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### ***Heart disease, cholesterol and nutritional supplements.***

Cardiovascular disease (CVD) especially coronary heart disease remains the leading cause of mortality in the Western world. In addition, CVD is the cause of substantial morbidity and premature incapacity. It is a most significant burden on both the health and social services of New Zealand. Reading the popular press and health publications alike, it would seem that if one focuses on regular exercise, eating a diet with less than 30% of energy from fats, and getting one's blood cholesterol level below 5 mmol.L<sup>-1</sup> then all will be well. Much has been written about cholesterol in both the popular and medical press over the past three decades but has any of the research and educational efforts made a difference? Is there any evidence even suggesting that the hundreds of millions of dollars that are spent on cholesterol lowering drugs and programs have improved mortality or morbidity? Have we been big enough to admit the need for change when the evidence disagrees with the hypothesis? Is cholesterol the villain or has it been framed?

This paper challenges orthodox medicine's view of the role of cholesterol in vascular disease and suggests that we need to go back to basics. It suggests that we need to revisit Hippocrates basic tenet; make food your medicine and make medicines your food. It argues from a scientific premise that not only is our drug interventionist paradigm wrong, but so is our fetish with macronutritional tenets. Micronutrients and nanonutrients have an invaluable, though non-exclusive, role in both restoring and maintaining a well society.

### ***Cholesterol analysis***

Cholesterol is essential for life. It is incorporated into all cell walls and is a precursor of many hormones. Cholesterol, as routinely analysed in the clinical laboratory, consists of so-called good cholesterol (HDL-c) and bad cholesterol (LDL-c). There are also very low-density lipoproteins (VLDL) and chylomicrons that consist mainly of triglycerides. Total cholesterol gives no indication of the ratio of the good and bad types. LDL-c is about 80% of the total cholesterol. Very often cholesterol analysis and lipoprotein electrophoresis are performed immediately following a heart 'scare'

when the patient is often stressed. Results taken within a month of such events are unreliable, yet they are often used to place patients on longterm therapy. LDL-c is usually determined using a mathematical formula using total cholesterol, HDL-c and triglycerides. Changes of 10% between measurements performed in a well-standardised and quality controlled laboratory are not clinically significant yet are used clinically. OTC tests, whilst appearing to be both accurate and precise, are approximately 50% less reliable than those performed in an accredited laboratory. A scan of pharmacy use of OTC cholesterol assays (in Auckland) suggests that they are infrequently performed. This raises questions about standardisation, quality control, and interpretation of results. Treatment decisions based on cholesterol alone lack a scientific foundation.

### ***Aetiology of heart disease***

The orthodox view of cholesterol is that it is a major cause of heart disease yet there is a significant lack of evidence in the scientific literature to establish a cause and effect. A prospective, longitudinal assessment of 8,251 subjects in the (USA) National Health and Nutrition Examination Survey, (NHANES I) followup study assessed the important roles of modifiable dietary and behavioural characteristics in the causation and prevention of coronary heart disease (CHD).<sup>1</sup> Analysing 10-year followup data the researchers studied 492 with cardiovascular events and 7,759 without events during the followup period (1971-75 to 1982-84). The statistical analysis of the data revealed that alcohol intake, dietary riboflavin, dietary iron, serum magnesium, leisure time exercise, habitual physical activity, and female gender were factors that were independently, significantly, and inversely associated with coronary heart and vascular disease deaths and hospitalisations. Positive significant independent determinants of CHD events included cigarette smoking, maximum body weight, and age. Cholesterol as a cause was conspicuous by its absence. Subsequent nutritional studies have started to look more closely at micronutrients and have discovered highly significant relationships between their intake and wellbeing yet none of this information is referred to in public education material and it is illegal for manufacturers of food and nutritional supplements to make health claims.

### ***Cholesterol and CVD***

The scientific literature is totally lacking in evidence to support drug intervention in lowering slight to moderately raised blood cholesterol. This is because blood cholesterol is not a major risk factor; in fact, most heart patients have normal cholesterol levels.<sup>2</sup> A study of nearly 20,000 men and women with heart disease in Copenhagen demonstrated that only those with blood cholesterol levels in the top 5% were at risk of developing heart disease.<sup>3</sup> A causal relationship was not established. Many other studies have reached similar conclusions. In 1980 Beaglehole cautioned against cholesterol lowering strategies as his teams 11 year study showed an inverse relationship between serum cholesterol levels and overall mortality in Maori men.<sup>4</sup>

Risk factors associated with heart disease are multifactorial and complex. This is anathema to the modern medico-centric model of diseases having single cause and effect which in turn promotes a single “magical” treatment policy. How many of your patients are on drugs to moderate the side effects of other drugs?

