



E-ISSN: 2706-9575  
P-ISSN: 2706-9567  
IJARM 2022; 4(2): 77-83  
Received: 19-05-2022  
Accepted: 13-06-2022

All Author's Name given below  
the References

## Expert consensus on the role of nutraceuticals in improving patient care standards

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DOI: <https://doi.org/10.22271/27069567.2022.v4.i2b.410>

### Abstract

The foundational elements of cells and tissues are water, lipid, protein, mineral, vitamins, and carbohydrates. A healthy and varied diet, fortified food & nutraceuticals that provide appropriate macro and micronutrients are required to maintain healthy functioning and wear and tear of the human body. Nutraceuticals (Nutrition + pharmaceuticals) are isolated nutrients or dietary supplements that provide medical or health benefits, including the prevention and treatment of disease. Thus, nutriobiography and nutraceutical science are practical tools for every physician, along with dietary and other lifestyle measures. These approaches help to achieve primordial and quaternary prevention. It also enables better management of disorders and diseases along with the standard of care. A guidance document and consensus recommendations were required to facilitate the rational use of nutraceuticals. Fourteen experts gathered and deliberated on the latest data on nutraceuticals and their role in enhancing patient care. The resulting consensus will help optimal use of nutraceuticals and standard of care to improve patient's health span and achieve healthy aging.

**Keywords:** Nutrition + pharmaceuticals, nutraceuticals

### 1. Introduction

The study of human body composition has shown that building blocks of the human body are atoms or elements. Of the 106 elements,  $\approx$  only 50 are found in the human body, and six (oxygen, carbon, hydrogen, nitrogen, calcium, and phosphorus) of them account for > 98% of body weight.

At the molecular level, for a 70 kg reference, the man's body is composed of water (60%), lipid (19.1%), protein (15%), mineral (5.3%), and carbohydrates (1.4%) <sup>[1, 2]</sup>. Thus, a constant and appropriate intake of macro and micronutrients (vitamins & minerals) is required to keep the body and its tissues healthy and active.

The functioning of the human body/tissues/cells (made of different elements and molecules) is kept healthy and active by judicious consumption of macro and micronutrients through a healthy and varied diet. Micronutrient deficiencies affect around 2 billion people globally of all genders and ages. Though these deficiencies may not cause a specific disease, they can act as an exacerbating factor <sup>[3]</sup>. Thus, dietary and nutritional supplements, other lifestyle approaches, and standard of care have a role in the treatment plan.

Osteoporosis is associated with an age-related decrease in bone mass and skeletal fragility, resulting in increased fracture risk. The global prevalence of osteoporosis and osteopenia is 19.7% and 40.4% <sup>[4]</sup>. It is more in developing countries (22.1%) than developed countries (14.5%). Sarcopenia is an age-related condition associated with a decline in muscle mass and function, resulting in weakness, fatigue, frailty, and impairment in joint functioning and mobility <sup>[5]</sup>. Muscle cramps are sudden, transient, involuntary contractions of muscle fibers resulting in pain and discomfort. Neural impairment, disturbed cellular metabolism, electrolyte abnormalities, and reactive oxygen species contribute to the etiology of muscle cramps <sup>[6]</sup>.

Non-Alcoholic Fatty Liver Disease (NAFLD) is characterized by fatty deposits and inflammation in hepatic tissue.

