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NUTRITIONAL THERAPY FOR INTEGRATED HEALTH: CREATING SUSTAINABLE CHANGE

ABSTRACT

Objective: This essay addresses nutritional therapy as a part of integrated patient care, and how it could sustainably (e.g. for the next ten years or more) affect the health and wellbeing of the patients it serves.

Issues: The UK, but also other developed and even developing societies, are experiencing continuous deterioration and changes to our environment, modern food supplies, diet and lifestyles. Largely preventable chronic and degenerative conditions become an increasing financial burden on national healthcare systems. Despite genes being important determinants of health and illness, many chronic illnesses can have a genetic basis that is triggered by certain diet and lifestyle choices. Nutritional Therapy focuses on modifications to diet and lifestyle as the most important nutritional interventions. However, general confusion persists around health, nutrition and e.g. supplements, reflecting continued mixed messages in public and academic domains. Tougher European legislation is coming into effect in 2010, with implications on the health sector as a whole, nutritional therapy practice and public availability of certain products or information on safe and effective nutrition therapeutic interventions. Current lack of interest and time of GPs to consider this area as important may reflect the continued lack of nutrition science education in medical schools, and doctors lack knowledge to encourage their patients to make right choices regarding nutrition and e.g. supplement products.

Conclusion: Current issues demonstrate the continuous need for improved awareness and education around health, nutrition and supplements and their usage for the public, patients as well as medical and other healthcare professionals. Nutritional therapy can address some of the FIH's key points raised, making services accessible that address current unmet needs and existing health inequalities. It will also affect government targets, to increase patient choice, quality of care, and self-management of chronic conditions while decreasing overall costs. An integrated healthcare approach, that includes therapeutic coaching and nutrition counseling, could be a key tool in creating sustainable behaviour changes.

Prince's Foundation for Integrated Health

Student Essay Prize

Instructions and Competition Guidelines

“Describe an integrated approach to one area of patients care, and explain how it might still be affecting the health and wellbeing of the patients it serves in ten years time”

Word Count: **2-3,000 words** (plus academic references)

Deadline: 1st May 2010

Submit To: studentnetwork@fih.org.uk

FIH Awards: What are we looking for?

We are looking to celebrate innovative approaches to health and wellbeing.

Entries will need to demonstrate the following values and attributes:

- 1 Consideration of health in the widest sense, taking into account factors like lifestyle, environment and emotions.*
- 2 Offering services in a supportive and nurturing environment.*
- 3 Provision of services that address unmet needs and/or health inequalities.*
- 4 Involving service users in the ongoing development of the service.*
- 5 Striving to reduce inequalities and make services accessible.*
- 6 Tailoring services to the needs of individual users.*
- 7 Helping people take ownership of their own care.*
- 8 Having built positive relationships with other parts of the community.*
- 9 Undertaking audit and evaluation; and having a robust governance structure.*
- 10 The service is innovative.*

Word Count: 3,030

(excluding title, headings and appendix)

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2 Essay Objective

This essay addresses nutritional therapy as a part of integrated patient care, and how it could sustainably (e.g. for the next ten years or more) affect the health and wellbeing of the patients it serves. Some more specific aspects of nutritional therapy, e.g. the use of supplement products, will also be explored since this practice has received mixed criticism in the past.

3 Introduction

3.1 Good Nutrition is Essential for Life: But doesn't a 'Normal' Diet Provide Everything We Need?

Nutritious, good quality food is vital to our existence providing energy and needed 'building blocks' from e.g. 'macro'-nutrients (e.g. proteins, fats, carbohydrates). It also provides 'micro'-nutrients, e.g. vitamins and minerals [e.g. A, C, E, zinc, magnesium, iron], normally needed only in minute amounts but essential for all body processes. In nature, these micronutrients are tightly enclosed within the 'food matrix', together with tens of thousands of other chemical compounds. Evolution has enabled us to take advantage of this mix of chemicals. With help of an adequate working digestive system we can utilise these nutrients that are needed for all metabolic functions.

Consuming insufficient amounts of dietary nutrients to satisfy our individual body's needs, a trend seen in both developing and industrialised countries, can over time lead to nutrient deficiencies and disease. But likewise, overconsumption, perhaps through excess use or inappropriate forms of concentrated compounds (e.g. in supplements), can prove harmful. It is generally difficult to consume an excess of 'micro'-nutrients from a 'normal' (unadulterated) diet alone.

The past 50 years have seen continuing changes to our environment, lifestyles, farming and food manufacturing methods, and functional food quality decreased dramatically (Thomas 2007; Thomas 2003; Fan *et al.*, 2008). Food consumption

may have increased in industrialised and 'fast food' nations. However, poor dietary choices coupled with increasing availability of nutritionally poor quality foods have made it challenging to satisfy underlying nutrient needs for the modern individual living in a fast-paced, environmentally challenged society. Together with decreasing levels of physical activity, increasing levels of obesity and other chronic degenerative problems have become major concerns worldwide, especially in the industrialised nations (WHO, 2010). Not micronutrient excess but micronutrient deficiencies (also called 'Type B'-Malnutrition) are becoming an increasingly important contributor to obesity prevalence; being part of and related to a range of other chronic and degenerative conditions of metabolic disorders (Garcia *et al.*, 2009).