### ***Education, diet and CVD***

Current educational information being promulgated by the NZHF and others does not discuss micronutrients. They may mention omega-3 fatty acids as protecting against heart disease, but then state that all oils are the same—this is simply not true. Olive oil, palm oil and flaxseed oil, among others, all have high levels of omega-3's as do certain fish oils. Palm oil is often not recommended as it has high saturated fat levels. There is a plethora of scientific evidence showing that the above oils all contribute towards maintaining a healthy vascular system and reducing CHD.

Increased dietary intake of magnesium has been promoted as an alternative to calcium antagonists to moderate heart disease. There is only scant evidence of calcium antagonists improving mortality in heart failure (Amlodipine is an exception). Magnesium is cheap, lacks adverse reactions, is effective and is not promoted by health officials.

There is a wealth of research that shows that increased consumption of milk products impacts significantly on hypertension yet heart patients avoid dairy products because of dairy products (false) implication in vascular disease. Margarine is encouraged by macronutritionists, yet it is acknowledged that trans-fatty acids, produced during the

hydrogenation of oils in the manufacture of margarine, are a major cause of illness. Some publications such as the NZHF's rightly mention trans-fatty acids as villains, yet they never associate them with margarine. It is another myth that margarine is better for you than butter—the opposite appears to be closer to the truth. The public is lead to believe that butter is full of cholesterol—yet a 500-gram pack contains less than a peanut sized amount. 90% of the body's cholesterol is manufactured in the liver.

As early as 1984 there was solid evidence from the USA NHANES-1 study that not only was blood pressure lowest amongst people not intentionally trying to restrict sodium intake (another myth) but that there is an inverse relationship between calcium in the diet and risk of hypertension.<sup>5</sup> This is not incorporated into educational material.

### ***Folic acid and CVD***

There is a rapidly emerging body of scientific research implicating raised blood homocysteine levels in the damage to vascular walls. Cholesterol appears to be used by the body to plaster over cracks—damaged vascular walls being “repaired” by the villain cholesterol. Homocysteine is converted to methionine by the vitamin folic acid. The rise in homocysteine levels has been linked to low levels of blood and dietary folic acid. Recently the US Academy of Science Committee on Medicine acknowledged that the food chain was deficient in folic acid. Folic acid supplements, especially formulated as a multivitamin including B6, B12, magnesium and zinc have been shown to lower homocysteine levels which in turn reverses the damage to the vascular walls. In the longitudinal Physicians' Health Study in the USA, men who had a heart attack had higher levels of homocysteine than matched controls who remained free of heart disease.<sup>6</sup> Daily treatment with a B6, B12 and folic acid supplement returned homocysteine levels to normal within six weeks.<sup>7</sup>

There is a wealth of scientific evidence showing that a multivitamin containing folic acid not only protects against birth defects such as spina bifida, but also substantially reduces the risk of heart disease and stroke in the general population.<sup>8,9,10,11</sup> Based on USA research as many as 1,000 deaths from heart disease could be prevented annually if New Zealanders consumed protective amounts of folic acid.<sup>12</sup>

### ***Vitamin E & CVD***

There is also a large and growing body of evidence to support the relationship between vitamin E supplementation and substantially reducing the risk of cardiovascular disease. Epidemiological studies of over 100,000 subjects showed that longterm use of vitamin E supplements resulted in a 40% reduction in heart disease.<sup>13,14</sup> An epidemiological study of more than 11,000 elderly people in the USA found that users of both vitamin E and C supplements had a 53% decreased risk of death from heart disease and a 42% decreased risk of all-cause deaths compared to nonusers.<sup>15</sup> Compare that to the consensus of studies that shows that cholesterol-lowering drugs have zero impact on the risk of all-cause deaths! The Cambridge Heart Antioxidant Study, a randomised controlled clinical trial involving 2,000 men with known heart problems, showed that vitamin E at 400-800 iu per day reduced the risk of heart attacks by 75%.<sup>16</sup> The conclusion was that patients with angina and those who are at risk of heart disease should be given vitamin E supplements. No conventional foods provide these levels of vitamin E. A study of 34,000 postmenopausal women found that high vitamin E supplementation resulted in a 68% lower death rate from heart disease.<sup>17</sup> A study involving 87,000 nurses is reported to have shown a 41% reduction in risk of heart disease.<sup>18</sup>

These are phenomenal statistics that are being ignored by health advisors looking for medic-centric answers. There is no consensus of scientific data to demonstrate a net reduction in mortality or morbidity with hypolipidaemic lowering strategies using drugs. It is worth noting that 44% of cardiologists (in the USA) and 60% of dieticians are reported to use vitamins regularly, although only 37% of the physicians recommend them to their patients and even fewer dieticians.<sup>19,20</sup>