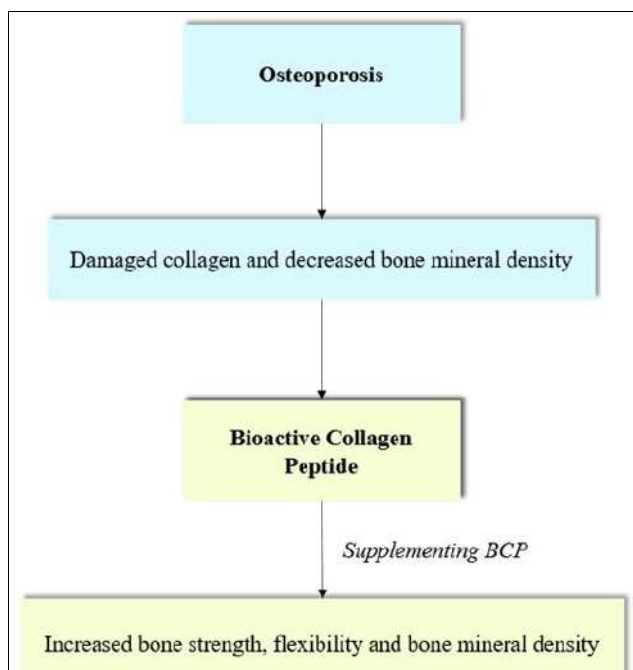
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Metabolic derangements like insulin resistance are also observed. NAFLD, over time, may progress to NASH (non-alcoholic steatohepatitis) and cirrhosis. Menopause is associated with significant hormonal changes and deficient estrogen levels, resulting in vasomotor symptoms (night sweats and hot flushes), anxiety, mood swings, etc., which markedly impairs quality of life. Brittle nails associated with damage and breaks/ splits in nails are commonly observed in females.

Chronic fatigue syndrome, aging, degenerative neurological disorders, cardiac diseases and hypertension, and cancer are characterized by mitochondrial and immune function changes. Sexual dysfunction is a common condition affecting men (10 - 52%) and women (25 - 63%), along with co-morbid conditions such as diabetes, hypertension, etc. Urinary tract infections (UTIs) are common bacterial infections seen in both females (recurrent UTIs) and males.

### 1.1 Management of Osteoporosis

Collagen (Type I) is the main component of bone (~28.5% of bone weight), and it forms a framework on which calcium, phosphorous and other minerals are deposited, resulting in the strength and flexibility of the skeletal system [7]. In osteoporosis, damage and breakdown of collagen lead to porous and weak bones. Bioactive collagen peptide (BCP) helps to augment collagen synthesis, resulting in better bone strength and flexibility and positive changes in bone mineral density (BMD) [8]. BCP supplementation, along with calcium & vitamin D, thus has a role in the management of osteopenia and osteoporosis (Figure 1).



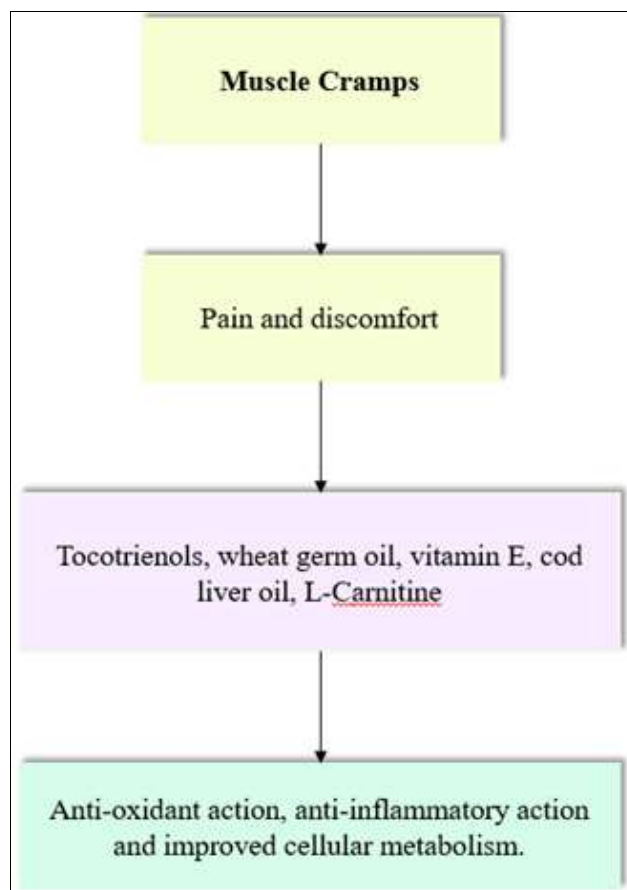
**Fig 1:** Role of BCP in osteoporosis

### 1.2 Management of Sarcopenia

Exercise, essential amino acids, and protein supplementation helps to restore muscle mass and functioning. Branched-chain amino acids (BCAAs) include leucine (Leu), isoleucine (Ile), and valine (Val). They regulate cellular processes and are the building blocks for protein synthesis. They also help enhance muscle mass and play a role in exercise training, cachexia (muscle wasting), and aging.

