

# Editorial

## **A Basic Flaw in Modern Medical Research**

When I was a graduate student studying for my Ph.D. in chemistry, before I became a medical student, one of the most fundamental rules of research was this: when you claim to repeat someone else's research you do, in fact, just that — repeat the work exactly as it was described. Then, if different results are found, the resulting controversy will lead to clarification and perhaps new findings. This may be described as a scientific controversy. If the research is not an exact replication of the original research, its conclusions have no scientific value. It required nearly ten years for neurophysiologists to repeat exactly the original work which demonstrated the presence of acetyl choline in nervous tissue. A number of reports, not repeating the method, failed to find it. Science will always be bedeviled and confused by investigators who, for a number of reasons, fail to reproduce work already published, but these faulty reports will eventually be buried in the dustbin of sloppy mechanical research.

But when workers fail to replicate work and then claim to have replicated, the damage done to us all and to science is immense and should not be tolerated. This would not be the case if

scientists took the time to read original reports. But too many do not, and freely accept the conclusions in the conclusions or the abstracts, or inherent in the title of the report. These reports where there is no replication but are reported as such are dishonest, harmful and should not be tolerated. I would expect that medical journals which have a high opinion of their own scientific integrity would be very careful to avoid these dishonest practices, but they do not. Peer review committees have a very poor record for detecting these badly re-,  
ported studies.

I will refer to a few examples only although every year I see continuing evidence of this failure to report honestly.

I first became aware of this when I read reports several years ago which claimed the authors had repeated the Shutes' researches on the connection between Vitamin E and heart disease and had not been able to duplicate their conclusions. When I read those original reports which failed to support the Shutes', I found that not a single paper followed Shutes' protocol. They used too little Vitamin E, often the wrong type, for too short a period. They could have concluded accurately that using too little Vitamin E, of

the wrong type, for too short a period of time had no therapeutic value. This would have been an accurate but not surprising conclusion.

Many years ago, a physician reported that women given desiccated thyroid which lowered their cholesterol levels had a very low breast cancer recurrence rate. Since then, a number of authors have treated women with breast cancer with pure thyroid hormone and were unable to confirm the earlier report. They then concluded there was no relation between thyroid and cancer. So far, I have not found a single report in the medical journal literature where investigators repeated the first report. Thus we may be missing a very important finding, i.e. that thyroid gland contains an anti cancer factor which is not thyroid hormone. Every cancer specialist "knows" there is no connection.

The most recent example of failure to replicate is the study by Moertel, C.G., Fleming, T.R., Creagan, E.T., Rubin, J., O'Connell, M.J. and Ames, M.M.: High-dose Vitamin C versus placebo in the treatment of patients with advanced cancer who have had no prior chemotherapy. *The New England Journal of Medicine*, vol. 312, pp. 137-141, January 17, 1985. In this report these authors wrote, "The present study was undertaken to test the thesis put forth by Cameron and Pauling that high dose Vitamin C is effective therapy for advanced cancer in patients who have had no previous exposure to chemotherapy." In other words, they implied they were attempting to repeat Cameron and Pauling's earlier studies. The same issue of NEJM contained a laudatory editorial which said, "It is difficult to find fault with the design or execution of this study. Ascorbic acid was given in the same daily dose and by the same route advocated by Cameron and Pauling."

I agree it is difficult to find fault with this design, but only if one does not expect it to be relevant to Cameron and Pauling's conclusions. Dr. Linus Pauling is properly incensed, as should be every good scientist. In his press release, January 26, 1985, he charged that the Mayo Clinic doctors had represented their study as a repetition and check of earlier studies reported by Drs. Cameron, Pauling and associates, whereas

in fact it deviated greatly. The press release said, "Dr. Cameron's patients received high-dose Vitamin C from the time when they began to take it until they died or until the present time, some of them for as much as 12 years. On the other hand, the Mayo Clinic patients received high-dose Vitamin C for only a short time, median 2.5 months. Moreover, none of the Mayo Clinic patients died while receiving Vitamin C. Their deaths occurred only after the Vitamin C had been taken away from them."

Moertel et al. never planned on keeping their patients on high-dose Vitamin C. Under Methods they wrote, "Therapy was continued as long as the patient was able to take oral medications or until there was evidence of marked progression of the malignant disease." Obviously, Moertel et al. tested Vitamin C as if it was like a drug used in chemotherapy; drugs so toxic they can not be taken daily for as long as patients survive because they would increase the death rate. Vitamin C is not a drug. It is a vitamin which enhances the body's ability to deal with stress and resist invasion, and must be taken always.

Moertel et al. can not see Vitamin C as anything but a non chemotherapeutic chemotherapy and used it as they would use a new, toxic, chemotherapeutic drug. Under Patient Compliance they note, "The median duration of drug intake was 2.5 months with Vitamin C (range, one day to 15.6 months)." Here they call Vitamin C a drug, which for them it is.

Figure 2 in their paper shows that half the patients survived one year and one survived two years. Yet, not a single patient took Vitamin C longer than 15.6 months. In other words, all the Vitamin C group were off their vitamin about 9 months (on the average) before they died and they included in the Vitamin C group at least one case who took Vitamin C for one *day* only. We do not know how many more were on Vitamin C for equally negligible periods of time. From my series of nearly 30 cases with terminal cancer I have found that patients must survive at least 30 days before they show any response.

It is clear the Mayo Clinic made no attempt to replicate Cameron and Pauling and in their conclusion they should have

made it clear their study was irrelevant to the basic scientific discussion whether or not Vitamin C enhances one's ability to fight cancer:

Failing to be scientific, these authors deem it necessary to lecture Linus Pauling as if he were a junior medical student. They conclude their paper, "Whether one is dealing with the treatment of the common cold or of cancer, and whether one is dealing with a benign vitamin or a highly toxic chemotherapy program, it would seem to serve the interest of the patient best for public advocacy of a proposed treatment to be withheld until that treatment had been proved effective by definitive studies of sound scientific design."

Gratuitous and silly advice! Would anyone be even looking at Vitamin C as an anti cancer factor if Linus Pauling had not brought this to the attention of the medical world?

As a psychiatrist I have often been ashamed of the poor scientific practises of my colleagues who claim to be scientists. Now, I realize we are no worse than any of the other medical professions.

Perhaps we should turn the clock back to a time when money was harder to get, and science was an avocation and not a profession.

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