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FACTS AND FACTOIDS: An Information Sheet for Patients by Abram Hoffer MD PhD FRCP(C)

Fact: Something that has really occurred or is the case: hence a datum of experience, as distinct from conclusions. Loosely defined, something that is alleged to be, or might be a "fact."

Factoid: A factoid is a fact that never existed before it appeared in print, but has been reprinted ever since. It is truly launched if it first appears in a reputable medical journal like the *Journal of the American Medical Association* and republished in the *New York Times* which gives it international stature. A factoid, using simple Anglo Saxon terminology, is a lie, and like many lies and misconceptions, once it has been published develops a life of its own and is reprinted over and over, from textbook to textbook. The best example is the lie (factoid) that vitamin C causes kidney stones.

There is a close and intimate relationship between these definitions and the battle between the former vitamins-as-prevention and the current vitamins-as-treatment paradigms. A paradigm consists of a system of beliefs which are generally accepted by the supporters of the paradigm, usually a majority of the scientific establishment if we are considering medicine and science. It is a combination of facts and factoids, but the supporters of the paradigm will support both facts and factoids with equal fervor. Pirsig wrote, "You are never dedicated to something you have complete confidence in. No one is fanatically shouting that the sun is going to rise tomorrow. They know it's going to rise tomorrow. When people are fanatically dedicated to political or religious faiths or any other kind of dogmas or goals, it's always because these dogmas and goals are in doubt".

In most cases the facts and factoids comprising the paradigm are not properly labeled, and factoids will be accepted as facts. The paradigm is replaced in time by a new paradigm when enough of the factoids present in the original paradigm are either destroyed by new evidence or data or become facts by the accumulation of new data, new observations. A factoid may become a fact, but a fact can never revert to a factoid.

Factoids about vitamins are rampant on the internet because there is no editorial control as there are in the journals. In journals statements are

expected to be derived from previous publications and from data. On the internet they do not need any basis since they are merely ideas put forward by the writers. The internet also contains discussions of facts designed to explode the factoids. Other public media use either facts or factoids, depending on the current public opinion. If the opinion is positive for vitamins, facts are most often published. If the public opinion is judged to be negative, factoids receive easy publication.

Evidence Required to Establish Facts in Clinical Medicine

Clinical facts are based on clinical observations made by a clinician who can draw careful and honest conclusions from clinical data. These are one-to-one observations, patient and doctor. These kind of observations have fallen into disfavor with the medical establishment and are labeled anecdotal. These clinical trials are basic to the whole field of medicine because no therapeutic trials will ever be undertaken until one or more physicians find that the treatment has some value, even even if only for a few patients.

The clinical observations are reinforced by special ways of collecting the data called controlled clinical trials.

- 1) Historical controls - A number of patients are given the treatment and the outcome of treatment over the follow-up period is compared with the expected outcome based upon the history of that disease as established by many observers. Thus if a disease kills every patient and if a treatment saves half of them over the same follow-up period, then one will conclude that the treatment had value. This is the traditional way of running therapeutic trials. This is the least expensive way of testing treatments but is no longer considered scientific.
- 2) Controlled comparison therapeutic trials based on probability theory and the need for equal samples of patients from the treatment and the control (no treatment) group. This is similar to the first method except that it uses current controls, not historical controls. The decisions as to whether the patients will receive the control treatment, i.e. no treatment, or the research treatment, is based on random selection to remove bias.
- 3) Prospective single blind controlled therapeutic trials. With these experiments the investigators and evaluators of the results of treatment know whether the patients got the research treatment or the control treatment but the patients are not told. That, of course, does not mean that they do not know.
- 4) Prospective double blind randomized double blind therapeutic trials. In these trials the treatment is allocated by random selection and neither the patients nor the investigators know from which group each patient is derived. Under my direction Psychiatric Services Branch, Department of Public Health, Saskatchewan, conducted the first psychiatric controlled trials of this type, completing six between 1952 and 1960. We compared the therapeutic effect of vitamin B-3 (niacin and niacinamide) against

placebo in schizophrenic patients. In this way I contributed to the development of a method which is now the gold standard but which has never been calibrated, i.e. shown to do what it is supposed to do. It is an awkward, very costly method best suited for institutions with a lot of money and little imagination, and meets the needs of the U.S. FDA and Health Protection Branch in Canada, medical journals and granting agencies. It is a treatment trial which probably is not as valuable as the direct clinical examination which is so derided today as anecdotal. However, fewer than one-quarter of the treatments commonly used in medicine and surgery have been tested in this way.

