nutrition and health

Editorial

Precision nutrition at the crossroads: translational challenges and bottlenecks hampering the promise

Nutrition and Health
2025, Vol. 31(3) 801–804

DOI: 10.1177/02601060251374126
journals.sagepub.com/home/nah
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Precision or personalized nutrition (PN), underpinned by the domains of nutrigenomics and nutrigenetics, provides dietary advice solutions tailored to individual attributes, representing a paradigm shift in terms of a move away from generalized dietary guidelines to more accurate and targeted data-driven individualized recommendations. The approach is rooted in the notion that each individual responds differently to various dietary components owing to their unique blueprint, which involves genetic and metabolic profiles, gut microbiome makeup, underlying health status, and external factors such as lifestyle, sleep patterns, environmental exposures, and social influences. The advancements in PN can offer more insights into how genetic biomarkers, microbiome composition, and metabolic signatures aid in predicting the long-term impact of diet (both in terms of benefit and detriment) on the health of individuals (Berry et al., 2020).

Some high-quality studies, such as the Personalized Responses to Dietary Composition Trial (PREDICT), a hallmark large-scale, prospective, open-label, multi-center, hybrid clinical-nutritional study (Berry et al., 2020) involving more than 6000 individuals (and various phases, PREDICT 1, 2, and 3) across both UK and USA, provide significant validation for the inter-individual variability in terms of postprandial metabolic (glycemic and lipemic) responses (glucose, insulin, triglycerides, and inflammation) to standardized meals, whereby even identical twins demonstrated substantial variations in metabolic responses to similar type of foods, underscoring the complexity of gene-diet interactions (Berry et al., 2023). An earlier study by Zeevi et al. (Zeevi et al., 2015) reported similar findings across an 800-person cohort. The data collected through smartphones, smart wearables (e.g., smartwatches, fitness trackers), as well as diagnostic tests, can be analysed and integrated using machine learning algorithms for the generation of quantitative and qualitative "just-in-time" (JIT) individualized nutritional advice for patients/clients (Berciano et al., 2022). While the prospects of PN as a valuable scientific tool are promising, its integration into real-world public health and clinical settings faces considerable challenges, whereby various translational bottlenecks, ranging from technological and scientific to regulatory and ethical, continue to impede the wide-scale implementation.

Evidence gaps and population diversity present the first significant hurdle in the context of scientific and technological constraints. Evidence increasingly suggests that, to date, most of the PN studies have involved cohorts from high-income countries (HICs), characterized by a general lack of ethnic heterogeneity and sociocultural diversity, and therefore, resulting in the genetic variations and dietary patterns unique to diverse populations getting overlooked in the process (Mphasha and Mothiba, 2025). This, invariably, could manifest in limitations such as the restricted transferability of findings and broad-term applicability of outcomes related to gene-diet interactions and identified metabolic phenotypes (metabotypes) across heterogeneous populations. Some studies (Westerman et al., 2023) also indicate specific gene-diet interactions differing in terms of genetic ancestry and cultural contexts. And although collaborative projects such as the gene-nutrient interactions (GeNuIne) collaboration have undertaken efforts to study gene-diet interactions in multi-ethnic settings, the limited size and scope of such endeavors highlight the need for expanded, large-scale, ethnically-diverse investigations for robust validation of gene-diet associations (Vimaleswaran, 2021). Moreover, the inclusion of social determinants of health (SDOH), such as economic stability (income), education, and social and cultural practices of diverse populations, can further enhance the acceptability and effectiveness of PN interventions (Szakály et al., 2021). The affordability of multi-omics data (genomic, proteomic, metabolomic, microbiomic) acquisition, integration, and analytical tools also remains a significant impediment, particularly in the context of large-scale use, and low- and middle-income countries (LMICs), where the PN research and application is marred with resource limitations such as underdeveloped healthcare infrastructure, shortage of trained personnel, lack of culturally specific dietary models, and high cost of diagnostic tools (Mphasha and Mothiba, 2025). Furthermore, the integration of diverse omic data types (genomics, transcriptomics, microbiome sequencing, epigenomics, and metabolomics) for the formulation of actionable PN recommendations necessitates the handling of very large and complex heterogeneous, high-dimensional datasets (big data) and requires advanced computational infrastructure related to data storage and management, a considerable challenge in under-resourced settings (Duan et al., 2025).