### 1.3 Management of Muscle Cramps

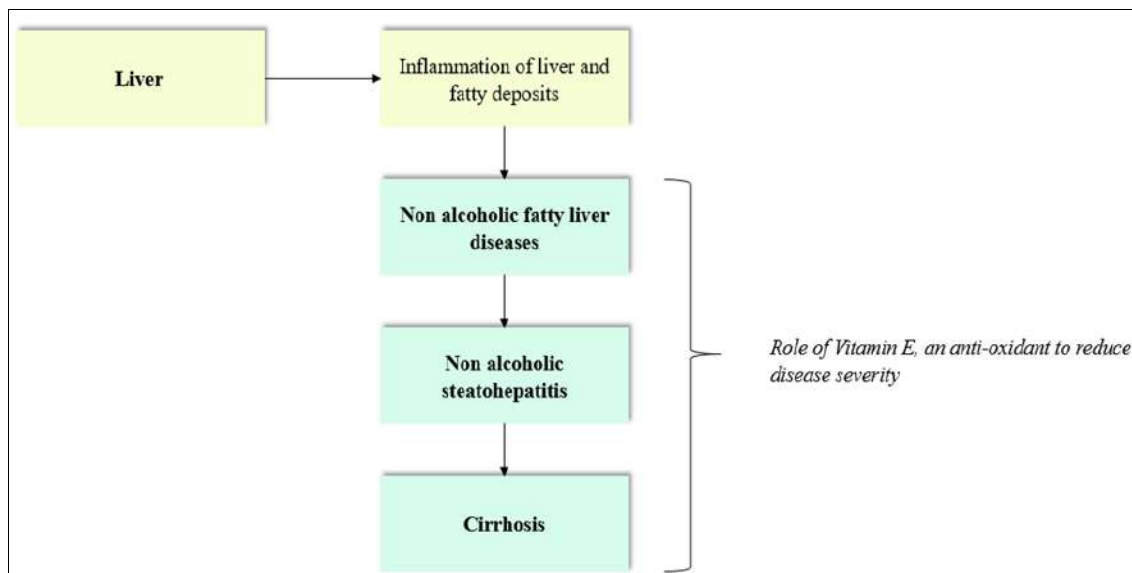
Tocotrienols, cod liver oil, wheat germ oil, and L-carnitine are effective in muscle cramps as they reduce oxidative stress, have anti-inflammatory action, and improve cellular metabolism (Figure 2).



**Fig 2:** Role of nutraceuticals in muscle cramps

### 1.4 Management of Non-Alcoholic Fatty Liver Disease (NAFLD)

Vitamin E's potent antioxidant activity has a role in NAFLD and NASH (Figure 3). In the Pioglitazone Versus Vitamin E versus Placebo for the Treatment of Non-Diabetic Patients with Nonalcoholic Steatohepatitis (PIVENS) trial, vitamin E therapy induced a clinical improvement in NASH (43% vs. 19%,  $P = 0.001$ ), but pioglitazone did not (34% vs. 19%,  $P = 0.04$ ) [9].



**Fig 3:** Role of Vitamin E in Liver disease

### 1.5 Management of Menopausal Symptoms

Linoleic acid (60%–80%) and  $\gamma$ -linolenic acid (8%–14%) are the main ingredients of evening primrose oil (EPO). It has estrogenic properties (estrogen agonist and antagonist activity) and anti-inflammatory and anti-proliferative actions via cyclooxygenase and lipoxygenase pathways. They thus help to manage menopausal symptoms (vasomotor) and post-menopausal osteoporosis [10].

