

# The Evolution of Personalised Nutrition: Key findings

Despite several decades of scientific progress underpinning personalised nutrition, scientific uncertainties remain.

Although at least 40 years of bio-medical research have generated a convincing scientific evidence base for the proof of principle that dietary personalisation approaches can be effective by using personal genetic, microbiome, and blood biomarkers, at least in a clinical or interventional study setting, considerable uncertainties remain. These arise from the vast complexity of the human physiological responses to food intake. Simple correlations between single genes or biomarkers, or even “a handful” of them as reported in earlier studies, are not sufficient for creating robust and scientifically valid tests. Even most recent products on the market that offer algorithm-based analysis of a few dozen genes are not considered scientifically valid enough to justify personalised interventional advice.

Uncertainties emerge in particular due to the fact that genetic variation at the genome level might only play a very minor role in metabolic response to food intake (with rare exceptions) as more recent results indicate that epigenetic regulation is much more important, but is currently not well enough understood to enable affordable commercial testing. Despite much media attention around recent findings in the gut microbiome field, actionable scientific understanding is at an early stage and advice given does not go much beyond earlier recommendations, such as eating more fibre being beneficial for gut health. The most robust parameters to test for are well-established clinical parameters, such as blood glucose/insulin levels, or lipids in a weight loss setting, but these would not require additional personalisation to be actionable.

However, it is expected that the rapidly growing scientific fields of epigenetics, metabolomics, biomarker discovery, and more affordable WGS, may deliver new results in the coming decade that will not only change the current science base of PN, but will also strengthen its validity to enable better commercial applications. The speed with which these new discoveries may emerge will depend greatly on investment into the basic science of these sectors to be able to lead up to large interventional studies. Large investments are needed as these are areas of science that are far more complex than DNA-based research, and technologies required are still less robust and much more expensive than most recent DNA sequencing and analysis approaches.

## **Technology and investor push drive a growing PN start-up sector, but technical and commercial challenges limit longer-term growth**

A strong technology push in the areas of DNA sequencing and D2C testing devices, such as for at home blood and DNA testing kits, as well as commercial big data analysis solutions has been driven by increasing investor interest in the bio-medical sector for the past two decades. In addition, large players in the food processing and pharmaceutical sectors are supporting the PN start-up sector more recently. This has enabled PN providers to offer affordable (but still expensive for most) testing for biomarkers and nutritional advice based on advanced software solutions for data analysis and interpretation, easily accessible for consumers via smartphone apps.

However, PN companies face a number of technical as well as business challenges that appear currently hard to solve in the near future. To provide high quality services the underlying science base is complex and involves integrating large data streams from DNA, biomarker, and personal lifestyle information into scientifically sound advice. Although many providers involve nutritionists most of the advice is generated by algorithms which raises technical issues with quality control along the “data supply chain” from different test laboratories to the “rules” that underpin algorithm design, all affecting scientific validity. For PN providers using wet lab tests, such as for DNA and blood, the logistics and laboratory services are still expensive and costs to grow laboratory capacity with growing customer numbers are considerable even when outsourced to third parties abroad.

Currently business models are converging on very similar solutions that can offer services from £100 upwards either via subscription models or more expensive one-off solutions, but consumers need still to be convinced to make longer-term commitments. To grow beyond the curiosity market segment and reach larger market shares has been difficult for all providers that have been on the market so far. If claims made by companies can be believed, they reach a few thousand to just over 100,000 customers within a few years. A study surveying genomics based nutrition companies worldwide has found around 45 active companies in 2020, with around 20 in the US and Europe respectively and a handful in Australia and Asia (Floris et al., 2020). This compares with for example DNA based ancestry services, which could sell up to a few million one-off tests in over five years globally.

Selling actual personalised food products is currently not commercially viable, which is the reason why PN providers that offer personalised products do so in the form of vitamins and supplements. However, future integration with a growing food personalisation industry could lead to synergies supporting growth of the PN sector.

## **Consumers are becoming more receptive to PN services but are far from convinced**

A number of consumer trends align well with the offerings of PN. Increasing customisation of consumer products and services as well as food has been shaping many industries over the past two decades. In addition, health awareness in relation to food has been increasing for decades despite also increasing obesity in most countries. Several sub-markets for vegans and vegetarians, or consumers with certain allergies are increasingly well established and in many countries growing, which might prime consumer interest further for more individual customisation of nutrition. Consumer acceptance (of possibly 30% willing to try PN services in some countries) has been studied in the past decade and has been found stagnant, due to a number of reasons. These include a lack of motivation to commit longer-term to health interventions, prioritising taste and texture as well as price in food choices, a lack of education to understand the benefits of a commercial health offering based on complex science, current costs of PN services, as well as scepticism around science and data security and privacy issues. Moreover, should PN be promoted by regulators in the future, considerable social barriers exist in the context of current food inequalities in the UK.