In the UK, recent government surveys have confirmed prevalence of various micronutrient deficiencies in 'healthy' populations consuming a 'normal' diet; particularly in low income groups (FSA, 2007).

3.2 Chronic Disease Healthcare Burden Continues to Grow

Despite the growing knowledge that our changing environment, diet and lifestyles can influence genetic expression ('epigenetics') and play an increasing role in chronic disease prevalence, management and prevention of these conditions remain challenging. With chronic diseases, we mean principally cardiovascular diseases, cancer, chronic respiratory diseases, and diabetes. These are often complex conditions with multi-factorial aetiology that develop over time. They are now regarded as leading causes of death and disability, particularly in industrialised nations, and globally contribute to 60% of all deaths annually (WHO, 2010). This is expected to rise by 23% over the next 20 to 25 years, while deaths due to other causes are expected to remain roughly stable through to 2030 (PwC, 2008).

Over the next 10 years almost five million people in the UK will die from a chronic condition (FIH, 2007). At the 2009 Foundation for Integrated Health (FIH) conference, speakers highlighted that in the UK, 80% of current health care

spending has been attributed to chronic conditions which afflict 44% of the population. More than half of health care spending is on behalf of people with multiple chronic conditions. In 2008, UK NHS costs for cancer alone reached more than £5 billion, while the total cost of cancer (including productivity losses) was estimated around £18 billion. By 2020 this costs is forecast to go up to nearly £25 billion (Featherstone and Whitham, 2010).

Living with a chronic disease has a significant impact on a person's quality of life, including their family, and many people are living with more than one chronic condition. The UK Department of Health (DoH) reported that people with chronic conditions are significantly more likely to see their GP (accounting for about 80% of GP consultations), to be admitted as inpatients, and to use more inpatient days than those without such conditions (DoH, 2007).

Various UK government initiatives are aiming to address the need to raise public 'health' awareness, e.g. by encouraging the public to consume more fruits and vegetables (e.g. '5-A-Day' targets since 2000), to smoke less (NHS smoking cessation programs; UK smoking ban since 2007 for all enclosed public places) and to be more physically active (NHS Change for Life initiative, 2009).

3.3 Beliefs, Attitudes, and Behaviours of Supplement Users

Media reports can have significant impact on consumer awareness and understanding of health. This is true for other areas of the 'health industry', e.g. dietary or food supplements. Often, supplements are regarded as a 'health insurance' or even to 'compensate' for an individual's dietary and lifestyle choices, especially from 'heavy' users (Mintel, 2007; Just, 2010). However, a most recent Food Standards Agency (FSA) survey found that knowledge of what consumers are taking and their potential beneficial or adverse effects is limited (2008).

Despite popular use of supplements, the majority of supplement users do not tell their medical doctors or health professionals about their supplementation, and GPs don't tend to inquire (Curtis and Gaylord, 2005; Halsted, 2003; Just, 2010). Sufferers of chronic conditions, who are on regular prescription drugs, are even more likely to use concurrent supplementation (Satia *et al.*, 2009; Neuhaus, 2003).

Major contributing factors to these problems are a public perception that these products are inherently safe, and the lack of knowledge and time to discuss these products in the medical profession (Phua, 2009; Blendon, 2001; Ashar *et al.*, 2007; Rayman, 1999; Just, 2010).

3.4 Public Confusion is driven by Persisting Contradictory Claims in Media and Academia

Media information (newspapers, magazines, TV, radio, internet) largely drives consumer information. Functional foods, 'health' and supplement markets had seen phenomenal growth, particularly over the past decades. E.g. supplements are now increasingly advertised and widely available from supermarkets, high-street 'health' stores, pharmacies, independent distributors, and over the internet (with international and largely unregulated distribution). Global supplement sales are estimated to reach nearly 200 billion in 2010, nearly tripling from 2005 (Thurston, 2008). In the UK, annual supplement sales reached £364 m in 2007 and it is estimated that at least 40% of the population consume vitamin and mineral supplement products (Mintel, 2007).

Despite the prevalent use there is however little rigorous scientific information to guide consumers. The public use of supplements, especially for e.g. general health maintenance, and even a nutritional therapists' recommendation for short-term high-dose supplementation for individual therapeutic nutrition intervention protocols has received some medical and media criticism in the past. This general public confusion about nutrition and supplements is largely driven by

persisting contradictory, controversial and mixed messages in academic (Tatsioni *et al.*, 2007) and public media domains (**Appendix Tables A-B**).

There has been growing awareness to the potential role of nutrition and the use of supplements in increasing total nutrient intakes for improving health, chronic disease amelioration and prevention (Garcia *et al.*, 2009; Burnett-Hartman *et al.*, 2009; Wienecke and Gruenwald, 2007; Fletcher and Fairfield, 2002). However, conflicting evidence in academic literature suggests potential risk of excessive intakes, finding no evidence of benefit and in certain circumstances even risk of increased mortality rates (Satia *et al.*, 2009; Murphy *et al.*, 2007; Huang *et al.*, 2006).

Pocobelli *et al.* (2009) had attributed limited efficacy to unmeasured healthy behaviors, considered more common in supplement users. Ongoing observational studies have shown supplement usage positively correlated with intake of fruits and vegetables, physical activity and certain regular medication usage, like non-steroidal anti-inflammatory drugs (White *et al.*, 2004). These factors are also considered major confounding variables in supplement-efficacy research.