Despite the burgeoning market potential, the regulatory landscape for PN products and services is hampered by a marked lack of harmonized global regulatory frameworks/standards, owing to the emergent nature of PN, a still-developing evidence base, and process innovation outpacing the development of credible regulatory pathways required for real-world evidence (RWE) generation, approval, and reimbursement, labeling, and regulation of health claims (Bremer, 2025); factors pivotal to addressing the challenges of regulatory transparency, enhancing consumer trust, and engagement, and safe commercialization (Berciano et al., 2022). In this regard, the trifecta of research, industry, and regulatory bodies is vital for establishing effective and credible consensus frameworks for defining PN, setting scientific and commercial standards, and clarification of permissible health claims. These harmonized approaches can ensure replicability and comparability of research findings (Berciano et al., 2022), as well as position PN as an effective strategy for broad-spectrum public health and consumer solutions, while circumventing trade barriers. Data privacy and governance in the context of PN present another ethical and regulatory challenge. Genomic data acquired from clients/patients often contains sensitive and profoundly personal and familial information, with significant implications for not only the individuals but also blood relatives across several generations (Foresman et al., 2025). Security breaches and unauthorized access can lead to exposure of this uniquely identifiable and sensitive information, including that related to health, ancestry, and biometrics. Data security spanning the entirety of the genomic data cycle, encompassing the storage, transmission, and computation phases, therefore, is the key dynamic in this regard as the individuals may also find it difficult to understand how to control where and when their personal information is being used or shared, as the consent granted for one purpose might not extend to other future cases, culminating in both ethical and regulatory dilemmas (Pham, 2025). Clear consent management and governance frameworks, and tools, such as privacy-preserving technologies (PPTs) (cryptography, anonymization, differential privacy), can significantly enhance consumer and public trust (Oliva et al., 2024). However, such technologies incur high acquisition and operational costs, creating a further ethical dilemma in the form of healthcare disparities and inequities, whereby only the more affluent and privileged classes have access to these technologies, while exacerbating the situation even further for low-income and marginalized population groups (Yao et al., 2022).

Integration of PN into existing healthcare settings involves multifaceted challenges, in particular, multidisciplinary training programs for the healthcare workforce, workflow adaptation, and alignment with existing (as well as local) dietary guidelines and standards. Moreover, the curricula for medical and healthcare professionals often lack adequate nutritional education and training, making it significantly difficult for these professionals to transform dietary guidelines into practical and individualized nutrition advice for patients (Korylchuk et al., 2024). Additionally, the incorporation of PN into existing workflows and systems poses further operational complications such as coordination and communication bottlenecks, scheduling conflicts, and increased budgetary allocations for sourcing of appropriate technological platforms for collaboration and data sharing, further burdening resource-constrained scenarios (Bedsaul-Fryer et al., 2023). PN integration, therefore, faces both scalability and sustainability challenges. Resource constraints, lack of standardized approaches, and difficulties associated with the integration of diverse data sources (dietary, genomic, biometric) severely impact both the rigor and scalability aspects of PN models across diverse populations and healthcare systems. Similarly, upgraded digital infrastructure is required for continuous and real-time data monitoring (RTDM) from wearables such as the continuous glucose monitors (CGMs), for ensuring interoperability between these devices and electronic health records (EHRs) (Aleppo et al., 2025). Cultural and contextual adaptation is another significant concern in the context of PN integration into diverse public health settings. PN recommendations generally emphasize nutrient-dense, minimally processed, or specialty foods, and this may present both cultural and operational dilemmas, as these recommendations might be incompatible with local, cultural, or traditional cuisines, religious obligations (kosher, halal, etc.), cultural norms, ingrained dietary rituals, or may include unfamiliar foods. Evidence also indicates that PN recommendations based on Western-centric databases and dietary models are often non-inclusive, neglecting indigenous/ethnic food systems, vulnerable population groups, and therefore, result in poor adherence (Livingstone et al., 2023). Affordability and sustained availability of the foods included in the PN recommendations across various regions might not be realistically feasible in real-world scenarios, as various factors such as seasonal variations, local agricultural conditions, over-reliance on food imports, and economic disparities may restrict adequate and consistent access (Kuri et al., 2024).

Premature commercialization without sound and robust, scientifically validated evidence can not only contribute to erosion of consumer trust, but also cause harm, in particular, when it concerns products/tools or services such as PN, or other health-centered innovations. This can severely undermine other future public health initiatives, regardless of how genuinely beneficial they are. Also, when innovation outpaces corresponding regulation, the likelihood of commercial actors exploiting regulatory uncertainties and loopholes increases significantly, with many resorting to employing misleading claims to capture consumer interest. Increasingly, companies are trying to market direct-to-consumer genetic testing (DTC-GT) kits and direct-to-consumer microbiome testing (DTC-MT) kits, often relying on preliminary or selective research findings (without strong, reproducible, and multicenter validation) (Kallergi and Zwijnenberg, 2025), as well as using marketing language that borders on healthwashing and