### ***Omega-3 fatty acids and CVD***

A number of oils, including olive oil, flaxseed oil and certain fish oils contain high levels of omega-3 fatty acids, which are well documented in helping to prevent heart disease. Dietary flaxseed oil has both anti-atherogenic and anti-inflammatory properties attenuating the decline in renal function and reduced glomerular injury with favourable effects on blood pressure, lipids, and urinary prostaglandins.<sup>21</sup>

### ***Cholesterol, violent deaths and cancer***

Human and animal research indicates that low or lowered cholesterol levels may reduce central serotonin activity, which in turn is causally linked to violent behaviours. A meta-analysis study of all reported literature between 1965 and 1995, reported that many trials support a significant relation between low or lowered cholesterol levels and violence ( $P < 0.001$ ) and that data on this association conform to Hill's criteria for a causal association.<sup>22</sup> Dr Boyd Swinburn, from the NZHF and Dr Stuart Jessamine, senior medical advisor at the Ministry of Health, are both reported as acknowledging this.<sup>23</sup> The problem is that blood cholesterol levels exhibit what is known as a 'U' curve; very high levels are associated with the risk of vascular disease (though not causally) and levels much below 4.1 mmol.L<sup>-1</sup> or artificially lowered levels are associated with increased depression and a significant increase in violent deaths such as murder, suicide, and car accidents (causally) and a variety of cancers. There is no magical level above or below which risk can be determined. A patient on both hypolipidaemic and antidepressant drugs should have both medications reviewed. Health Authorities keep touting 5.2 mmol.L<sup>-1</sup> (200 mg/100 ml) as if it is something special. There is no one reference-range for serum cholesterol—the reference levels increase with age and are higher in males than females. There is no scientific basis for one range for all ages. The American Heart Association encourages testing in children as young as two years old!<sup>24</sup> This is both morally and scientifically wrong. They acknowledge that there is no scientific evidence to support such a policy advising that, “it is a clinical decision.”

### ***Total fat and CVD***

The NZHF and dietetic groups keep pushing the “reduce your fat intake to below 30% of total calories and eat meat and five fruit and veg and you will have a healthy heart.” Unfortunately there is no scientific basis for this premise. The Inuits from the Arctic and the Southern Europeans have very high-fat diets; over 50% in some cases, yet have very low levels of heart disease. Analysis of their food reveals that a macronutrition (protein, carbohydrate & fat) approach is wrong. Micronutrients hold the answers. The NZHF says that all oils are the same. This is simply not true. They say that saturated fats are the villains—again they have no scientific evidence to support this. Northern European diet does have higher saturated fat levels (of animal origin) and it does have higher levels of heart disease but this does not demonstrate a

cause and effect. It is another macronutritionist myth that seemed a good idea at the time. There is strong evidence that higher intakes of fat, saturated fat and monounsaturated fat are associated with reduced risk of ischaemic stroke.<sup>25</sup>

### ***Medical practice and science***

How often has society been lead to believe that a particular medical practice was scientifically based only to discover that it was in fact built on myth? Thacker & Banter's paradigm changing review of medical literature (nearly 200 medical reports) relating to episiotomy in childbirth failed to find any evidence in support of the practice.<sup>26</sup> Contrary to medical opinion that had evolved over 120 years it had no benefits to mother or baby and produced substantial longterm side effects for the woman. Medical advice to parents used to be to lie baby on their tummies to prevent cot death—research showed that this in fact increased the rate of cot death and the advice in now to lie babies on their backs. Medical advice to asthmatics has been to use synthetic pillows rather than feather pillows, as these are less allergenic—recent research has proven this to be the opposite of the truth. It used to be that diabetic coma patients were treated vigorously to return all biochemical indicators to normal as soon as possible—this proved to be deadly for the patients. It is popularly believed that intervention in high blood pressure will reduce disease and death. Yet as Professor Lionel Opie of University of Capetown fame said, when speaking at the recent Society of Hospital Pharmacists Association conference in Adelaide, “Diuretics improve symptoms but no data suggests that patient will live longer.” Average cholesterol blood levels in the USA have fallen slightly over the past 20 years [though this may be due to more specific analytical methods] with a slight but statistically insignificant change in either total or saturated fat intakes.<sup>27</sup> Even so, markedly more American citizens of all ages are overweight compared to twenty years ago. The US Department of Agriculture recently acknowledged that research using identical twins showed that fat intake had no bearing on total calories consumed, and hence weight gained.<sup>28</sup> Western societies' fetish with fat is a macronutritionist's myth. We are told that saturated fat is bad for you, yet a diet high in olive oil, which has a saturated fat concentration of 14% (high by oil standards) protects against heart disease.