Industry advocates have criticised limited financial resources available for supplement research, arguing that “natural” products cannot be patented unlike pharmaceutical drugs. This provides little motivation for big pharmaceutical companies to fund larger and well designed studies. Furthermore, negative studies were often critiqued for using synthetically derived compounds applied in isolation. When reviewing academic research this is often not clearly disclosed as many scientists still believe that ‘form’ [natural vs. synthetic] is irrelevant. However, synthetic compounds are inherently different from ‘naturally’ derived compounds, in physical properties, activity, bioavailability and side-effects/ toxicity (Feher and Schmidt, 2003; Thiel, 2000; Smallbone, 2000; see also **Appendix Figure 5**). This currently creates a contradiction in itself, as most supplements today are in fact synthetically created in the laboratory, often linked to pharmaceutical companies.

Despite contradictory messages health and supplements markets are forecast to grow at single to double-digit (Mintel, 2007; Hakimi, 2008).

3.5 European Legislation Changes in 2010: A Result of Regulatory Issues and Safety Concerns

The above issues have contributed to growing public safety concerns, particularly from the medical profession, driven by limited scientific evidence for efficacy, reports of adverse effects, drug-nutrient-interactions, and reported deaths. This put pressure on government regulators, who in the past, have been accused of inappropriately regulating many publicly available health and supplement products, in regards to ingredients, dosages, manufacturing processes and unsubstantiated label claims.

According to the US poison control centre there were an estimated 3,100 major adverse events and 150 deaths from supplements reported in the US in the last 10 years. From pharmaceutical drugs there were 190,000 major adverse events and 14,000 deaths reported in that same period (**Table 1, Figure A**). Comparing this to foods, the US Centers for Disease Control and Prevention (CDC) estimates that 76 million Americans get sick, including 300,000 hospitalisations and 5,000 deaths from food-borne illnesses *each* year. This would equate to nearly a million hospitalisations and 50,000 deaths over a 10 year-period (www.cdc.gov/DataStatistics/).

Table 1. 10-Year Review of Reported Adverse Events from Supplement and Pharmaceutical Use in the US*

Type	Number of Exposures	Number of Adverse Event Outcomes			
		Minor	Moderate	Major	Death
Dietary Supplements					
1999	81,546	6,350	2,222	799	14
2000	88,166	7,184	3,344	748	20
2001	91,271	7,621	2,922	294	19
2002	99,528	8,645	3,457	328	11
2003	112,126	8,814	3,438	298	25
2004	120,382	8,795	2,891	298	22
2005	118,313	7,924	2,531	154	27
2006	102,984	5,464	1,188	56	6
2007	108,585	5,478	1,195	76	3
2008	113,154	5,598	1,205	65	3
Total	1,036,055	71,873	24,393	3,116	150
<i>Average p.a.</i>	<i>103,606</i>	<i>7,187</i>	<i>2,439</i>	<i>312</i>	<i>15</i>
Pharmaceutical Drugs					
1999	1,020,598	150,049	62,964	15,173	987
2000	1,111,465	172,591	90,834	19,900	1,412
2001	1,190,016	187,639	100,384	22,931	1,730
2002	1,281,336	199,702	111,445	25,373	2,130
2003	1,336,209	206,154	116,815	25,584	2,054
2004	1,389,156	213,112	126,861	27,603	2,148
2005	1,412,834	210,495	129,026	29,171	2,598
2006	972,073	105,218	46,308	6,809	507
2007	1,015,101	106,684	48,879	6,708	407
2008	1,049,594	110,774	50,614	7,217	350
Total	11,778,382	1,662,418	884,130	186,469	14,323
<i>Average p.a.</i>	<i>1,177,838</i>	<i>166,242</i>	<i>88,413</i>	<i>18,647</i>	<i>1,432</i>
Dietary Supplements as a proportion of Pharmaceutical Drugs					
	8.8%	4.3%	2.8%	1.7%	1.0%
Incidence Rates (based on numbers of reported exposures and events)					
Dietary Supplements		6.94%	2.35%	0.30%	0.01%
Pharmaceutical Drugs		14.11%	7.51%	1.58%	0.12%

* This data is compiled from Annual Reports between 1999-2008 available from the American Association of Poison Control Centre (AAPCC), National Poison Data System (NPDS); dietary supplements include all reported minerals, vitamin and specialty supplements (including amino acids, homeopathic and herbal remedies). P.a.= per annum. For more information go to www.aapcc.org.



Figure A. Numbers of Reported Major Adverse Events and Deaths from Reported Exposures to Pharmaceutical drugs and Dietary Supplements, 1999-2008*

* This data is compiled from Annual Reports between 1999-2008 available from the American Association of Poison Control Centre (AAPCC), National Poison Data System (NPDS). Supplements include all reported minerals, vitamin and specialty supplements (including amino acids, homeopathic and herbal remedies). For more information go to www.aapcc.org.

It appears that in most instances, dietary supplements and herbal medicines are relatively harmless when used appropriately, however, unnecessary or reckless use of these products can lead to problems (Phua, 2009). What is more challenging to assess, is the proportion of events that are not reported or those that could have been caused due to concurrent use of different products, including herbal and pharmaceutical preparations. Botanicals and nutritional supplements, like other biological agents, act at multiple sites in the body. This can produce many effects, some of which may not be detectable on routine clinical or toxicology testing (Curtis and Gaylord, 2005). Despite knowledge that certain products, particularly botanicals, can interfere with drug metabolism ('drug-nutrient interactions'), research examining prevalence and overall effect of users mixing various types of supplements of different quality, dosage and potency, also in combination with regular pharmaceutical prescription drugs over longer periods of time is lacking.