Evidence Required to Establish Factoids in Clinical Medicine

No evidence is required. When discussing side effects and toxicity a whole new set of variables are introduced. For establishing toxicity no controlled trials are needed. The originators of the factoids may develop their factoid on the basis of a theoretical examination of the literature, or it may arise from their own bias against a treatment. It often arises out of faulty experiments which later can not be confirmed. Thus critics of a new treatment demand that the proponents provide airtight facts based upon a large number of double blind controlled experiments, but they will also attack the use of the treatment based upon toxicity for which there is no basis. One of the best examples of this occurred when it was concluded that folic acid would decrease the incidence of congenital abnormalities. The publication of this fact, which it is now, was followed by a series of irate letters in the medical journals written by physicians who bemoaned the fact that these tiny amounts of folic acid would be toxic. We hear no more of this now. The factoid about toxicity has vanished and the fact of its efficacy remains.

A recent example is the statement by oncologists that antioxidants (by which they usually mean vitamin C) will decrease the therapeutic value of chemotherapy for treating cancer. In fact there are no clinical series which show that the patients given vitamin C and chemotherapy fare worse than those not given this vitamin. On the contrary, all the published series show just the opposite. I have treated over 1130 cases with large doses of vitamin C and most of them had chemotherapy. I have examined the follow-up data and find that the mean difference on prolongation of life was heavily in favor of the use of the vitamins. Recently Prasad KN et al, after reviewing seventy-one scientific papers found no evidence that antioxidants interfered with the therapeutic effect of chemotherapy. Even earlier Simone CB et al, on the basis of a large number of clinical studies (he also examined seventy-one scientific papers) came to the same conclusion. Not one subject reported a worsening of symptoms. He concluded, "...cancer patients should modify their lifestyles using the Ten Point Plan, which included modifying nutritional factors and **taking certain vitamins and minerals especially if they are receiving chemotherapy**, and/or radiation." (The emphasis of this last part of the sentence is mine).

Labriola et al concluded that vitamin C may prevent the therapeutic effect

of chemotherapy if given concurrently and recommended that antioxidants be withheld until after the chemotherapy is completed. He based his conclusion on one case. His report elicited three rebuttals, Reilly, Gignac, and Lamson and Brignall. I will not repeat the arguments but it was evident that Dr. Labriola was not convinced by the points put forward by Reilly and Gignac. I think the factoid repeated by Dr. Labriola would have a much better chance of becoming a fact if he had considered the following points:

(1) What is the therapeutic value of chemotherapy without any antioxidants? Even within the field of standard oncology there is a debate whether chemotherapy has any merit except for a small number of cancers, Moss¹⁵. Before one can claim that a treatment has been inhibited, surely there must be pretty good evidence that the treatment has any merit to begin with. It is possible (we do not know the probability for this) that chemotherapy interferes with the therapeutic value of the antioxidants. Almost all the studies testing large doses of vitamin C yielded positive results while there is no such unanimity with respect to chemotherapy.

(2) The difference between possibility and probability. Most people do not distinguish between these two. Theoretically anything is possible, and it is certainly possible that taking vitamin C might prevent the toxic beneficial effect of chemotherapy. In the same way when one buys a lottery ticket it is possible they may win. People confuse these two terms, which is why lotteries are so popular. The relevant statistic is the probability. What is the probability that patients receiving vitamin C during their chemotherapy will not fare as well? The lottery ticket may give one a probability of winning of one in a million and the possibility that vitamin C may prevent the therapeutic effect of chemotherapy may be equally low. We can only assume from the literature reviewed by Simone, by Prasad, by Lamson and Brignall, and more recently by Moss, that the real probability must be extremely low. As I have pointed out earlier, I have seen no evidence that adding vitamin C inhibited the therapeutic effect of chemotherapy. Just the opposite. Patients on my orthomolecular program live substantially longer and about 40 percent achieved over four year cure rates.

(3) If he had not tried to bolster his argument by referring so frequently to the peer reviewed journal in which his paper appeared. This is certainly no guarantee of fact. The first factoid that vitamin C caused kidney stones appeared in eminently peer-reviewed journals. All the factoids regarding vitamins appeared first in peer reviewed journals. I can assure you that articles attacking the use of vitamins have very ready access to peer-reviewed journals. But they would not have accepted the report had they tried to conclude from one patient that vitamin C taken during chemotherapy was therapeutic. This would not even be sent to the peer review committee because they do not accept anecdotes - unless of course they consider them scientific because they contain something adverse against vitamins.

(4) Moss points out that oncologists have no objection to using xenobiotic antioxidants during chemotherapy. This includes Amifostine which decreases the toxicity of radiation but is too toxic on its own and is not used; Mesna, a drug used around the world to protect against the toxic side effects of ifosfamide which damages the urinary system; and Cardiozane, which counters Adriamycin's toxicity. There are over 500 papers showing the safety of Cardiozane. In one clinical trial using a drug similar to Adriamycin one-quarter of the patients suffered damage to their hearts. When given Cardiozane concurrently only 7% did. Thus it appears that only orthomolecular or natural antioxidants are potentially dangerous. Synthetic antioxidants protect against the toxic effect of drugs but do not increase their therapeutic value. In sharp contrast, natural antioxidants not only protect against the toxic effect of drugs but also increase their efficacy in destroying cancer cells.

