Time to Reject the “One Size Fits All” Myth

时间拒绝了“一刀切”的神话

Es hora de rechazar el “Un tamaño para todos” mito

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One of the great myths in modern medicine is the assertion that “one size fits all.” This myth is especially egregious in the realm of diet and nutrition. One dose of vitamin D? For young and old? Thin and overweight? Black and white? Tampa and Anchorage? It does not make scientific sense.

Likewise, consider this myth’s power in nutritional research: one dose of a single nutrient for all participants with no regard to baseline status? Do all participants really start at the same baseline state? Scientific sense requires a different template than a pharmaceutical trial. Variable dosages are needed to achieve a predetermined serum or functional level. Yet how many such trials exist? Truly, only a handful can be found in PubMed.

And finally, is there truly one diet for optimal health? Is it Ornish or Atkins? Vegan or Paleo? Mediterranean or Okinawan? Presuming the existence of a singular best diet makes no sense when we consider the quite heterogeneous genetic status of humans. Should the Inuit, the Masai, and you follow the same “ideal” diet?

Perhaps the greatest challenge to the “one size fits all” myth is the new power of advanced laboratory testing to define an individual’s unique genetic, nutritional, and metabolic state. This new technology translates to a new power for health professionals to create customized treatment plans that address nonpharmaceutical interventions with strong biological plausibility. Health professionals who practice “interventional nutrition,” “nutrigenomics,” or the copyrighted and legally prevented “functional medicine” explicitly reject the “one size fits all” myth with rational prescription of dietary choices, nutrients, and over-the-counter supplements to effect specific biochemical pathways or biophysical goals.

Behind this disruption is the undeniable truth that the highest-quality scientific evidence allows health professionals to state only that “on average…” a given patient will benefit from a given intervention.

Patient-centered, nonpharmaceutical prescriptions represent a necessary counter-balancing force to the excesses of “evidence-based” consensus statements or algorithms that define the standard of care and overlook nutrition/metabolism concerns. Imagine the capacity to move from an “on average…” evidence-based counseling approach to partnering with your patient for an “n of 1” trial based upon a deep understanding of his or her unique physiology.

These technologies will be seen as quite disruptive or even revolutionary and therefore will be opposed. For example, consider the threat that the consumer genetic data website 23andme.com represented to the US Food and Drug Administration (FDA). The FDA legally prevented 23andme.com from sharing its customers’ gene polymorphism/gene variance reports with its customers. This represented a new version of “You can’t handle the truth.” (Thankfully, gene variance reports based on one’s 23andme.com data can

Five Common Catastrophes in Clinical Nutrition Research

Wrong population: Vitamin supplementation in persons with normal functional status of the vitamin will not demonstrate a difference. This does not mean that supplementation and replenishment of a documented deficiency will not result in a positive outcome.

Insufficient numbers: The lower the risk, severity, frequency, or interference with quality of life, the greater the numbers needed to demonstrate an intervention’s effect.

Wrong intervention: Insufficient dose? Inappropriate agent? Insufficient time? For example, daily intake of 400 IUs of vitamin D in an obese, deficient population will not effect any positive changes over time. Likewise, very high doses of vitamin D for short periods of time in the same population may also not effect a positive change.

Wrong comparison: Intervention studies too often compare apples with oranges. Any comparison population cannot be too different from the intervention population. Different populations mean that nearly anything can be proven, especially if one selects the comparison group with a desired outcome in mind.

Wrong outcome measures: Serum measurements are needed before, with, and/or after the intervention. This documents a nutrient’s insufficiency/sufficiency, change in concentration as well as the participant’s adherence with the intervention. Laboratory measurements must be reliable, taken at the right time, and consistently applied. For subjective outcomes, the questionnaires used must be validated for the population and the intervention.
The 23andme.com story represents the threat found in low-cost, readily accessible laboratory data that empower patients in an era of internet-based, highly motivated, crowd-sourced, knowledge-generating communities. Have a child with autism? A family member with severe chronic fatigue? Have a chronic, unexplained illness yourself? And, most importantly, despite best efforts by all involved, are they or you not being helped by the conventional medical system? Then you understand the motivation for so many to bypass the conventional medical system and go into the blogosphere to learn from the experience of others. Necessity is the mother of invention. And motivated patients are inventing new means of getting their medical needs met.

To be fair to the FDA and other safety advocates, patients empowered by data and shared experience may not know what they do not know. This means that, as Ruth Lindquist et al have said, “self-diagnosis and self-treatment may result in self-malpractice.” And this means that more than ever before, patients now need teams of health professionals who can empower, advocate, and counsel from an informed perspective on the rational use of diet and dietary supplements. This means health professionals who can reduce the patient’s sense of being overwhelmed by data, options, and marketing. This means health professionals with the capacity to connect gene variance data with epigenetic biomarkers, etc, to determine the significance and potential consequences of the data. And this means that we still need human connections that support perspective, awareness, and healing. All are important elements that make for an effective action plan.

Additionally, to generate the evidence base for optimal use of these laboratory technologies, both funders and principal investigators need to recognize that the pharmaceutical research template does not apply to clinical nutrition research. This means rethinking the twin aims of “one dose that fits all” and “targeting one enzyme, one receptor, or one biomarker.” In clinical nutrition, heterogeneous baselines and responses are the norm. Interventions that affect multiple nodes of a complex web of interconnected pathways are the norm. These insights open up a new world of clinical research opportunities.

Finally, to advance the evidence base, progressive clinicians need to participate in greater, more inclusive dialogues to share insights and knowledge from their experience. This includes the capacity to both contribute to and critically evaluate the medical literature with rigor. Along this line, please see the sidebars entitled “Five Common Catastrophes in Clinical Nutrition Research” and “Rules for (Healthcare) Revolutionaries.”

A final note: Readers of Global Advances in Health and Medicine are keenly interested in transforming both the quality of clinical research and the quality of clinical care. In this issue, we address the twin topics of diet and nutrition with articles that will both inform and inspire. New to this issue is a forum with divergent perspectives from highly esteemed experts representing many healing traditions on the question, “What to eat when you can’t eat?” The surprising answer? There are rational, logical options beyond what most physicians, nurses, dieticians, and pharmacists are taught to recommend.

As always, we seek to publish what is both provocative and helpful. Each article in this issue seeks to advance your knowledge and support your professional growth. And as always, we welcome your constructive feedback and recommendations.

With the publication of this issue, I am thrilled to pass on the journal’s editorship to two internationally respected leaders, Mary Jo Kreitzer, PhD, RN, FAAN, and Robert Saper, MD, MPH. They will bring great personal and professional skills to this role. They will ensure that this journal continues to grow and continues to support the transformation of medicine. To each reader, thank you very much for your continued support of Global Advances in Health and Medicine. In advance, thank you very much for supporting Drs Kreitzer and Saper in their role as co–editors-in-chief.

And finally, many thanks for the work you do to make our world a healthier place!

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