information. HP1 stated, *'It is the closest thing you have to a crystal ball for your future health.'*

PGT-NG will reduce the guesswork around diet and lifestyle choices: Websites promised that results would inform not only highly specific, but also easy to implement recommendations that would improve health. HP11 claimed, *'You will be provided with practical, easy to understand information on how you can modify your diet and lifestyle according to your individual genetic profile to optimize your health.'*

PGT-NG is relevant to healthy people: Language such as 'maximise' health, and 'reach your full potential' implied that even though the consumer may think they are healthy, there is more that could be done to take health to the 'next level'. HP31 wrote, *'We specialise in Nutrigenomic DNA testing and can use the information to help structure a plan to help you reach your full health potential.'*

Discussion

Findings reveal that online PGT-NG information does not adequately communicate the complexities of nutritional genomics, including issues of clinical validity and utility. Websites emphasised genetic determination and the superiority of PGT-NG over other forms of dietary advice, and overall, the tone of the websites was positive, motivational and empowering. Empowerment is a common marketing strategy, particularly in health promotion,³⁵ and the 'empowerment rhetoric' features heavily in DTC-PGT advertising.^{21,22,32,36-38}

Previous analyses of direct-to-consumer PGT (for health and non-health purposes) websites highlight that key information is often missing,^{18,19,32} and ultimately, the websites assessed as part of this study lacked sufficient information to facilitate informed decision-making. However, the analysis focused on information available in the main body of each websites. Three of the websites contained links to a 'terms and conditions' page and a 'privacy policy' page in the website footer. These pages contained more detailed information regarding data sharing and data usage but were not included in the analysis as potential consumers rarely engage with this information when browsing online. Recently, however, Hall *et al.*¹⁸ conducted an analysis of pre-purchase information available on websites offering health and wellness PGT, finding that even within 'terms and conditions' and 'privacy policy' pages, transparency was poor.

Misleading marketing of PGT-NG not only puts the public at risk of wasted money and wasted time, but is also a way to potentially evade Australian regulation. While the Therapeutic Goods Association produced regulatory requirements for PGT-NG in 2010,³⁹ and advertising for all health related direct-to-consumer genetic tests in 2017,⁴⁰ it is unclear how these requirements are monitored. As such, testing companies may take advantage of this blurry regulatory landscape.

Despite three of the four PGT-NG testing companies marketing their tests to a range of HPs, this research has revealed that uptake of test facilitation is particularly prevalent in the CAM community in Australia. Most of these CAM providers relied on information taken directly from the PGT-NG company websites, decreasing understandability scores despite the lay target-audience. It is clearly a challenge to communicate scientifically accurate information in the context of consumer-orientated advertising.³² This reliance on PGT-NG testing company website information also brings into question the ability of these CAM providers to deliver adequate pre-test advice to consumers.

While test facilitation through a HP aims to minimise the risk that consumers may misinterpret their results, there remains concern that many providers may not be competent to interpret results.⁴¹ Further, although guidelines published by Grimaldi *et al.*⁶ are a positive step towards ensuring PGT-NG is standardised and evidence-based, the authors argue that determining the clinical utility of associated dietary advice is the responsibility of the HP. Although it has been suggested that nutritionists and

dietitians are well placed to deliver nutritional genomic advice to clients,²⁷ this group has reported low knowledge and low confidence in Australia and internationally.^{42,43} In light of these findings,^{42,43} and the poor quality of the online information by CAM providers, the assumption made by Grimaldi *et al.*⁶ may not yet be entirely appropriate.