(5) Dr. Labroila emphasizes that long term studies must be used. I agree and for this reason I have followed up my patients since 1977. In my series, hardly any patients receiving chemotherapy but no antioxidants survived very long. But chemotherapy is used by many oncologists who know it will not extend life because there is nothing else that they can do and they feel they have to do something.

In conclusion, as the proponents of the old paradigm see it, facts are facts only after double blind controlled experiments conducted by the right investigators from the correct school and published in the correct medical journals. Factoids can be thought up by anyone and immediately become facts in the profession if the factoid attacks the evidence against the new paradigm.

Current Factoids:

About Megadose Vitamin C

These factoids are based upon hypotheses. There is no clinical data to support any of them and almost all studies show that they are not true or real. They are not supported by any studies.

- causes kidney stones,
- causes kidney damage,
- causes pernicious anemia,
- decreases fertility in women,
- causes liver damage,
- causes iron overload and toxicity,
- is dangerous for diabetics by interfering with glucose tests,
- causes cancer,
- inhibits chemotherapy,
- prevents radiation from being effective
- prevented Linus Pauling from living longer
- prevents surgical scars from healing.

I should have used weasel terms - instead of "causes" by writing "may

cause." Because using the word may allows the proponent of the factoid to leave the suggestion that these factoids are true but leaves an escape path in case they turn out not to be true. The author can then claim, "well I did not say that these factors were true. I merely suggested that they might be true." There is the usual confusion of probability and possibility. If a phenomenon occurs once out of a million tries the probability is one out of a million, but there is no value attached to the possibility. It is indeed possible. Again, the enormous sale of lottery tickets depends upon confusing the public in this way. Or looked at in another way, if the probability of winning a lottery is one in ten million if one buys one ticket, and the probability is zero if one does not buy the ticket, then one can say that dividing the ratio one in ten million by zero yields the enormous probability of infinity that one will win the lottery. Any number divided by zero yields infinitesimal large values. Critics of megavitamin therapy never give any probability values since they know they are close to zero.

About Megadose Niacin

The factoid niacin causes liver damage is analyzed thoroughly by William Parsons Jr, who shows that niacin will often increase liver function tests but that these increases do not arise from liver pathology. Since I began using megadoses of this vitamin in 1952 I have seen a few cases of obstructive-type jaundice which cleared when niacin was stopped, and in one case I had to resume the use of niacin because the patient's schizophrenia recurred. He recovered and the jaundice did not recur. I have seen so few cases of jaundice that there is little evidence that the jaundice arose from the use of the niacin. Jaundice has a natural occurrence rate and from any series of patients a few will get jaundice from other factors. In rare cases too much niacin causes nausea and vomiting, and if this persists because the niacin is not decreased or stopped the dehydration might be a factor. I have seen no cases in the past fifteen years. The main danger from taking niacin is not jaundice, it is that people will live longer.

Factoids in the Making

It is very interesting, even if frustrating, to witness the manufacture of factoids. A new one may soon be born. It is that niacin is dangerous because it increases the plasma homocysteine levels. Garg et al reported that niacin increased homocysteine levels. Apparently no other B vitamins were given. After a tough battle for acceptance the homocysteine findings are recognized as playing a role in atherosclerotic heart disease. But the reduction in the abnormal cholesterol levels and the increase in HDL decreases the risk of heart disease. The Coronary Drug Study, Canner et al, showed that over a fifteen year follow up mortality was decreased by 11% by niacin and longevity increased by two years. In this study niacin was used as a drug which lowered elevated cholesterol levels. No other vitamins were used. Garg et al are aware of this. They referred to the report by Basu et al that the niacin induced increase in homocysteine levels did not interfere with its normalizing effect on blood lipids. And they pose the question whether it would be beneficial for patients on long term niacin treatment to take other B vitamins such as folic acid. My answer is

that of course it would be beneficial, and since 1965 I have routinely given my patients one of the B-complex formulations such as B-complex 50's or 100's. These provide pyridoxine, folic acid and vitamin B-12 as well as other vitamins. Adding these vitamins inevitably will be beneficial since the other vitamins have therapeutic properties of their own in addition to keeping homocysteine levels from going too high. But even niacin alone was beneficial, not harmful. And this confirms what I have seen since 1952 when I began to use megadoses of niacin and niacinamide for schizophrenia and for other conditions, including elevated cholesterol levels and arthritis. The authors did not invent any factoid but it is highly probable that some of the readers of that report will ignore almost the whole report except that niacin elevates homocysteine and therefore will increase the risk of heart disease. You will soon see this factoid repeated endlessly.