## **Regulatory uncertainty might slow growth of a trustworthy personalised nutrition sector**

Personalised nutrition services are currently not explicitly regulated anywhere in the world. However, a number of existing regulatory frameworks in the UK apply already to some aspects of the PN services and may affect their evolution. These include regulation for genetic testing in a healthcare setting, GDPR concerning data handling, and if providers sell supplements or vitamins all legislation under the General Food Law, the Food Safety Act (FSA remit) as well as the Food

Information Regulation 2014 and the Food Supplements (England) Regulation 2003. In addition, the UK government has committed to a supportive regulatory environment for DNA technologies for the benefit of public health, which may lead to quicker translation of DNA based findings into applications. Despite a favourable environment for such technologies in the UK, challenges remain for commercial providers to create viable businesses.

In order to increase consumer trust and to guide companies' decision-making, clear guidelines would be helpful for the PN context regarding certification standards for the validity of laboratory test results, data analysis, and personal data encryption, privacy and security. Currently it is up to providers to self-assess whether they believe their tests meet certification criteria, they can choose which ISO laboratory or data encryption standards they wish to implement, and have no clear instructions on how to communicate personal DNA and biomarker-based results to customers. Although some providers do explain which certifications they adhere to, and most declare to comply with GDPR, consumers have no way of understanding whether these are legally appropriate or binding.

In addition, regulatory responsibilities are currently unclear for the sector as PN operates in between the health/wellness and food sectors and different regulators would be responsible for different aspects of a PN offering. This affects for example definitions of food vs. medicine, or various claims being made by providers regarding health benefits of certain foods, ingredients, or supplements. The currently uncertain regulatory situation may lead to low quality service offerings for consumers and difficult decision making among businesses, which may slow, or prevent growth of a high quality PN sector.

## **The most likely science trends to shape the PN sector over the coming decade are glucose monitoring and gut microbiome analysis**

Among currently used technologies possibly advice based on glucose monitoring and gut microbiome analysis may prove to become more robust and actionable than advice based on other current technologies. The former is based on several weeks of 24/7 glucose monitoring in the blood, which can give a good indication how the daily dynamics of the metabolism function, and then advice can be tailored around when during the day best to eat certain foods, the response to which can then again be monitored and efficient strategies for weight reduction or improvement of athletic performance can be developed. Despite delivering relevant personal data many consumers will be hesitant to wear a monitoring device that may be inconvenient in everyday life. Smaller, less invasive devices may help growth in that market.

Results from the gut microbiome field will become more robust, but even current fundamental insights, such as that consuming more fibre will lead to many health benefits are clearly actionable and relatively easy to implement, which will be important for wider consumer uptake.

## **Personalised nutrition is likely to remain niche for the foreseeable future, limiting the potential for broad impact on public health**

Although PN holds the promise of transforming the food system towards highly tailored diets optimised for the individual to deliver consumer and public health benefits, the scientific challenges, costs, limited consumer interest, and other factors identified in this report are likely to inhibit widespread adoption, at least in the short to medium term. PN and personalised foods will likely remain niche, catering to an affluent, educated minority for the foreseeable future, and as such will have limited impact on the wider society and broader public health agenda. Moreover,

the benefits of PN seem somewhat marginal when compared to what is already understood about a healthy diet. Simply following existing guidelines on fruit, vegetables, fibre, red meat and alcohol consumption, and the acknowledged benefits of prebiotics and probiotics would achieve significant improvements in health and disease reduction for many. Furthermore, the segment of society that could most benefit from personalised nutritional advice, those in lower income brackets, is the least able to afford such PN services or quality personalised foods. Therefore, it could be argued that rather than focusing on PN, the more important and expedient approach for policymakers would be to focus on addressing income inequality and poverty, consumer education on what constitutes a healthy diet, improved access to quality wholesome food, restrictions on access to foods that are known to be detrimental to health and encouraging and facilitating more active lifestyles.