Clearly there is a need for greater training and educational support for HPs practising both conventional and complementary/alternative medicine who are interested in adopting PGT-NG into their practice.⁴⁴ Recognising this, Hurlimann *et al.*⁷ produced pre- and post-test counselling recommendations that should be addressed by HPs facilitating PGT-NG. The authors reinforce that pre- and post-test counselling, along with HP training, is essential to ensure consumers make informed choices to pursue PGT-NG.⁷

Currently in Australia, however, there is a distinct lack of independent bodies offering courses in nutritional genomics appropriate for HPs to upskill, as most require the completion of further tertiary studies.⁴⁴ Instead, HPs must acquire accreditation with certain PGT-NG testing companies before offering testing. Thus, many HPs have no choice but to rely on the testing companies for training and support. Already, interviews with North American HPs who facilitated health-related PGT with their patients revealed that most relied heavily upon testing company resources to counsel their patients.²⁶ As with HPs using testing company information for their own websites,

this reliance represents a conflict of interest, such that clients may receive biased or inadequate advice.

The PGT-NG testing company websites analysed in this study offered no information regarding what the in-house training involves and how competency is assessed. While the websites were professional in appearance, the poor ratings given to the PGT-NG testing company websites, which were then reflected in the information provided by the CAM providers, is a worrying indication of the quality of the training.

Given the potential that nutritional genomics offers the field of nutrition and dietetics, it is essential that the workforce is adequately supported to provide clients with high quality care and advice.^{7,42} One place to start is neutral, evidence-based information available to consumers online. Thus, the findings from this study have revealed a need for greater nutritional genomics knowledge amongst HPs, and the importance of dissemination of accurate online information to the public.

Two healthcare provider websites had ceased advertising PGT-NG within the timeframe of the data collection and analysis. Further, since this time of analysis Company 4 had updated their website to include many more of the framework content items, including laboratory accreditation and data storage. Thus, given how rapidly the area is changing, findings only represent a 'snapshot in time'. The study also only depicts the Australian landscape, however, given the growing popularity of

nutritional genomics, findings can still inform a range of HPs, both nationally and internationally.

The authors propose a basic checklist of information that should be included on a website offering PGT-NG facilitation (see supplementary Table 1). Transparent information will help ensure both the public and HPs interested in PGT-NG are supported and informed.

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Conflict of interest

Melissa Adamski was involved in the development and is involved in the ongoing delivery of professional development courses, through Monash University, for healthcare professionals on nutritional genomics. She is also an Accredited Practising Dietitian who provides educational and consultancy services in nutritional genomics; these services do not include offering genetic test services. The remaining authors declare no conflict of interest.

Authorship

Erin Tutty drafted the manuscript, which was reviewed by the remaining authors. All authors are in agreement with the manuscript and declare that the content has not been published elsewhere.

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Figure legends

Figure 1: Novel framework for analysing online personal genomic testing for nutrition and wellness content

Website text was also collected for each assessment category. Screenshots were taken following analysis.

¹Risk was defined as a potential adverse event occurring as a result of testing e.g. finding out unwanted information

Figure 2: Quality of information on websites offering personal genomic testing for nutrition and wellness

The bars represent the scores for the healthcare provider websites, and the circles represent the scores for the testing companies (1, 2 and 3).

Criteria for Assessing the Quality of Information:

Depth	The detail provided in the information.
Accuracy	The degree to which the information was correct, as validated by the current literature.
Exaggeration	The extent to which the information was overstated or overemphasised.
Understand-ability	How easy the text was to comprehend as a layperson. Encompassed the use of plain language and correct spelling and grammar. Aided by scores from the Flesch Reading Ease ^a , a freely available online scoring program into which the website text was copied.
Credibility	The perceived trustworthiness of the information. Included the tone of language, use of scientific evidence and the professionalism of the website.

^aWhere 0-30.0 = *Very difficult*, 30.0-60.0= *Difficult*, 60.0-70.0= *Plain English*, 80.0-100.0= *Easy*

Note: None of the healthcare provider websites included the third quality assessment