### ***Micronutrients and nanonutrients***

Micronutrient deficiency can not only cause severe symptoms, but may also cause more subtle sub-clinical effects on tissue function, including immune deficiency and oxidative damage.<sup>29</sup> The duration of a deficiency state, which is necessary before such effects are clinically significant, is not known. Most biochemical tests are relatively insensitive in detecting changes in micronutrient status, although they do provide a crude index. Many tests are non-specific, being affected by the acute phase response as well as by nutritional status. Cellular tests are more sensitive and specific than tests in plasma but are more complex and cost a lot more so they are therefore not routinely available.

In summary, if medical science applied its understanding of cholesterol and heart disease to crime or house fires it would conclude that police and fire fighters respectively cause them—simply by association. There is a significant absence of scientific data to support many of the so-called preventative strategies that are commonplace in medicine. At best they are palliative; at worst they cause significant iatrogenic disease. Over 100,000 Americans die every year from medicines. That equates to approximately 1,250 iatrogenic deaths caused by drugs every year in New Zealand. There is a rapidly increasing flow of science that points to natural and complementary health care products as offering, effective and safe solutions to the wellbeing of humanity.

Worldwide sales of dietary supplements in 1996 were in the region of \$US 28 billion and increasing at approximately 20% per annum.<sup>30</sup> Dietary supplements are here to stay. Moves by regulators to restrict access to vitamins, minerals, herbs and things like that will fail as e-business via the Internet and the use of couriers will continue to flourish if natural and complementary healthcare products are not given their rightful place in society.

Society in general and patients in particular want more gentle, effective and “natural” approaches to chronic illnesses. They are turned off by the impersonality of medico-centric practice. Widespread frustration exists concerning conventional medicines’ inability to effectively treat chronic illnesses. The public wants a holistic approach to their healthcare, not hurried interactions with professionals who are paid on a per volume basis.



As pharmacists worldwide review their role in health care they have the opportunity to provide a sensitive interface between two legitimate yet very different approaches to wellbeing ensuring that their customers reap the benefits of both. Dietary supplements are no longer alternatives. Society and science have given them their rightful place in the wellness industry—it is time for health care practitioners to follow suit.

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<sup>1</sup> Journal of the American College of Nutrition, 1995; 14(1):71-79

<sup>2</sup> Lancet, 1994; 344: 1182-1186

<sup>3</sup> British Medical Journal, 1994; 309:11-15

<sup>4</sup> British Medical Journal, 1980; 280:285-287

<sup>5</sup> Science, 1984; 224:29

<sup>6</sup> Journal of the American Medical Association, 1992; 268:877-881

<sup>7</sup> American Journal of Clinical Nutrition, 1993; 57:47-53

<sup>8</sup> Journal of the American Medical Association, 1995; 274:1049-1057

<sup>9</sup> New England Journal of Medicine, 1995; 332:286-291

<sup>10</sup> Journal of the American Medical Association, 1997; 277:1775-1781

<sup>11</sup> Journal of the American Medical Association, 1998; 279:359-364

<sup>12</sup> Journal of the American Medical Association, 1995; 274:1049-1057

<sup>13</sup> New England Journal of Medicine, 1993; 328:1444-1449

<sup>14</sup> New England Journal of Medicine, 1993; 328:1450-1456

<sup>15</sup> American Journal of Clinical Nutrition, 1996; 64:190-196

<sup>16</sup> Lancet 1996; 347:781-786

<sup>17</sup> New England Journal of Medicine, 1996; 334:1156-1162

<sup>18</sup> New England Journal of Medicine, 1993; 328:1444-1449

<sup>19</sup> American Journal of Cardiology, 1997; 79:1558-1560

<sup>20</sup> Journal of the American Dietetic Association, 1984; 84:795-800

<sup>21</sup> American Journal of Kidney Diseases, 25(2):320-9

<sup>22</sup> Annals of Internal Medicine, 1998; 128(6):478-487

<sup>23</sup> NZ Truth, 17/7/98

<sup>24</sup> AHA Website

<sup>25</sup> Journal of the American Medical Association, 1997; 278(24) 2185-6

<sup>26</sup> Obstetrical and Gynaecological Survey, 1982; 38(6):322-338

<sup>27</sup> Third Report on Nutrition Monitoring in the USA, US Department of Agriculture

<sup>28</sup> American Journal of Clinical Nutrition, 1997, 66:1332-1339

<sup>29</sup> Nutrition, 1997; 13(9):825-8

<sup>30</sup> Report of The [US Congress] Commission On Dietary Supplement Labels, November 1997.