New EU legislation will come into effect in 2010, partly to harmonise laws across the EU facilitating trade and movement of goods or services between the member states and partly to provide high-levels of consumer protection. The key EU laws are the Food Supplements Directive (FSD) and Nutrition and Health Claims Regulation (NHCR), passed originally in 2002 and 2006 respectively (see Appendix for more information). On 1st January 2010 it became illegal to sell forms of vitamins and minerals that are not on the FSD's "Positive List", which is far from an exhaustive list of safe and effective 'forms' of vitamins and minerals. During the next stage of the new regulation, 'maximum permitted levels' (**MPLs**) of micronutrients (for supplements and food fortification) will be set, which has been heavily critiqued by the Alliance for Natural Health (**ANH**) questioning the scientific validity of current risk assessment analysis methods (Verkerk and Hickey, 2010). ANH is concerned that these MPLs are too low for a nutrient to have any therapeutic effects. They also claim that beta-carotene normally found in just one large carrot or selenium found in 1-2 Brazil nuts may exceed these MPLs. Furthermore, it is feared that compounds above set MPLs could be soon considered drugs and fall under medicinal law.

Particularly in the UK, this has contributed to growing uncertainty over future public availability, quantity and quality of certain supplement products that are currently available (**Figure 2**). The legislation changes will have inherent implications for the health industry as well as availability of appropriate consumer and patient information in this area.

Figure 2. Industry Concerns over New EU Legislation Changes

According to director David Adams, of the UK's Health Food Manufacturers' Association (HFMA; Appendix), the biggest threat are these suggested MPLs and that all claims for non-VMS products 'will' be banned. The HFMA estimates that the UK industry could suffer £100 million sales losses, with more than 4,000 job losses and more than 700 independent health stores closing. This could lead to competition from imports of higher potency supplements, e.g. from Guernsey and Jersey (currently £20 million sales) or other countries that remain outside UK and EU medicines and food legislative regimes, contributing to unregulated supply.

4 Nutritional Therapy for Integrated Healthcare

The previous sections have aimed to give some insight into current issues in regards to our continuous deterioration and changes to our environment, modern food supplies, diet and lifestyles and increasing chronic disease burden on modern healthcare systems. Persisting confusion around health, nutrition and e.g. supplements, reflects continued mixed messages in public and academic domains. Current legislation changes will furthermore affect the health sector as a whole and nutritional therapy practice, in terms of availability of certain therapeutic products, making certain health recommendations or health claims about products or foods, despite known safety and efficacy from existing research and evidence-informed practice.

Current lack of interest and time for the majority of GPs to consider this area as important may reflect the continued lack of nutrition science education in medical schools, and doctors lack knowledge to encourage their patients to make right choices regarding nutrition and e.g. supplement products (Ashar *et al.*, 2007; Blendon, 2001; Rayman, 1999; Just, 2010). It also demonstrates the continuous need for improved awareness and education around health, nutrition and supplements and their usage for the public as well as medical and other healthcare professionals. Independent nutritional therapists, and other appropriately trained nutrition health professionals could take a leading role in advising doctors and patients in this area when making evidence-based and evidence-‘informed’ recommendations based on clinical practice and scientific facts.

Genes that we inherit from our parents are important determinants of health and illness, however, many chronic illnesses can have a genetic basis that are triggered by certain diet and lifestyle choices. For example, the World Cancer Research Fund has highlighted estimates that 60% of the most common cancers are preventable through appropriate diet and lifestyle changes (WCRF, 2007). Nutritional Therapy is part of Complementary and Alternative Medicine and focuses on modifications to diet and lifestyle as the most important nutritional interventions.

Nutritional Therapy is the study and application of nutrition science to support the promotion and maintenance of good health, peak or optimal performance, disease prevention and control – throughout all life stages. The educational academic training increasingly encourages application of the functional medicine model, which enables investigation of different body functions and how they relate with each other to gain a more complete health picture (www.bant.org.uk).

Generally this includes personal one-to-one consultations, comprehensive health history taking, dietary analyses, and individual biochemical/ metabolic functional laboratory testing to formulate strategies and individualised food, nutrition and lifestyle plans. At the heart of the dietary treatment protocols are the application of knowledge that additional factors like lifestyle, environment, genetic expression and emotions are inextricably linked with the functional model. Treatment protocols may include supplements, based on appropriate laboratory investigations, latest scientific research and evidence-informed practice.

Supplements however, cannot compensate for an individual's shortcomings in regards to poor dietary and lifestyle choices. Therapeutic coaching and nutrition counselling can help facilitate practical and positive choices in regards to diet and lifestyles. To achieve sustainable change, these integrated skills are as important, if not more than nutritional recommendations given alone.

This involves working in private practice or as a member of integrated polyclinics together with conventional/ medical and complementary healthcare practitioners. Training encourages nutritional therapists to adopt the routine habit of informing GPs about their shared patients seeking nutritional therapy advice, to encourage multi-disciplinary communication for improved patient care management. It is generally expected that these services are offered in a supportive and nurturing environment based on its inherent principles and philosophies.

