

Optimal Health

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ISM HEALTH WATCH

Are Clinical Trials Short-Changing Us?

ISSUE:

It seems that every week major randomised clinical trials report varying results regarding whether vitamin and mineral supplements work to prevent disease. Can thousands of conferring studies about the health value of nutrients *all* be wrong? What can you believe any more?

ISM POSITION:

No one questions the importance of randomised clinical trials (RCTs). But are they suitable as a stand-alone way of determining if nutrients are beneficial or not? RCTs in essence, pull a nutrient out of context and follow the same methodology as used for the testing of drugs.



For food and pharmaceutical items that do not normally form part of the usual food chain, RCTs are useful because such compounds can be tested and retested. But micronutrients, that are found in a wide array of foods and in synergistic combinations with other nutrients (i.e., ISM), do not lend themselves to a form of study that isolates one at a fixed dose for a set period of time.

Recent results of the Selenium and Vitamin E Cancer Prevention Trial (SELECT) and the Physicians' Health Study II (PHSII) in the *Journal of the American Medical Association*, are prime examples of the dubious application of the drug model to nutrients.

Guess what the results showed?. No effect! Hence, the media jumps on the bandwagon and produce headlines such as "*Vitamins do not cut cancer risk*". This is an over-simplification of the situation, and a damaging one. Will consumers read this and consider their vitamins as ineffective? (Questions over the quality of the journalism are another topic.)

FACTORS FOR ALL TO CONSIDER:

Why do we continue to spend millions of dollars on studies that pull nutrients out of context? Where's the control group? Are the people in the placebo group actually taking supplements on the side? How long is the latency period for the disease in question? Let's address these issues one by one.

(1) For many nutritional studies **a true control group doesn't exist**. As an example, you cannot remove vitamin C totally from someone's diet. It's both unethical and practically impossible.

The PHSII study authors admit that the population was well-nourished. So, could we ever have expected to see any effect? They also admit that this only applies to one dose. Is a study with one dose ... of one nutrient ... in a well-nourished population, enough to conclude that selenium, vitamin E, and/or vitamin C are ineffective against prostate cancer?

Putting it a different way, ultimately we're comparing someone with a good diet, to someone with a good diet plus a little extra vitamin C. What if people in the control group had a real love of vitamin C laden oranges?

(2) **Are placebo group participants also taking supplements on the side?** This is exactly what happened with the WHI study that showed no differences between people in the calcium plus vitamin D group and the placebo group. It turns out that many of the participants in the placebo group were also taking calcium pills..... 'Oops'!

(3) **And then the question of latency is critical.** If it takes upwards of 10 to 15 years for a disease to develop, (eg. colorectal cancer) and the study participants are free of the disease at baseline, then can we be hugely surprised or disappointed if we see no nutraceutical benefits after six years of supplementation? No!

Despite this knowledge, many regulatory authorities tie all health claims on data only to the 'gold standard' - randomised clinical trial.

So where does that leave us?

Many scientists and healthcare practitioners believe that we are over-reliant on RCTs. They call for science to be taken in its entirety, including *in vitro*, animal, case series and epidemiological studies.

Dr. David Sackett, OC, FRSC, a pioneer in Evidence-Based Medicine (EBM) who founded the first department of clinical epidemiology at McMaster, and then Oxford Centre for EBM said it very well.....

"EBM is not just about randomized trials. EBM is saying: Here is a problem we have to solve and what is the best evidence we have right now? If it's a randomized trial or, even better, a systematic review, great! If not, what is the next best evidence? In many cases we can't wait to do the trial. Indeed, the evidence-based practitioner of medicine..... would say: This is a problem I have to solve today, so what is the best evidence available to me? I'll take what I can get but at least I'm going to look for evidence, not just depend on the experts."

ISM believes - and is supported with overwhelming scientific evidence - that synergistic nutrition has a direct and fundamental bearing on the quality of our health. Thousands of epidemiologic studies have consistently shown that nutrition plays a crucial role in the prevention of chronic diseases. ISM's new nutraceutical research database

Nutraview (www.aminomics.com/nutraview.htm) is a portal into hundreds and hundreds of abstracts, from peer-reviewed literature, on the positive impact that nutraceuticals have on various diseases and chronic conditions.