### 1.6 Management of Brittle Nails, Scaling Problems, and Hair Loss

Brittle nails are managed with biotin (Vitamin B<sub>7</sub>) and essential amino acids [11]. Biotin, essential fatty acids, and essential amino acids also have a role in hair loss and skin conditions associated with scaling.

### 1.7 Management of Chronic Fatigue Syndrome, Aging, Degenerative Neurological Disorders, Cardiac Diseases and Hypertension, and Cancer Treatment

Co-enzyme Q<sub>10</sub> (CoQ<sub>10</sub>) is a bioenergetic nutraceutical as it boosts mitochondrial function. In addition, it has antioxidants and neutralizes reactive oxygen species [12]. Myalgic encephalomyelitis/chronic fatigue syndrome (ME/CFS) is characterized by idiopathic chronic fatigue not relieved by rest [13]. The standard cognitive behavioral therapy and graded exercise work in only 22% of ME/CFS patients. Hence CoQ<sub>10</sub> has a role in these patients.

As mitochondrial dysfunction and increased oxidative stress have a role in degenerative neurological disorders and cardiovascular conditions, CoQ<sub>10</sub> is often used in patients with Parkinson's disease, Alzheimer's disease, amyotrophic lateral sclerosis, stroke, cardiac disease, and hypertension. CoQ<sub>10</sub> is also an adjuvant cancer treatment due to its additional immunostimulatory action.

### 1.8 Management of Sexual Dysfunction

Safed Musli (*Chlorophytum borivilianum*) is one of our revered traditional medicines ('white gold' or 'divya aushad') widely used for ages for sexual dysfunction [14]. Pine bark extract (*Pycnogenol*) and L-arginine, via their action on nitric oxide pathways, are effective in erectile dysfunction and help to increase sperm count and motility [15].

### 1.9 Management of Urinary Dysfunction

Repeat use of antibiotics for recurrent urinary tract infections (UTIs) poses a challenge to antibiotic resistance [16]. Hence nutraceuticals like cranberry extract, which prevents adhesion of bacteria and inflammatory reactions in the urinary tissues, are commonly used to manage UTIs [17].

### 1.10 Prevention of Diseases and Role of Nutraceuticals

Recently there has been a significant shift in the mindset of certain sections of society towards health, well-being, and fitness. It complements the change in focus of the medical community towards the practice of preventive medicine.

Preventive approaches in the past included primary, secondary and tertiary prevention. It has now evolved into the concept of primordial prevention [18] (reducing chances of occurrence of risk factors for a disease) and quaternary prevention [19] (minimize/ optimize the use of medical and surgical intervention with approaches that are more patient-friendly and appropriate without significantly impairing the outcomes).

Due to flexy working hours & night shifts, many people are deprived of their proper sleep & normal sleep cycle. Sleep deprivation & tensions lead to "executive stress syndrome," which manifests as effects of sleep deprivation, loss of appetite, loss of libido, cognitive decline & mood swings.

Diet and other lifestyle interventions and nutraceuticals are the critical approaches by which a physician can support his patients to achieve primordial and quaternary prevention. In addition, nutraceuticals have a role in geroprotection, i.e., slowdown, inhibition, or reversal of age-related decline (as a composite of disease, dysfunction, and, ultimately, death) as elaborated below [20]:

- Ginkgo biloba and Ginseng help to overcome fatigue, enhance mood, and improves cognition [21].
- Garlic has antioxidant, anti-inflammatory, and lipid-lowering properties [22].
- Green tea provides high antioxidant activity [23].
- Glutamic acid supports neuronal communication.
- Mixed carotenoids have antioxidant and immunity-enhancing activity.
- Citrus flavonoids scavenge free radicals, improve glucose tolerance and insulin sensitivity, and modulate lipid metabolism.