Nutritional Therapist can be on the NHS Directory of Complementary and Alternative Practitioners. Currently, primary care can get funding in certain circumstances for nutritional therapists through practice-based commissioning (e.g. polyclinics). However, there is little funding for nutritional therapy services in

the hospital environment. To fulfil *patient choice*, nutritional therapy services currently still need to be funded via different financing streams (e.g. via existing charitable bodies like the Dimbleby Foundation at Guy's and St Thomas Hospital) or else requires patients with the financial capacity to afford this service privately in addition to their conventional health care services.

It would be helpful in future to support statutory regulation of nutritional therapists; however, at this point in time certain political complexities around current professional boundaries (**Figure 3**) making this challenging before the next 4-5 years.

Figure 3. Nutrition Health Professions Different to Nutritional Therapy

Nutritional Therapy is different to other nutrition health professions

Nutritional Therapists must meet National Occupation Standards (NOS) for Nutritional Therapy, are however not yet required to be statutory regulated (like e.g. dietitians). Current voluntary registering bodies in the UK are the British Association of Applied Nutrition & Nutritional Therapy (BANT), who has currently more than 2,300 members registered, the Nutritional Therapy Council (NTC), and the newly set-up Complementary and Natural Healthcare Council (CNHC) which is now administering the regulatory process.

Note: *Only dietitians and nutritional therapists are trained in clinical practice to give one-on-one personal health advice. Both groups must practise with full professional indemnity insurance.*

- **Dietitians:** work principally in the National Health Service (NHS) and are regulated by the Health Professions Council, their professional body being the British Dietetic Association. They use nutrition science predominantly to devise eating plans for patients to treat medical conditions, e.g. in the hospital environment. They also work to promote good health by helping to facilitate a positive change in food choices amongst individuals, groups and communities.
- **Nutrition scientists:** are often **nutritionists** and are registered with the Nutrition Society. They often work outside a clinical context: in the food industry, in research and academia, in government and other agencies. They are qualified to provide information to the public about food and healthy eating in general, but not about special therapeutic diets. E.g. they can explain links between different foods (e.g. meats, vegetables, fruits, convenience foods, drinks) and nutrient composition using the 'Balance of Good Health' model (www.eatwell.gov.uk) and may review and analyse client's food diaries and other lifestyle changes to promote health and e.g. appropriate body mass index, according to general government guidelines.
- **Public health nutritionists, toxicologists and food scientists:** work together to provide policy managers and legislators with advice needed to promote health in the population at large.

For more information on the differences between dietitians, nutritionists and nutritional therapists go to <http://www.bant.org.uk/bant/jsp/nutritionTitles.faces>, or

5 Conclusion

The previous sections have explored why Nutritional Therapy is an important aspect of integrated patient care, and how it can sustainably affect the health and wellbeing of the patients. We have also shown how Nutritional Therapy can address some of the FIH's key points raised - to strive to make services accessible that could address current unmet needs and existing health inequalities. This furthermore affects government targets, aiming to increase quality of care, patient choice, and self-management of chronic conditions while decreasing costs.

Though reduction of NHS costs and long-term cost-effectiveness of Nutritional Therapy may be challenging to calculate at this point, it could be argued that anything positively affecting the chronic disease burden will have likely a dramatic impact on future healthcare costs in this area. 'How' actual integration can happen more effectively depends largely on the current regulatory developments and increasing acceptance in the medical professions of its contributing value in e.g. chronic disease amelioration, management and prevention efforts (**Figure 4**).

The Centre of Nutrition Education and Lifestyle Management (CNELM) teach undergraduate degrees in nutrition validated by Middlesex University and postgraduate courses accredited by Middlesex University leading to MSc degree level (www.cnelm.co.uk).

CNELM has taught its students how our current understanding of the scientific data and clinical experience in nutritional medicine and therapy leads us to the conclusion that:

- Integrating skills that help clients to make sustainable change is as important, if not more, than nutritional recommendations given
- Modifications to diet and lifestyle are the most important nutritional interventions
- For several reasons it is not easy for people to obtain all the nutrients they need for the best of health from food alone

- Nutritional products can be supportive as an adjunct but not an alternative to a good diet
- Nutritional products should be used with care and have the potential to cause harm if used inappropriately and out of context
- Laboratory assessment is invaluable in understanding unique nutritional requirements and helps tailor individual nutritional programmes and provide a means of monitoring progress
- Supporting critical day to day body processes is a better approach to promoting wellness than just managing symptoms or treating disease

Personalised healthcare is also becoming possible for many people at risk of certain chronic illnesses based on understanding of our genetic inheritance, diet and lifestyle. As genetic research continues to develop this field of preventative healthcare, application of nutrition and lifestyle interventions through nutrition medicine and therapy will become even more important.

