

DEATH OF THE EXPERT

This is an edited transcript from a lecture given by Dr. Gonzalez to a group of physicians and other health care providers, nutritionist, and health coaches at a business conference in 2016. There are some colloquialisms and references to slides in this edited transcript. However, continuity of thought is maintained in editing.

In these modern times the primary source of nutrition and medical information is the internet. And on the internet ...journalists, celebrities, professional bloggers all vie for “likes” and popular clicks of approval. Many pay for this attention. And these sources, especially journalists are smarter about how to present the information to sound very scientific-like. A popular source for these media-types is a website called PubMed. Many of you know this source if you are a health care provider. PubMed is a free public search engine that tracks scientific articles published by Medical Literature Analysis and Retrieval System Online (i.e. MEDLINE). Physicians spend anywhere from 7 to 10 years in training studying how to read, understand, evaluate, and integrate complex scientific studies. Journalists or professional bloggers rely on PubMed to sort out and do all that training for them. Most are reading only the abstracts (brief summaries) of the entire article. Some go further and validate with “experts” what they are reading in PubMed. Some even read the entire article.. but... are not equipped to understand the nuances of scientific study and jargon. So, what gets printed? A single line of summarized sensationalism that gets the public attention. Article content gets filled with misleading information regardless of whether there is any scientific basis or clinical application for the statement. All of which results in badly designed studies with sensational findings reported as medical breakthroughs. Worse, the attention misleads good doctors and provides a basis for poor government policy which leads to poor public health. This has been described well in a 2003 review published in the American Journal of Medicine (114:477-484). Researchers reviewed 101 scientific articles published between 1979 to 1983 claiming certain “technology had novel or therapeutic promises.” After 20 years only one study had any widespread use or clinical application. 100 sensationalized blogs, articles, headlines, pseudo expert publications would have been shot down cold. Studies in nutrition and supplement are excellent examples of pseudo-expert abuse. Here are some examples:

June 2014 Time magazine published on their front cover article “Eat Butter.” This was followed by the NY Times article by Mark Bittman “Butter is Back!” followed by The Guardian article “Butter is Bad – A Myth.” All this based on a meta-analysis study published in the Annals of Internal Medicine (Chowdhury et al.) showing coronary risk does not seem in direct relation to the consumption of fatty acids, including butter. This went around the world to the glee of butter basting steak eaters of the world. These pro-butter sensationalized headlines were all followed by an out-lash of “what the hell” by the scientific community. I was inundated by patients asking me about the media articles.

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There are thousands of scientific articles showing that saturated animal fat is hazardous to your health. And in fact, has been clinically shown applicable in whole populations (Laatikainen, Critchley, et al. 2005). Finland had greatly reduced its huge rates of CV disease by specifically decreasing butter, as well as increasing veggie and fruit intake. Time magazine uses scientific journalists and science consultants. How could they get it so wrong? First, the Time Magazine article was based on two meta-analysis studies. For review purposes, a meta-analysis combines the data from many smaller studies and looks for trends. Ideally, meta-analyses correct for small sample size and chance findings by zooming out and evaluating the preponderance of evidence. The Time reporter did not actually prove or illustrate with good literature review that butter and other sources of saturated fat are good for us. But that is what got reported as “fact.” This shows the lack of the ability of the non-scientist to understand what a study is and how to use it... It is difficult enough for us scientists to review and sort out the junk-reporting as I will illustrate a bit later....

The person best to describe this TIME magazine folly is Dr. David Katz, editor of the journal [Childhood Obesity](#), as well as director of a [health research center](#) at Yale. He stated:

“You never get a good answer to a bad question. They asked: Do we see variation in heart disease rates with the observable variation in fatty acid intake in our population? The answer, for the most part, was no. Well, frankly there wasn’t much variation in the consumption of fats by the people in this study, compared to people who eat optimally. So the question and answer, although reasonable, wasn’t very illuminating. If you have a small variation in x and ask is there a big variation in y, and the answer is no, then you’re kind of left saying, ‘Well, duh.’”

The NY Times and Time Magazine articles were seriously flawed with sloppy reporting and flawed analysis of the endorsement to eat butter. Worse, the reporting was on flawed meta-analyses of which I had written to the editors of the Annals of Internal Medicine expressing my concern for the poor analyses and the editors failure to recognize that prior to publishing the study. Letters from experts all over the world were written. The frustration is that little was said about the real science or the media hype. And thus..... I conclude..... The Death of the Expert.

People including physicians will listen to the hype simply because it is in our nature to do so when repetitively being hit over the head with this type of mis-information....Now, I could go on for an hour on the issues of this paper, the media reaction, the scientific world’s reaction, and how the media misleads physicians and the public alike. But we need to move on... I get passionate about this because all of you who are listening are probably trying to do the right thing and you are guided by these important Journals and we count on them to do the right thing....