- Melatonin <sup>[24]</sup>, a secretion of the penial body, helps alleviate the sleep deprivation effects & the harmful effect of aging.
- Brahmi <sup>[25]</sup> has been used for ages for memory improvement.
- Some fruits like avocado, blueberries, walnuts & foods like salmon, fish & green tea are also mood elevators.

Optimal use of these nutraceuticals/ dietary approaches thus has a significant role in enhancing the health and well-being of society.

### 1.11 Diseases across Lifespan, including Age-Related Diseases

Derangement in diet and other lifestyle factors impairs functioning at the cellular and tissue level, often resulting in different disorders and diseases across the lifespan. Pathogenesis of these conditions is multifactorial, including a nutritional component. Dietary and other lifestyle interventions and nutraceuticals are essential elements of the treatment plan.

Although current management guidelines often recommend established pharmaceutical and lifestyle approaches, the scientific literature also supports an evidence-based practice rooted in the paradigm of nutraceuticals. Since the famous Hippocrates' quote (400 BC), "Let food be thy medicine and medicine be thy food," the role of nutraceuticals has evolved rapidly in leaps and bounds. It has resulted from the generation of a large body of scientific and clinical evidence and continues to race ahead into an era of precision nutrition <sup>[26]</sup>.

#### 1.11.1 Personalized Nutrition and Nutribiography

Nutritional approaches have evolved from generalized and group guidance to personalized methods (individualized + goal-based advice and monitoring) and advanced toward precision nutrition (phenotypic + genotypic approaches) <sup>[27, 28]</sup>. As the science of precision nutrition is evolving, personalized nutrition has gained widespread acceptance due to ease of access (often online/ app-based) under the guidance of health and fitness coaches and medical practitioners.

Studies have shown that personalized nutrition using a healthy and varied diet is significantly better than generalized dietary approaches. Outcomes can be further augmented with the appropriate use of nutraceuticals (oral/ parental). Thus, the need of the hour is that every patient presenting to a physician's clinic needs to undergo a "nutribiography," that is, the effect that an individual's dietary history and supplementation can have on their clinical signs and symptoms and pathogenesis of their disorder <sup>[20]</sup>. It will ensure that the physician can individualize appropriate nutraceuticals and medical and surgical interventions to improve patient care and outcomes.

### 1.12 Patient Education, Treatment Compliance, and Regulations for Nutraceuticals

Every health care provider should have systems to conduct a nutribiography of their patients and assess other lifestyle factors critical for health and wellness. It will help physicians know a patient's current dietary habits and supplement intake. Patient education needs to be conducted and should be used to highlight the importance of diet and

other lifestyle factors and the role of nutraceuticals. Any misinformation or irrational supplement use by patients must be identified and corrected. The patient expectation of outcomes with dietary and nutraceutical interventions must be realistic. Standard care should be provided along with nutraceuticals to ensure patient care is not compromised in an acute setting.

The use of nutraceuticals in the correct dose and duration should be emphasized to patients to ensure optimal outcomes. The physician needs to guide a patient in selecting an appropriate nutraceutical formulation. As often, cost factors may result in the consumption of poor-quality nutraceuticals resulting in poor outcomes and safety concerns.

Drugs used in modern medicine have stringent regulatory requirements to confirm their efficacy and safety using the highest level of evidence generation (often randomized, double-blind, active control studies). In contrast, regulations governing nutraceuticals are still evolving with no such stringent requirements <sup>[29]</sup>. Despite this flexibility, considerable clinical data has been generated for various nutraceutical formulations.

## 2. Need for expert consensus

Given the considerable role of diet and nutritional components in common disorders seen by a physician, there is often a requirement to complement nutraceuticals with standard drugs. A need for an expert consensus was felt to generate guidance on the evidence-based use of nutraceuticals.

## 3. Methodology

Fourteen experts (physicians and endocrinologists) discussed recent and ongoing medical research that had implications for the re-evaluation of routine medical practice. In addition, they shared and considered their views and experiences on nutraceuticals in various disorders. It led to the development of three consensus statements, which are provided below.