Figure 4. Next Steps for Successful Integration of Nutritional Therapists into existing Healthcare Structures

Next Steps

To enable successful integration not only on a primary care level but also on a tertiary care level (hospital environment) over the next 5-7 years, further political, government-wide engagement and national regulatory changes will have to happen:

- Clearer definitions and government-wide acceptance of the unique differences between roles and responsibilities of the currently existing nutrition health professionals
- Increased Government support and realisation of statutory regulation of nutritional therapists
- Increasing government and medical acceptance that nutritional medicine and therapy plays a key role in improving long-term patient outcomes, enabling patient choice, and decreasing health inequalities
- Improved support from the medical profession to accept safe and effective nutritional medicine and therapy as a valid, scientific, complementary adjunct to conventional medical care as part of a patient care pathway
- Increased recognition that nutritional therapy can address the growing need for awareness, education and specialisation in the knowledge of drug-nutrient-interactions. This is particularly important when tackling current issues of patients' self-supplementation behaviours with concurrent medication while choosing not to tell their medical practitioners about this.

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7 Appendix

This section includes additional supportive information, however, is excluded from the essay word count.

7.1 Differences of Supplement Products

Figure 5. Differences between Natural and Synthetic Supplement Products

Natural vs. Synthetic: 'Natural' compounds derived from foods are generally considered safer and much more usable ('bioavailable') for the human body, being highly diverse compounds whose biological and physiochemical actions are highly specific/ selective (Feher and Schmidt, 2003; Thiel, 2000; Smallbone, 2000). However, many if not most supplement products contain 'synthetically' derived compounds. Products can carry the 'natural' or 'food source, - grown or - based' label, if they have been derived from cultured yeast, algae, bacteria or other foods – however, synthetic nutrients are often used during these processes (e.g. 'FoodState'). Other companies may use organic wholefood concentrates and add glandular animal source concentrates or medicinal herb concentrates to their products. This makes it challenging to identify true 'organic' and wholefood sources and if certain combinations are safe, particularly when individuals are on multiple combinatory pharmaceutical medication. In order to remove public confusion, recent 'voluntary' standard ideas like the '**Naturally Occurring Standard**' (**NOS**), (Clement *et al.*, 2009) have been introduced; however, only a handful of manufacturers yet have this certification.

Clement B, Treadway S, Gabbay S (2009), The Naturally Occurring Standard [online]. [Accessed 15th March 2010]. Available from: <http://www.nosg.org/pdf/NOSResearchPaper.pdf>

7.2 Persistence of Contradictory Media Messages

Table A gives examples of persisting mixed media messages e.g. regarding vitamins, quoting leading British newspapers stories and their academic literature sources between 2008 and 2009.

Table A. Selection of Key Mixed Media News Stories on Vitamin Supplements between 2008 and 2009

Positive News Stories	Corresponding scientific references
<ul style="list-style-type: none"> • Independent, 16/02/08, reported that scientists at the University of California, Berkely have found that vitamin deficiency may cause modern ills 	<p><i>Based on comments from Prof. Bruce Ames and on his previous studies, e.g. J Nutr. 2003 May;133(5 Suppl 1):15448-8S</i></p>
<ul style="list-style-type: none"> • Daily Telegraph, 09/02/09, reported on research from the University of British Columbia, in EVancouver, Canada, that men who take vitamin C supplements are less likely to develop gout 	<p><i>Based on study involving 46,994 participant's in a 20 year follow-up, Arch Intern Med. 2009 Mar 9;169(5):502-7</i></p>
<ul style="list-style-type: none"> • BBC, 21/05/09, reported on research from the University of Manchester that Vitamin D is the 'key to healthy brain' 	<p><i>Based on study on 3,000 European men, J Neurol Neurosurg Psychiatry. 2009 Jul;80(7):722-9</i></p>
<ul style="list-style-type: none"> • Guardian, 19/06/09, reported that scientists found that Antioxidants can slow loss of sight in old age 	<p><i>Based on study on 433 participants, Ophthalmic Epidemiol. 2008 Nov-Dec;15(6):389-401</i></p>
<ul style="list-style-type: none"> • Daily Mail, 02/10/09, reported on research published in the <i>British Medical Journal</i> that vitamins save pensioners from frequent falls 	<p><i>Based on a meta-analysis of eight randomised controlled trials on Vitamin D involving 2,446 participants, BMJ. 2009 Oct 1;339:b3692</i></p>
Negative News Stories	Corresponding scientific references
<ul style="list-style-type: none"> • Daily Telegraph, 16/04/08, reported on research from Copenhagen University that vitamin pills 'increase the risk of early death' 	<p><i>Systematic review of 67 randomised controlled trials on 232,550 healthy people Cochrane Database Syst Rev. 2008 Apr 16;(2):CD007176</i></p>
<ul style="list-style-type: none"> • Daily Mail, 28/10/08, reported that researchers from Fred Hutchinson Cancer Research Centre in Seattle had to stop US prostate cancer study as supplements failed to prevent getting the disease. 	<p><i>Selenium and Vitamin E Cancer Prevention Trial (SELECT) conducted by University of Texas and M. D. Anderson Cancer Center involving 35,533 American men, JAMA. 2009 Jan 7;301(1):39-51</i></p>
<ul style="list-style-type: none"> • Independent, 10/02/09, reported on 'the world's largest study into the subject' found multivitamin supplements are a 'waste of time' 	<p><i>US study into prevention of cancer, heart disease or death, involving 161,808 middle-aged women, Arch Intern Med. 2009 Feb 9;169(3):294-304</i></p>
<ul style="list-style-type: none"> • BBC, 29/02/09, reported on research from University of Washington, Seattle, that latest research found Vitamin E linked to lung cancer 	<p><i>'Especially in smokers' -, based on the VITamins And Lifestyle (VITAL) study involving 77,126 participants, Am J Epidemiol. 2009 Apr 1;169(7):815-28</i></p>
<ul style="list-style-type: none"> • BBC, 24/06/09, reported that Vitamin D supplements were a factor in the death of a pensioner ("supplements 'factor' in OAP death") 	<p><i>Inquest on coroner's statement blaming Vitamin D supplements as cause of death; undetected blood cancer affected fluctuating blood calcium levels</i></p>
<ul style="list-style-type: none"> • Independent, 20/12/09, reported on two studies showing that antioxidants could blunt the benefits of physical exercise, mentioning that supplements prevent the body to produce its own 	<p><i>Two small studies, one from University of Jena, Germany, involving 39 participants, Proc Natl Acad Sci U S A. 2009 May 26;106(21):8665-70, the other from University of Porto, Portugal, involving 20 participants, Med Sci Sports Exerc. 2009 Sep;41(9):1752-60</i></p>