Article is courtesy of ISM with excerpts from articles by Stephen Daniells, science editor for NutraIngredients and Jeffrey Blumberg, Professor of Nutrition Science and Policy at the Jean Mayer USDA Human Nutrition Research Center.

***We must turn to nature itself, to the observations of the body
in health and in disease to learn the truth.***

- Hippocrates

Proud of Our Product Control

We are often asked ***what is unique about ISM's products.***

Aside from the fact that we customize core amino chemistry to meet your body's deficiencies – we also use only the most pure organic materials available. We will NOT compromise the integrity of our product for cost, availability or any other reason. Only the absolute best compounds –“pharmaceutical grade”- are used in all of our formulations. Why?

What differentiates Pharmaceutical Grade Product?

The three different grades of raw materials used in products are:



Pharmaceutical Grade - meets pharmaceutical standards

Food Grade - meets standards set for human consumption

Feed Grade - meets standards set for animal consumption

It's important to know that the vitamins, minerals and micronutrients that you see on drug and grocery store shelves are not pharmaceutical quality because of the way they are manufactured. Often they contain high amounts of toxic chemicals like PCBs, dioxin and mercury which are all extremely toxic to human beings.

(1) Production Guidelines

“Pharmaceutical grade” means that the product has been manufactured under GMP conditions and is safe, pure and effective. Under GMP (Good Manufacturing Practices) every step of the process is documented by using established SOPs (Standard Operating Procedures). This includes training, equipment, raw materials, facilities, and final release criteria. Everything can be traced back to the date, time, person, lot number, and piece of equipment used.

Simply put, you can define "pharmaceutical grade" once it passes ultra-stringent purity standards. These standards require impurities to be measured and verified by a third party and the results printed on a Certificate of Analysis (COA). ISM produces a COA for every product and every batch we compound.

(2) Raw Material

Pharmaceutical grade raw material used to make ISM compounds have been tested using procedures designated in pharmaceutical monographs. There is a range of purity given for test results of pharmaceutical grade materials, such as 97-100%.

Drugstore variety are made from food grade raw materials to food grade manufacturing standards. To give you an idea of what these two statements mean: imagine a chocolate chip cookie factory. When you get the final product, there may be two chocolate chips in one cookie and five in another. Okay for chocolate chip cookies, but do you really want to use supplements manufactured to the same standards as chocolate chip cookies? The fact is, you can't guarantee the purity, strength, quality or identity of the ingredients within an over-the-counter supplement whereas ISM's pharmaceutical grade compounds contain exactly what they say they contain in the measurements stated.

(3) Quality and Purity

The main difference is of quality and purity. Impure ingredients are used by many companies. Regulatory bodies do not require manufacturers to list ingredients (on the nutritional labels) if they are not added when making the final dosage form. Many times the raw materials may contain only 60 - 90% (or much less) of the listed ingredients, along with 10% or more corn starch and lactose. Lactose and corn are known allergens for some people. These items have been known to cause digestive disturbances and weaken the immune system

ISM's pharmaceutical grade compounds must be in excess of 99% purity containing no binders, fillers, excipients (substances used as dilutents for a drug), dyes or unknown substances.

(4) Bioavailability

For a supplement to be effective, it has to be absorbed and used up by the body. Bioavailability is the extent to which a substance can be broken down and actually used by the body. Your supermarket variety supplement is manufactured using the least expensive ingredients which means they'll be in a form not easily broken down by the body. They also contain a lot of fillers and binding agents (these are substances used to make the pills stick together and be big enough to swallow). But if your body can't break the vitamin down and can't use the form it's given, you will not benefit from taking it and you will effectively and literally be flushing your money down the toilet.

(5) Hypoallergenic (non-allergy producing)

In the preparation of ISM products, every possible care has been taken in formulation and production to ensure minimum instance of allergic reactions.