## 4. Expert Opinion

Nutraceuticals are required to achieve, maintain, and sustain health by individualizing their use for every patient. The first step is to conduct a baseline assessment based on age and co-morbidity, appropriate scales, and diet photos. Proper formulation, quality, dose, dosage schedule, bioavailability, and disease condition must be identified to optimize outcomes. All healthcare stakeholders should advocate lifestyle interventions while providing supplementation with nutraceuticals. Patient engagement and education are required to overcome myths and facts. With the rising geriatric population and the phenomenon of young aging, nutraceuticals are a valuable tool for physicians to help manage health and wellness. Nutraceutical use should be governed by evidence-based medicine and a pharmacological basis of action. The working population, post-COVID-19 (coronavirus disease), and young, aging patients will also benefit from the holistic concept of nutraceuticals.

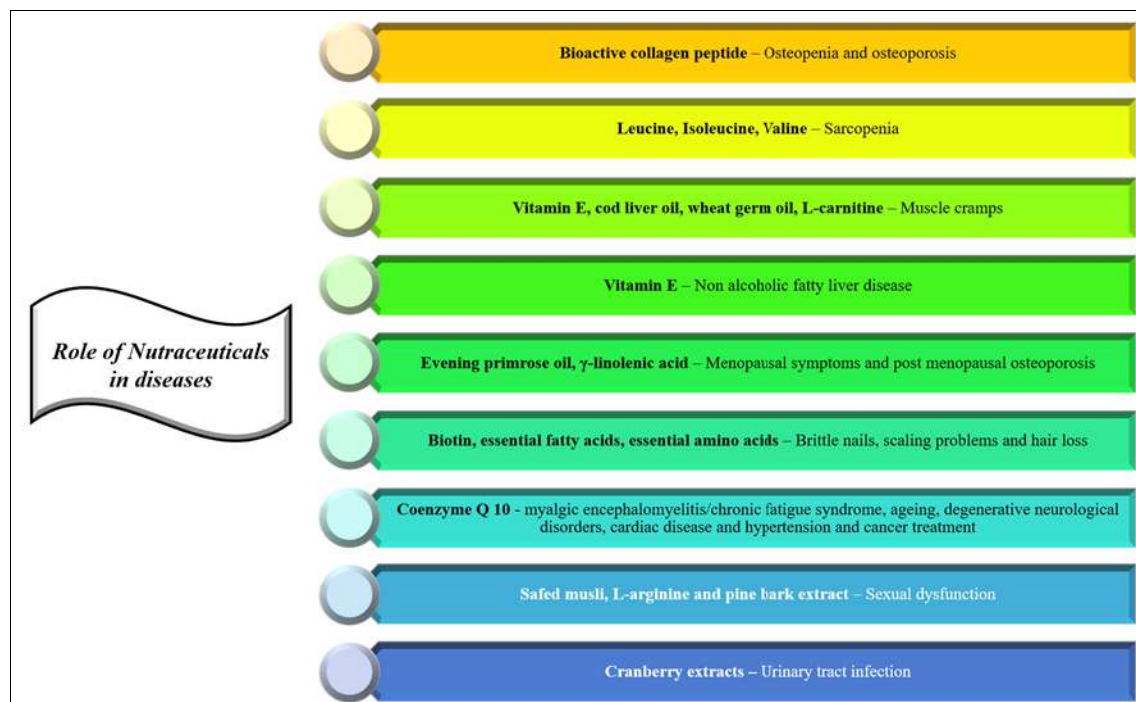
## 5. Expert Consensus

The expert consensus statements have been presented in Table 1 and figure 4



**Table 1:** Consensus Statements

| Serial Number | Consensus Statements   |
|---------------|--|
| Consensus 1   | <p>There is a role of Nutraceuticals in disorders and diseases across the lifespan</p> <ul style="list-style-type: none"> <li>▪ Bioactive collagen peptides in osteopenia and osteoporosis;</li> <li>▪ Essential amino acids (EAAs) and proteins in sarcopenia;</li> <li>▪ BCAA (Branched-chain amino acids) in exercise training, cachexia (muscle wasting), and aging;</li> <li>▪ Vitamin E (tocotrienols), cod liver oil, wheat germ oil, and L-carnitine in muscle cramps;</li> <li>▪ Vitamin E in non-alcoholic fatty liver disease (NAFLD);</li> <li>▪ Evening primrose oil for menopausal symptoms and post-menopausal osteoporosis;</li> <li>▪ Biotin, essential fatty acids (EFAs), and EAAs for brittle nails, scaling problems, and hair loss;</li> <li>▪ Coenzyme Q<sub>10</sub> in myalgic encephalomyelitis/chronic fatigue syndrome (ME/CFS), aging, degenerative neurological disorders (Parkinson's disease, Alzheimer's disease, amyotrophic lateral sclerosis, and stroke), cardiac disease and hypertension, and cancer treatment;</li> <li>▪ Safed Musli, L-arginine, and pine bark extract for sexual dysfunction;</li> <li>▪ Testosterone supplements in PADAM (partial androgen deficiency in aging males); and</li> <li>▪ Cranberry extracts and probiotics in elderly and females for urinary health.</li> </ul> |