Recently, more news reports depicted supplements in a negative light. Different newspapers published their various versions of the same story. 'Recycling' of old news also appeared, which was excluded. To the lay person, this may not always be obvious without doing further research, especially since media articles rarely reference their academic sources fully.

Various recent popular science books have also aimed to uncover controversies in this area (**Table B**).

Positive	Short Description
<ul style="list-style-type: none"> • "Supplements Exposed: The Truth They Don't Want You to Know about Vitamins, Minerals, and Their Effects on Your Health" by Dr Brian R. Clement (2010), 1st edition, Career Press/New Page Books 	<p>"Nearly all supplements sold are synthetics created in pharmaceutical industry labs. As a result, they can be toxic to your health...Nearly all medical science studies of nutrients and human health have used synthetics rather than natural nutrients, which throws the accuracy of all negative laboratory results into serious doubt." - <i>Excerpt</i></p> <p>"This...book guides you through the minefield of choices you face every time you buy vitamins and minerals. It shows you how to decipher product labels that are otherwise deceptive, how to choose naturally occurring (plant-derived) supplements, why recommended daily allowances spread confusion, and much more." - <i>Description on back cover</i></p>
<ul style="list-style-type: none"> • "Vitamin C: The Real Story: The Remarkable and Controversial Story of Vitamin C" by Dr Steve Hickey and Dr Andrew W. Saul (2008), Basic Health Publications 	<p>"This book tells the story of how the controversy about vitamin C has grown and continues even as increasing evidence demonstrates the value of the orthomolecular approach." - <i>Description on back cover</i></p>
Negative	Short Description
<ul style="list-style-type: none"> • "Natural Causes – death, lies, and politics in America's vitamin and herbal supplement industry" by Dan Hurley (2007), 1st edition, Broadway Books 	<p>"For many years the vitamin and herbal supplement industry has gotten a free pass from the media and academia – despite the fact that there is little proof of efficacy and plenty of reason for concern..." - <i>Quoted on the back cover by Arthur Caplan, chair, Department of Medical Ethics, and director, Center for Bioethics, University of Pennsylvania, describing the book as "a must-read where this dismal state of affairs has at last been corrected".</i></p> <p>This book gives insight in the history and development of US supplements market, safety concerns, as well as successes and challenges of government legislation and regulation efforts.</p>
<ul style="list-style-type: none"> • "Bad Science" by Dr Ben Goldacre (2009), HarperPerennial 	<p>"...with the objective to enlighten the public and to dispense fast and powerful relief from: scaremongering journalists, pill-pushing nutritionists, flaky statistics and evil pharmaceutical corporations..." – <i>Description on back cover on this well-publicised book by the Guardian columnist and medical doctor Dr Ben Goldacre.</i></p>

It is outside the scope of this essay to critically appraise the mentioned academic literature, news stories, or books on their scientific validity. However, these examples highlight the continued contradictory claims about supplements in public and academic domains.

7.3 European Legislation Changes and Its Impacts

Expert opinion on the topic European legislation changes affecting supplement markets, Dr Robert Verkerk, Executive & Scientific Director, Alliance for Natural Health, email communication, 20th January 2010:

“Although the Food Supplements Directive was passed in 2002, neither industry nor consumers have yet to experience the full weight of its provisions. On 1st January 2010 it became illegal to sell forms of vitamins and minerals not on the Directive’s ‘Positive List’. This list is far from an exhaustive list of safe and effective vitamins and minerals; it is instead one based on successful approvals by the European Food Safety Authority following submission by companies with the resources capable of preparing dossiers. The loss of particular vitamins and minerals and their respective forms will impact those who have valued the more specialist products present in health stores or used by nutritional practitioners. For consumers who were previously buying their food supplements from pharmacy and supermarket chains, they will notice no difference. Among the losses include all forms of vanadium that many have used successfully to help better regulate their blood sugar levels and silver products that have been widely used for over 100 years as a ‘natural’ antibiotic. Hot on the heels of this ban is a proposal soon to be forthcoming from the European Commission detailing its approach to the harmonisation of maximum dose limits for vitamin and mineral food supplements across the EU. The Alliance for Natural Health has been at the forefront of critiquing the methods under consideration and many of these have been shown to be either scientifically irrational or flawed. If the EC proceeds on its current course very severe restrictions to dosages will occur in those European markets such as the UK, Ireland, Holland and Sweden that have typically tolerated the availability of higher dose and advanced forms of supplements. We have just published a paper in the peer review journal *Toxicology* that explains the many problems associated with the scientific approaches being developed by European institutions. We believe there is still time with a concerted effort from consumers and the industry, as well as from parliamentarians both from the Member States and particularly in Europe, to push for a scientifically rational and legally proportionate approach that ensures that the present diversity of food supplements, with their unparalleled history of safe use, remain on European markets.”