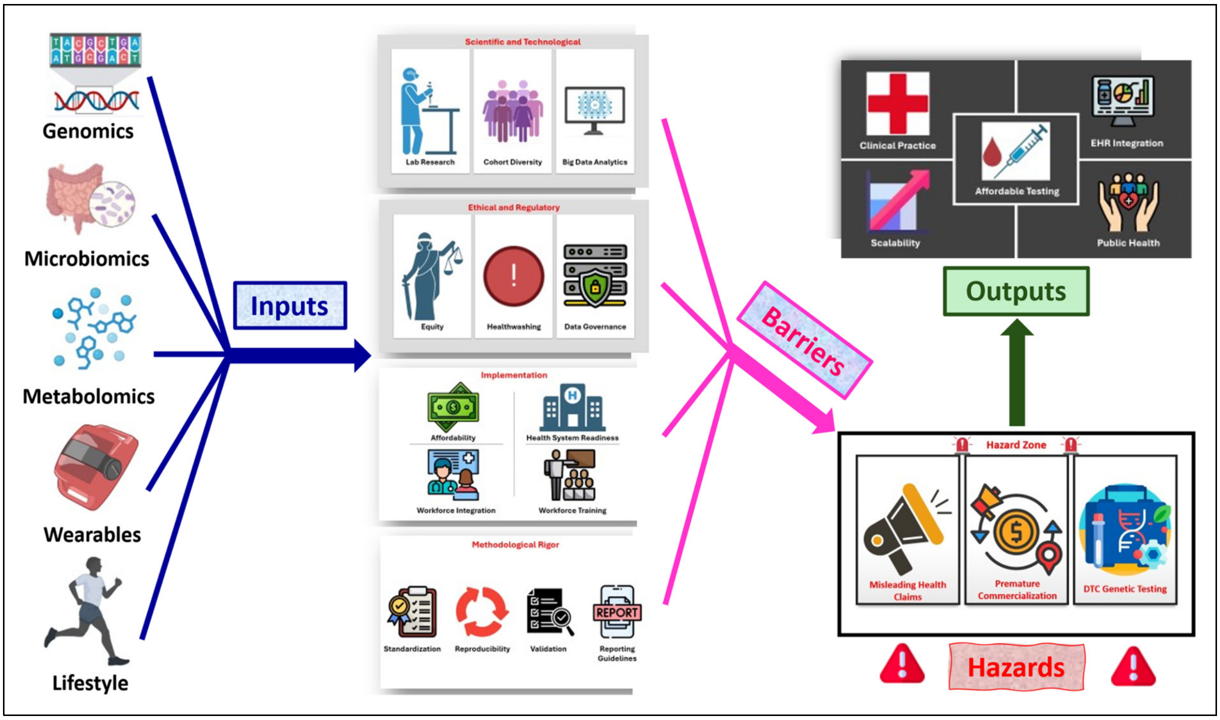

Figure 1. Precision nutrition in the context of translation vs. promise, highlighting the complex interplay between various inputs, translational barriers, hazards, and outputs.

misrepresented health claims (Berciano et al., 2022). Many companies offering PN products and services also try to frame them as 'wellness' products/services, rather than medical/health interventions, bypassing stringent safety and efficacy standards, and therefore, creating a regulatory gray zone (Simon et al., 2022). Another persistent challenge for PN remains the methodological rigor, which requires standardized protocols, validated predictive models, and reproducible biomarker measurements (Petre et al., 2025), for translating PN from a proof-of-concept (POC) promise to a practice-ready public health intervention. And although various reporting guidelines, such as the Consolidated Standards of Reporting Trials–Artificial Intelligence (CONSORT-AI), and Recommendations for Machine-learning-based Science (REFORMS) have started to address the concerns traditionally attributed to transparency and reproducibility in many AI and machine learning (ML)-driven studies ("black box" concerns, users can see the input and the outputs, but not the reasoning inside), their uptake in mainstream nutrition research remains inadequate (Wu et al., 2025). Therefore, without widespread adoption and utilization of discipline-specific reporting guideline extensions, such as the Strengthening the Reporting of Observational Studies in Epidemiology–Nutritional Epidemiology (STROBE-nut), PN risks progressing on shaky methodological foundations, limiting its credibility, as well as the real-world impact. Figure 1 illustrates the highly complicated relationship between various translational barriers that continue to impede the implementation of PN interventions.

In conclusion, PN is at a critical juncture, as the research landscape is increasingly demonstrating inter-individual variability in terms of dietary responses. However, there is a dearth of harmonized protocols for the integration of data from various omics sources, and therefore, the translation of this data into actionable dietary advice is hindered by a host of unmitigated scientific, technological, ethical, regulatory, and operational barriers. The future roadmap, in this regard, should prioritize four synergistic strategies:

1. Expansion and strengthening of the existing evidence base through large-scale, longitudinal, and multi-ethnic studies, incorporating SDOH as well, for ensuring broader applicability, diversity, and inclusion.
2. Enhancing methodological rigor through mainstream adoption of various reporting guidelines and standardization of both multi-omic and biomarker protocols for improved translatability and reproducibility.
3. Restructuring and overhauling of ethical and regulatory frameworks to broaden oversight, ensure compliance, and eliminate gray areas. This can be achieved through the development of harmonized and globally recognized standards for data security and governance, informed consent, health claims, responsible commercialization, and building, safeguarding, and maintaining consumer trust and transparency.
4. Streamlining of implementation pathways by embedding PN into public health systems through human

resources for health (HRH) training, EHR integration, affordable AI and ML tools, and culturally-relevant dietary models, in particular, for LMICs, ensuring equity, scalability, and sustainability.

Declaration of conflicting interests

The authors declared no potential conflicts of interest with respect to the research, authorship, and/or publication of this article.

Funding

The authors received no financial support for the research, authorship, and/or publication of this article.

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