Niacin is a methyl acceptor and this may be the mechanism which leads to the elevation of homocysteine levels. Niacinamide is also a methyl acceptor but it has no effect on blood lipid levels. Its effect on homocysteine levels is not known but there is no evidence that it reduces life expectancy. On the contrary, it has great value in the treatment of senile states, both physical and mental, and in my series, if anything, tended to prolong life.

Kaufman had studied the use of this vitamin for the arthritides before 1950 and had published two books describing his remarkable results. Since that time this vitamin has been a very important component of the orthomolecular regimen for treating arthritis. Dr William Kaufman, my long term friend, died a few days ago (August 2000) at age 89. His very important work remains mostly ignored even after a double blind study showed him to be correct.

But Garg's report does raise very interesting questions which will have to be studied. The first is whether the elevation of homocysteine is an important factor but only in subjects who are not taking adequate levels of the other B vitamins, i.e. are not well nourished in orthomolecular terms. It is possible that in the presence of good nutrition the increase in homocysteine levels is not pathological at all and may even be beneficial.

Another potential factoid was trumped up by the press and received wide attention in all the media. The press reported that Dr. James Dwyer, University of San Diego Medical School, had found that the carotid arterial walls had been thickened by 500 milligrams of vitamin C daily. The press report cautioned against the use of vitamin C because this showed that the arteries were depositing plaque. But Professor Dwyer told Owen R. Fonorow they had used only one measure and had not used two other measures which would have shown the degree of focal plaque called the plaque index, nor the velocity ratio to determine whether or not plaque interfered with blood flow. He did not say that plaque had developed. Dr. Robert Cathcart with experience on over

25,000 patients since 1969 has seen no cases of heart disease developing in patients who did not have any when first seen. He added that the thickening of the vessel walls, if true, indicates that the thinning that occurs with age is reversed. I have used vitamin C in megadoses since 1952 and have not seen any cases of heart disease develop even after decades of use.

Recently Gokce, Keaney, Frei et al gave patients either a single dose of 2000 milligrams of vitamin C and 500 milligrams daily for thirty days and measured blood flow through the arteries. Blood flow increased nearly fifty percent after the single dose and this was sustained after the monthly treatment. They concluded that ascorbic acid treatment may benefit patients with coronary artery disease. This certainly effectively does not support the conclusion of Dwyer who did not measure blood flow.

The Good News

The opposite of a factoid is a fact. The good news is that as none of these factoids are true, the opposite is true. This summary statement is based upon literally thousands of published papers in medical literature and hundreds of books that have been published in the past twenty years. I can not provide references to these numerous clinical studies, but readers of the *Journal of Orthomolecular Medicine* have ready access to the facts and also to the book reviews of over one hundred of these books. The internet contains a large number of excellent discussions of vitamins and, of course, the facts and factoids which are current.

Vitamin C

<u>Alleged Toxicity</u>	<u>Factoid (Lies)</u>	<u>Fact</u>
Kidney	Stones	Decreases frequency
Kidney	Damage	No
Pernicious anemia	Yes	No
Fertility	Impaired	No
Liver damage	Yes	No
Iron overload	Theoretical	No clinical evidence
Glucose blood tests	Interferes	Not with modern tests
Cancer	Causes cancer	Therapeutic for cancer
Atherosclerosis	Increases	Prevents
Chemotherapy	Decreases efficacy	Increases efficacy
Radiation	Decreases effect	More effective
Surgery	Prevents healing	Increases healing rate and decreases scarring
Linus Pauling	Shortened his life	A ridiculous claim. He died age 94, fully mentally alert.

Conclusion

The factoids about vitamins, used in optimum doses when needed, are

not true, are not based upon clinical evidence, do not have any studies including double blind controlled clinical data to support them, and are used primarily to attack the new paradigm, the vitamins-as-treatment paradigm. Be wary of factoids whether they are in print, on the internet, in the news media, on radio or on television. If you hear of any new factoids, please let me know so I can add to my collection.

The unfortunate result of these lies is that patients are made fearful, some will stop taking their vitamins, medical costs will increase since patients want to see their doctor again to discuss these matters, and more patients will relapse. The harm done by these factoids is immeasurable, but fortunately is slowly decreasing as the population becomes more knowledgeable and sophisticated about nutrition and nutrients. In the same way that drug companies are not allowed to make false therapeutic claims about their products, we need a system which will neutralize the factoids as they are proposed. And above all we need the public media to become much more intelligent and less subservient to major papers like the *New York Times*.

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