## **The larger objective of a personalised foods sector presents much greater potential for impact, but is counter to the current food system**

Personalised foods, such as personalised ready-made meals, meal kits, and personalised restaurant and take-away meals offer consumers the opportunity to more easily integrate PN advisory services into their daily diet and meal routines, and are more likely to lock consumers into extended programmes so improving the potential for successful health changes. However, a fundamental barrier to production of personalised foods is the structure of the current food system which is built on mass production, designed to deliver food products at high rates of productivity and economies of scale, offering convenience with enhanced shelf-life, and often largely indifferent to regional context and cultural tradition. It is possibly the very opposite of the system required to deliver personalised foods. Process modifications and novel food technologies are proposed as potentially holding the key to the needed transformation towards mass-customisation and personalisation of foods. However, the extent to which this can be achieved and the costs of delivering highly personalised products is unclear at present. While niche providers offering premium personalised food services already exist and can be expected to grow, wide-spread adoption may be quite limited.

## **Food safety and food fraud risks associated with PN**

Assessing the food safety and public health risk of PN is complicated. Most PN providers are not subject to FSA or Department of Health and Social Care regulation, so their services and the scientific basis and quality of advice are not monitored or controlled. This may present some risk where extreme advice is offered (recommending excessive quantities of certain nutrients for example), but like most common dietary advice, seems unlikely to present serious risks for consumers at large. Where PN is combined with a functional food, vitamin, or other food supplement offering, these are covered by food standards regulation, so again risk should be minimal. The more likely outcome, if negative, is that the proposed benefits of a recommended diet simply do not materialise. This latter issue may relate to misleading advice and potentially fraudulent claims of science-based advice.

Personalised foods on the other hand do potentially represent a food safety and food fraud risk that may need to be considered by FSA. One of the benefits of the current mass-production-based food system is that product composition, production hygiene, labelling, and other factors are well defined and relatively easily monitored for compliance. With a shift towards ever more personalised food offerings, possibly with highly localised production and using novel on-demand production systems such as 3D printing, compliance monitoring, validation of ingredient lists, control for allergens and contamination, etc becomes far more complicated for the regulator.

## **Stratified nutrition may become more relevant than personalised solutions**

As discussed above there are significant challenges to introducing PN and personalised foods, and the potential for broad uptake and hence broad impact on public health is therefore limited. However, one potential outcome of development in the PN sector is a far more comprehensive understanding of dietary response in populations and sub-populations. This knowledge may enable the Department of Health and Social Care to offer better guidance at the population level on diet, and enable food manufacturers to offer a wider selection of stratified nutrition products, similar to current gluten-free, vegan, lactose-free and other such offerings, targeting particular sub-groups of the population based on broad phenotype or genotype characteristics. Enhanced stratified nutrition may therefore ultimately be the main outcome of the current PN initiatives.

## **Industry pressure to monetise personal PN data**

A variety of business models are emerging in the personalised nutrition and personalised food sectors, but few are profitable, and even the largest and best-funded operations struggle to survive once the initial venture funding is exhausted. Identifying an economically viable business model is challenging because of the high upfront costs associated with establishing a PN system and creating the underpinning datasets, the value proposition to the consumer is still not very clear, high prices discourage consumer engagement, and difficulty in retaining consumers for the long-term as results may not be readily apparent.

One potential solution is to attempt to monetise consumer personal data, as is the standard model in much of the digital economy, and increasingly being deployed in food rapid delivery services to subsidise the customer experience. Such two-sided models have consumers paying for PN advice on one side, and buyers/users of personal data including advertisers and food/wellness/lifestyle providers on the other side. The highly personalised type of data that PN services gather, covering all aspects of lifestyle, health, diet, physical activity, habits, genetic makeup, etc. could be significantly more valuable than data currently gathered through social media and other channels, and hence highly lucrative for targeted advertising and for example to support product development initiatives, tailored subscription offerings, insurance, etc.

The grey area in which PN operates, outside of the food sector regulation and outside health and medical regulation may enable such business models to be pursued, but raises significant privacy and ethical issues. Consumer resistance and regulatory intervention may be anticipated to prohibit such use of personal data, but there is likely to be significant pressure from the industry, justified based on contribution to societal and public health objectives, to try to pursue such business models.

## **A potential role for the NHS in provision of PN services**

One of the identified barriers to adoption of PN services is a lack of trust in private sector enterprise for delivery of such services and protection of personal data. Delivering PN services within the National Health Service, through local GP clinics may address these consumer issues, and at the same time enable access for those unable to afford private services. If and when the benefits of PN are more clearly defined, the NHS may prove to be the most expedient vehicle to deliver on large-scale public health goals in the UK. As always with the NHS, funding would be a challenge, and it may be that the private sector would need to be involved as a partner, but the long-term benefits of PN interventions for society and the cost savings associated with reduced incidences of diet-related disease may offer economic justification.