Further Information on EU Legislative Changes Concerning Supplements

The purpose of introducing a wide-ranging EU legislation is to largely harmonise laws across the EU, thereby replacing relevant national laws. EU laws predominantly consist of directives and regulations. Directives only come into effect once they are transposed into member state laws via statutory instruments. Regulations, on the other hand, come into force immediately across all EU member states once they are signed off in Brussels. Most EU laws affecting natural health have the main two aims of (1) facilitating trade and movement of goods or services between the member states and (2) to provide high-level of consumer protection. Often, these requirements can conflict with one another (ANH, 2009).

The four key EU laws that are going to impact the natural health sector are:

- Food Supplements Directive (Directive 2002/46/EC)
- Nutrition and Health Claims Regulation (Regulation (EC) No 1924/2006)

- Human Medicinal Products Directive (Directive 2001/83/ED, amending Directive 2004/27/EC)
- Traditional Herbal Medicinal Products Directive (amending Directive 2004/24/EC).

Food law across the EU is controlled by the General Food Law Regulation (EC 178/2002) while medicinal law is controlled by the Human Medicinal Products Directive.

Two major aims: 1) consumer protection and facilitating trade and 2) movement of goods or services between the member states (Article 95 of the EU Treaty of the EU).

Most countries have fairly similar regulations for nutrition claims (based on EU Directive 90/496). Certain structure-function and health claims (e.g. disease-risk reduction claims) are prohibited under EU Directive 200/13/EU but European countries differ in their implementation.

For further information, see also:

- “Supplement Ban May Breach EU Law, Says Alliance for Natural Health (ANH)”, 13th November, 2009, <http://www.nutraingredients.com/Regulation/Supplement-ban-may-breach-EU-law-says-ANH>
- Study: EU vitamin level-setting methods ‘fatally flawed’, 13th January 2010, <http://www.nutraingredients.com/Regulation/Study-EU-vitamin-level-setting-methods-fatally-flawed>,
- ANH’s Freedom of Choice campaign: <http://www.anhcampaign.org/campaigns/freedom-health-choice>
- Alliance for Natural Health (ANH). (2008) The good, the bad and the ugly of EU natural health legislation. In: *Verkerk RH. How Do We Move Natural Medicine into the Mainstream? CAM Expo. 25 October 2009.* London: Lecture handout.

Expert opinion on the of topic European legislation changes affecting supplement markets, David Adams, Special Projects Director, Health Food Manufacturers' Association (HFMA), email communication, 15th February 2010:

“GENERAL COMMENTS

- There are very roughly 25k different food supplement products (different ingredients &/or potencies &/or brands) available in the UK
- About 2/3 of sales value in the UK is in non-vitamin/mineral (‘Other Substances’) supplements

FOOD SUPPLEMENTS DIRECTIVE (FSD)

This is 2- (or possibly 3- stage) legislation

- My 2005 [CNN] quote related to vitamin/mineral ingredients – stage 1 of the legislation – because a ‘positive list’ of ingredients omitted several important specialist ingredients
- In the event, submission of detailed safety dossiers resulted in the addition of 67 important nutrients to the ‘positive list’ (the HFMA was by far the major contributor to this development); as a result, there will be very few sales losses as a result of the stage

- The 2nd stage relates to the setting of 'maximum permitted levels' (MPLs): European Commission proposals are expected later this year and levels could be well below existing, relatively liberal. UK levels

A summary of potential impact of low MPLs (some thousands of products could be affected) as demonstrated in surveys conducted by the HFMA and NAHS (National Association of Health Stores) is:

- There is extreme sensitivity to the MPLs actually adopted
- Well over £100m of sales are at risk and most will be lost: in addition, there are several other major identifiable costs and potential stock write-offs
- This will impact particularly heavily on SME Small/Medium sized Enterprises) suppliers resulting in business closures
- From the NAHS survey, it is estimated that over 700 independent health food stores would close resulting in about 4,000 job losses
- An unintended consequence of low MPLs is that personal imports of higher potency supplements, notably from Guernsey and Jersey that remain outside UK and EU medicines and food legislative regimes, will increase from their current level of c. £20m. This would expose UK consumers to the dangers of unregulated supply

NUTRITION AND HEALTH CLAIMS REGULATION (NHCR)

- Attached is a recent trade press article that we wrote about this complex and very flawed legislation (my 2005 quote didn't cover this EU legislation which was only adopted at the end of 2006) [*available to readers on request, contact author (lara@yourfoodanalyst.com) or HFMA directly*]
- Most food supplements are heavily reliant on responsible health claims - on pack &/or in advertising &/or on websites - to inform their consumers
- The threat that nearly all claims for non-vitamin/mineral supplements will be banned threatens an even more negative impact than the imposition of low MPLs

EUROPEAN MARKET IMPACTS

- No data is available
- About 19 months ago, the European Commission commissioned a consultancy to review the impact of maximum levels on various member state markets but the results have yet to be published..."