— BENJAMIN —
GONZÁLEZ
— MD —

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Another good example is found in the world of multivitamin supplements and diets.... But First... I would like to review a basic principle in study technique. In medical science the randomized controlled clinical trial is considered to be the “gold standard” of research. Now this is not perfect and there are flaws to tying absolute results to these randomized clinical trials. Especially in the study of supplementation and diet. Let’s deconstruct the randomized controlled clinical trial. A trial is an experiment rather than an observational study. You take a group of people and do something to them and report the result. The clinical aspect is a setting in which a medical professional monitors the progress of the trial and patient outcomes. The controlled part includes additional groups that get no treatment, a variation of the treatment, or even a placebo to make sure the reported outcome was a result of the specific treatment. And finally the randomized idea is where patients have an equal and random chance of being assigned to any of the groups. This minimizes group differences that may affect outcomes. Reviewing the deconstruction of the RCT helps with understanding why nutritional and supplement studies are difficult to do and why many are so flawed. And why, if you count on these studies you need to be VERY careful how you choose to clinically apply them or advise others based on these study results. A missing aspect of this deconstruction and review of RCCT is the practical application of results..... but I will set that aside for now.

If we were to study a specific drug or screening protocol then the RCCT would make sense. A single variable with everything else a controlled constant is easily observed. But when the “variable” is a diet, or an undefined MTV, or even a surveyed supplement and the outcome desired is chronic disease improvement, the RCCT breaks down. Adherence to strict diets for more than a few weeks let alone the length of time it takes to see real changes in health is nearly impossible.The fatal flaw in most nutritional and supplement studies is that the length of time is shortened to make up for the difficulty in compliance of the participating patients. And outcomes such as the development of diabetes, heart disease, cancers, or even death are underreported. Let’s talk about some specific examples:

In Dec 17, 2013 the NY Times headlines read “**Skip The Supplements**” with quotes from the media articles stating “**Case is closed: Do not take your Vitamins**” and “**Vitamin pills are a waste of money, offer no benefits, and can be harmful.**” These media reports were based on articles published in the Annals of Internal Medicine that same week. The finality of such conclusions published in such a widely accepted medical journal as the Annals of IM was so shocking to me at that time I stopped all other scientific activity and relooked at my own understanding of diets and supplements with a fine-tooth comb. I reviewed and researched articles and I looked hard at the three articles published and what I found was more shocking: Real and absolute junk in research and publication. All the things I was taught throughout my career as a physician and scientist seemed to be tossed out the door by the journal’s editors, us scientists dearly hold on to and trust as good science sources...So let me explain..... I am a little lost in my slides here....[sic]

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Wait, I don't think I gave you the articles I am referencing yet. They are out of the Annals of IM. Published Dec 16, 2013. The first was titled "Oral High Dose MTV and minerals after MI" by Lamas et al. This was touted to be the end all answers to chelation therapy and oral MTV use in CV event recovery. 1708 patients with healthy kidneys defined as Cr less than 2.0 who had an MI less than 6 weeks prior to enrollment into the study were enrolled. The intervention was a random enrollment assigning a patient to either a 28 component MTV and mineral supplement or a placebo. Oh, and I need to mention the subjects were all over 50 years old...The primary end point was time to total death, recurrent MI, stroke, coronary revascularization, or hospitalization for angina. I chose this as one of the first articles to discuss because it illustrates many of the issues with nutritional and supplement studies I previously discussed. Now there were 2 arms to this study, the chelation therapy arm and the oral MTV arm. In the interest of time I will focus on the Supplement side of the study. It turns out the 28 component MTV actually showed an 11% reduction of primary endpoint when compared to placebo. And this was under the more stringent level of statistical significance of the $P < .036$ rather than the standard P value for statistical significance of 0.05. So, you would think, the authors and the proponents of MTV therapy in general would take this as very positive. Here is where the issues really stand out. First, the MTV was a random pick of MTV sourced from Douglas Labs, a popular source of supplements. Though it is one of the higher quality sourcing there have been issues with quality control over the years. Some of the issues include ingredient levels, issues with excipient ingredients, bioavailability issues.....