| Consensus 2   | <p>Nutraceuticals are required for maintaining health and well-being.</p> <ul style="list-style-type: none"> <li>▪ Ginseng, Ginkgo biloba, garlic, green tea, glutamic acid, mixed carotenoids, and citrus bioflavonoids help achieve a healthy body, active mind, and well-being.</li> <li>▪ Melatonin supplements relieve the symptoms of sleep deprivation &amp; slow down aging. Brahmi helps in cognitive functions &amp; some fruits help in mood elevation.</li> </ul>  |
| Consensus 3   | <p>Nutrition is integral to disease management and healthy aging.</p> <ul style="list-style-type: none"> <li>▪ A healthy and varied diet, fortified foods, and supplements must be individualized for every patient.</li> <li>▪ Due consideration is to be given to calorie requirement and co-morbidities present.</li> </ul>   |

**Fig 4:** Consensus on the role of nutrition in improving patient care

## 6. Conclusion

Advances in medical science over the last century have led to a significant increase in average lifespan across the world. It contrasts with health span, or healthy aging, which has not seen any meaningful shifts as disease prevalence and morbidity is still rising, and disease life span has increased due to more effective modern medicines<sup>[30]</sup>.

Healthy aging or a longer health span can be achieved by transitioning medical care from predominant therapeutic approaches to primordial and quaternary prevention. Nutraceuticals are one of the critical components, along with diet and other lifestyle approaches, which will aid physicians in achieving this significant milestone in enhancing patient health and well-being.

Nutraceuticals, apart from their preventive effects, are effective and well tolerated along with the standard of care in managing different disorders/diseases across age spectrums. Thus, nutriobiography and nutraceutical science are vital pillars in our approach to achieving a healthy body, active mind, and well-being, helping manage different disorders/diseases and enhancing patient care.

## 7. Acknowledgment

**Authorship:** All named authors meet the International Committee of Medical Journal Editors (ICMJE) criteria for authorship for this article, take responsibility for the integrity of the work, and have given their approval for this version to be published.

**Medical writing:** The authors acknowledge Dr. Manish R Garg, Mr. Hemen Ved, Dr. Sunaina Anand, and Ms. Janice Jacson Mandumpala from IntelliMed Healthcare Solutions LLP for medical writing support.

**Funding:** The publication fees are paid by Universal NutriScience (UNS) Pvt. Ltd.

**Compliance with Ethics Guidelines:** This article is based on previous studies and does not contain any new studies with human participants or animals performed by any authors.

**Data availability:** Data sharing does not apply to this article as no datasets were generated or analyzed during the current study.

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