	Name ¹	Date analysed ²
Testing	Fitgenes Personalised Health	26/4/17

item, an
 explanati
 on of
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 genetic
 variant is
 consider
 ed
 clinically
 valid.
Table 1:
 Websites
 included
 in the
 content
 analysis
 (N=39)

companies	myDNA	1/5/17
	Nutrigenomix	26/4/17
	smartDNA	26/4/17
Healthcare providers	Bayshore Naturpathic	24/4/17
	Blossom Clinic	17/5/17
	Bondi Health and Wellness	24/5/17
	Coffs Naturology	24/4/17
	Designer Nutrition Australia	17/5/17
	DNA Nutrition Group	27/4/17
	East West Naturopathy	21/4/17
	Elemental	24/5/17
	Food Matters Store	24/4/17
	Functional Wellness	24/4/17
	Gaining Health Naturally	24/5/17
	Good Nutrition	21/4/17
	Healthy Genes for Healthy Future	1/5/17
	Helix Optimised Wellness Solutions	27/4/17
	Mandurah Natural Therapies Centre	24/5/17
	Melbourne Natural Medicine Clinic	27/4/17
	Natural Body Lab	27/4/17
	Natural Health Perth	24/5/17
	Nature Cures	21/4/17
	Nutrition 4 Life Consultant Dieticians	27/4/17
	Nutrition and Wellbeing Clinic	28/4/17
	Penny Benjamin	28/4/17
	Possum Hollow Natural Health Clinic	28/4/17
	Prana Thrive	21/4/17
	Realize Health Family Health Clinic	24/5/17
	Reclaim Your Health	27/4/17
	Remede	21/4/17
	Sharon Johnston Naturopath	27/4/17
	Tania Flack Natural Health Solutions	24/4/17
	The Wellness Guru	26/5/17
	Unique Health and Wellness	17/5/17
	Urban Sense	15/5/17
	Vitality and Wellness Centre	26/5/17
	Wellness Vision	24/4/17
	Women's Health Naturally	24/5/17

Table 1 caption

¹Websites are presented alphabetically. Position within the table does not correspond to the ID number assigned to websites in-text.

²Findings represent a snapshot in time. Since the date of analysis, several websites have been updated or are now inactive/no longer offering personal genomic testing for nutrition and wellness.

Explanation of how the sample is destroyed

Explanation of any research done on sample

¹Assessed between February and May 2017. Changes may/have occurred in this time.

*Item used to assess the quality of the information

Figure 1 Novel framework for analysing online personal genomic testing for nutrition and wellness content

Category	Description	Rating Metric	Quality
Content	23 items relating to informational content (see Table 1)	Multiple choice-multiple answer, Yes/No	<p>Three content items were used to assess quality (see Table 1)</p> <ul style="list-style-type: none"> * Explanation of nutritional genomics * Explanation of the genes analysed and their relevance to health * Explanation of how the genetic variations are considered clinically valid <p>For websites that included these items, the explanations were rated on a Likert scale (1 = <i>not at all</i>, 2 = <i>somewhat</i>, 3 = <i>average</i>, 4 = <i>mostly</i>, 5 = <i>all the time</i>) across 5 dimensions (see Figure 2):</p> <ol style="list-style-type: none"> 1. Depth 2. Accuracy 3. Exaggeration 4. Understandability 5. Credibility
Service Information	Healthcare provider and consultation type (e.g. face-to-face)	Multiple choice-multiple answer	
Credibility of the service	Credibility of the service provider (e.g. qualifications listed)	Yes/No	
Currency	Date last updated easily viewable	Yes/No	
Balanced nature of the information	Presence of at least one benefit, risk ¹ and/or limitation	Yes/No	
Emotional appeals	Empowerment, entitlement, peace of mind, autonomy, fear, transformation, regret and excitement	Scale: 1 = <i>none</i> , 2 = <i>some</i> , 3 = <i>average</i> , 4 = <i>a lot</i> , 5 = <i>all</i>	
Images	Scientific, people, emotions, food and nature	Yes/No	

Figure 1.png

Figure 2 Quality of information on websites offering PGT for nutrition and wellness

Number of websites providing an explanation of nutritional genomics (n = 33)

Number of websites providing an explanation of the genes analysed in the test (n = 12)

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■ Not at All ■ Somewhat ■ Average ■ Mostly ■ All of the Time

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