Slide Reference Noted:

J Pharm Pharmaceut Sci (www.cspscanada.org) 9(1):40-49, 2006

Investigation of vitamin and mineral tablets and capsules on the Canadian market Raimar

Löbenberg¹, Wayne Steinke²

...and of course, not only the randomness of the combination of ingredients used in the MTV, and the one-a-day intake rather than the more appropriate biphasic and bioavailable intake of bid (twice a day) intake, but the lack of understanding of the basics of nutrient physiology.... that the levels of each of the 28 ingredients used may or may not have any effect whatsoever in CV improvement. In other words, as I mentioned in the beginning of this discussion, there is no standard for what defines a MTV let alone what kind of outcome can be expected when discussing different disease processes. So what kind of "Control" does a study like this actually have when trying to discern if "MTVs have an effect and are safe" for a specific disease process? Though the 11% improvement noted in the study did not reach the more stringent statistical significance it did show the total number of events were smaller. Here is another interesting factor illustrating compliance in nutritional and supplement studies. In this particular study, even at such a short timeframe, ..The number of patients who stopped their MTV or placebo was

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extremely high. 46% to be exact. Another interesting finding is that 45% of the participants were actually taking other supplements! How controlled of a study is that? And what about the complexity of CVD itself? These patients are on multiple pharmaceuticals: Ace inhibitors, aspirin, Beta blockers, statins, hypoglycemic of all types. And some of these medications were started AFTER the MI event. What about the effects of the pharmaceuticals contributing as confounders? Do you think the word “CONTROL” is a legitimate use in this “controlled trial?” I actually spoke to some of the authors including the lead author Dr Gervasio Lamas. He pointed to the fact that he did list the limitations and was ADAMANT that this trial had issues but still showed a possibility of safe use of MTV in this population. He too was dumbfounded at the media reaction to this publication. Now, I picked this study as the first to discuss because it illustrates the compounding issues noted in the other 2 studies published that month.

The 2nd study referenced by the media world as the end all to the MTV question was a review **“of the potential benefits and harms of vitamins and mineral supplements in community dwelling, nutrient-sufficient adults for the primary prevention of either cardiovascular disease or cancer.”** The authors reviewed 103 articles representing only 26 studies. These trials varied considerably in study design, recruitment criteria, and primary end points. Again, as I have emphasized as an issue with supplement studies... the trials here differed dramatically in the multivitamins or mineral products used. So, the conclusion that ... **“no consistent evidence that the included supplements affected CVD, cancer, or all-cause mortality in healthy individuals without known nutritional deficiencies.....”** is an interesting one.

Again, the media, and worse, health care providers including specialists, health watch groups, and primary care doctors alike all grasped at the headlines: “Vitamins are a waste!” and ran with it, rather than look at the actual study itself. So... Instead of going through the details of each of the 103 studies in this review... and their individual issues ...I think I can present this more succinctly. I think Everyone listening to this lecture [sic] would agree that each ingredient in a MTV supplement has its own mechanism of action, therapeutic dose potential and bioavailability of action. WOULD everyone agree? [sic] I mean if you have subjects taking in methylated folate and others taking in the pro-hormone Vitamin D while others may be taking a Omega-3 and you are comparing all these under the auspices of a single entity called a “MTV” in a Randomized Controlled Clinical Trial then that would not be very scientific now would it? That is what this review study did. And in fact, this particular study excluded MTVs with known therapeutic dosing ranges of certain ingredients and used MTV with only the US Food and Nutrition Board RDA levels. {*Dietary Reference Intake (DRI)*} You know, such as the recommended 600 IU of fat-soluble Vitamin D a day. Which is up from the 400 IU it used to be when I was diagnosed and treated for Vit D def in 1996 with a Vit D level of 6. I gotta[sic] tell you this story..... My IM doc put me on a 400 IU tab twice a day...yep, it did nothing. 3 years of rechecking and slowly increasing Vit D supplementation before finally getting my

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serum levels to 20.man, I am I digress [sic]..... So, this review study excluded any studies that had actual therapeutic levels of whatever nutrient discussed. In other words, any study concerning Vitamin D of more than 600 IU q day intake was eliminated. Another interesting aspect of this study was **that any patient with a nutrient deficiency were excluded** (my emphasis). So, you have to ask the question: What was this review's intended application?

What is truly unfortunate and again, one of the issues with studies on supplements is that these types of study designs were meant for pharmaceuticals and not for nutrients. This particular review adds very little to the knowledge and application of nutrients in the general population to prevent disease or the safety of MTV use.