What is the Value of Pharmaceutical Grade Compounds?

Consider this.....Imagine a supermarket vitamin tablet contains 100mg of an ingredient. This weight will also contain the binders and fillers to make it hold together. So potentially the actual vitamin or mineral is 15mg of the 100 mg. (Don't forget that the form may be one not readily broken down.) Now compare this to a ISM's pharmaceutical grade version in which 99% of the ingredient must be what is stated on the label. This means you would have to take eight times as many supermarket vitamins to get the same dosage as ISM's pharmaceutical grade product. So, as you are perusing the shelves and reach for the nearest (and cheapest) supplement - multiply the cost by eight and then ask yourself whether pharmaceutical grade products still seem expensive. Of course, if you already have an existing chronic condition or compromised immune system - do you really want to risk taking supplements that could add further toxins and impurities into your system?

ISM Announces Nutraview - www.aminomics.com/nutraview.htm



Nutrition provides not only essential nutrients needed for life but also other bioactive compounds for health promotion and disease prevention. Thousands of epidemiologic studies have consistently shown that nutrition plays a crucial role in the prevention of chronic diseases.

One of the problems people face in reversing disease is perceptual: the long-held belief that food and nutrients have relatively little to do with the development and progression of disease and the maintenance of health. The state of the North American population's health is sufficient proof of our

disregard of this fundamental health principle! Heart disease, cancer, and stroke are the top 3 leading causes of death in most industrialized countries. It is estimated that one third of all cancer deaths could be avoided through appropriate nutritional modification. This convincing evidence suggests that a change in dietary behavior is a practical strategy for significantly reducing the incidence of chronic diseases. ISM believes - and is supported with overwhelming scientific evidence - that nutrition has a direct and fundamental bearing on the quality of our health, more so even than the genes that we inherit.

“Nutraceutical” is a combination of the words “nutrition” and “pharmaceutical”. These are products isolated or purified from foods – that is, from nature – and which possess bioactive components that provide medical and health benefits.

Synergism - a Core ISM Philosophy - Evidence is plentiful in peer-reviewed literature of the positive impact that nutraceuticals have on various diseases and chronic conditions. It is important to consider the whole body when confronted with disease. Every system of the body works together. Nutraceuticals have complementary and overlapping mechanisms of action. This is known as synergism. A synergy exists between individual nutraceuticals, where they are found to perform more effectively in combination with each other – leading not only to an enhanced effect, but also to the need for lower doses to achieve the same result. The epidemiological evidence for the beneficial effect of nutrition in human health points in the direction of the impact of a range of nutraceuticals rather than a single component.

ISM's philosophy is to provide potent, high-grade multi-compounds of these components that reflect nature's variety. That is why a synergistic and personally-balanced nutraceutical formula, such as ISM's, is the most effective in supporting a healthy body.

“Nutravisit” is a portal into hundreds of abstracts from peer-reviewed literature on the positive impact that nutraceuticals have on various diseases and chronic conditions. It is not intended to be an exhaustive review, but a wide collection of supporting information that will help you make an informed choice.

The take-home message of "Nutravisit" is relatively simple: you don't have to go through life without a sense of vitality, and you don't have to accept diseases as inevitable parts of an age-related physical decline. ISM knows that you can feel better and reduce your risk of obesity, diabetes, heart disease, cancer, Alzheimer's disease and other age-related physical and mental disorders.

“Optimal Health” is written and produced by staff, associates and friends of Immune System Management Inc.

It is our philosophy that diverse health care modalities can work in conjunction with each other as part of a unified team rather than in competition. Such an integrated approach ultimately will lead to safer and more effective healthcare.

Optimal Health will act as gathering place and forum for comments and articles from medical professionals, educators and researchers from all health care specialties to the ultimate benefit of both the patient and the health care provider. We aim to share up-to-date news, information and diverse views for the growing integrative, alternative and complementary medicine movement, particularly as it applies to cancer and other chronic diseases.

Your comments and article contributions are welcome.

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