And finally, the 3rd study published that same week in the Annals of Internal Medicine by Grodstein, et al titled "Long term supplementation with MTV and cognition function in men" was a randomized trial from the Physician's Health Study Phase II (PHS 2) study. There are multiple arms to the PHS2 and 2 arms were used for the Grodstein Study looking at the 2 groups, one given a MTV (Centrum Silver) and the other a placebo. I saved this study as the final to discuss tonight because I was particularly appalled by the study itself and embarrassed to see it published in a journal so counted on by us physicians to bewell..... valid. This was the study that prompted me to write the editor.....Unfortunately, I have seen this study used by physicians and on health-watch websites..... and many of you use this study to say NO to MTV use for your patients..... First, the vitamin used itself. This particular vitamin is so well know to be junk. (slide of the product Centrum displayed) Real junk: Quick examples:

Centrum is produced by the pharmaceutical company Pfizer bringing in close to 1 billion in sales. It has been "improved" recently in their new product Centrum Blue" Have you seen the commercials? You know how they improved it? By putting mint in it..... yeah..... Anyway, Centrum uses mostly synthetic ingredients including synthetic vitamin E (dl-alpha-tocopherol) and beta carotene, the same kind that has been found to cause detrimental health problems like prostate and lung cancer. It uses the oxide form of magnesium, which only about 5% is absorbed. It contains hydrogenated palm oil, a trans-fat highly highly correlated to heart disease, not to mention all the artificial colors including FD#C Blue #2, Yellow #6 and Red #40 found to disrupt mitochondrial function.....all while having a very poor absorption and elimination rate..... all well studied....A study found in the Journal of Toxicology found that the dyes actually enter the bloodstream through the skin or digestive system, debunking previous expertise that the skin blocked it and the digestive system destroyed it first. This is alarming because these dyes have already been linked to ADHD, allergies and asthma, but due to the dye's ability to inhibit cellular respiration, a whole cascade of health effects...[sic]

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Another issue with this study was that the cognitive test was conducted an average of 2.5 years AFTER their subjects were randomized to either the MTV or placebo arm and in some cases up to 5 years after. In other words, the baseline cognitive assessment was useless, influenced by years of therapy, or no therapy in the case of the placebo arm. Another issue was there was no control of whether a subject was taking other MTVs and in fact it was known that 33% of the study subjects were taking other types of supplements. This is a seriously gross oversight and one I pointed out in my letter to the editor. How can this study come close to answering the question of MTV influence on cognitive function? Seriously!

A physician knowledgeable in proper supplement use does not typically recommend products like Centrum Silver, this product was not specifically designed to modulate cognitive function. Nor were there previous trials to suggest such an outcome. It is curious, then, that a study (PHS2) that was not designed for this primary end point, coupled with an intervention (Centrum Silver, 1 capsule/d) not designed for this primary end point can be evidence for anything—let alone be allowed publication in the Annals of IM or ...as a final answer to the question of MTV use?

All three of these studies I cited here are the 3 most cited by the naysayers of MTV or supplementation use including physicians advising patients on preventative health issues and by healthcare watch groups. Why? Because we TRUST these academic publications to vet poor studies and 2, because our society is media driven and it is easier to believe NY Times or a celebrity blog....than a physician like me who studies this day in and day out, applies what I study to actual patients and remain skeptic of any and all studies or such finalities as “Case Closed.” A true physician, a teacher of health, a true scientist, is a true skeptic, not a cynic. ... and has the passion to go head to head, nose to nose with those who disagree. I have bloodied my nose in the past and I am OK with that.....you should see the other guy [sic].

How can you really come up with definitive answers so powerful that you publish fatally final titles like “The end all answer to MTV use” and “Stop wasting your money on Vitamins?”

{Slide citation: Comerford KB, “recent Developments in MTV research” Adv Nutr. 2013 Nov; 4(6): 644–656}

A note about the term “Fortified Foods” and the Irony of recommending fortified foods: In general, you will not find dietitians recommending supplements, unless they are hospital based and then you will note the use of a general MTV that can be found at the end of the day in the toilet. Anyone have a story?.....However, you will find them recommending fortified foods. Let the irony settle in for a minute. Why would they say no to taking supplements, but choose to recommend food with added

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supplementation using poorly made synthetic vitamins? Because the American Dietetic Association is funded by processed food companies. This is how a diet of fortified cereal, fortified orange juice, low-fat dairy and artificial sweeteners became forced on the public and was recommended to my own father when he was hospitalized with renal failure of unclear etiology.

“In summary, everybody seems to be an expert. When you look at how a true expert is trained you begin to realize there is a difference between relative unbiased review and discussion and the hijacked review of scientific literature with a commercial agenda. It is difficult to have no bias what-so-ever. I am the first to state I have bias as I did at the beginning of this lecture. There is never a uniform agreement in medicine and that is a good thing. It allows for discussion and innovation. And though agreement may not occur, a mutual respect of a difference of opinion may allow for progression of solutions to medical problems. Is this not what we are all striving for? Future medical research protocols should continue to be scrutinized and improved. And it should be executed and interpreted within context of good science and practical application. No matter how smart The Food Babe is or a lay magazine science editor is, they will always have difficulty interpreting medical literature and applying it clinically. Now go out there and be the real expert. Thank you.

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