UNIVERSITY OF MINNESOTA

Twin Cities Campus

Division of Epidemiology
School of Public Health

Suite 300
1300 South Second Street
Minneapolis, MN 55454-1015
612-624-1818
Fax: 612-624-0315

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Dr. C. Garza
Division of Nutritional Sciences
Cornell University
127 Savage Hall
Ithaca, NY 14853

Dear Dr. Garza:

Many thanks for the agenda for October which is quite exciting. I have a number of reactions of the off-of-the-top-of-the-head variety, not to be regarded too seriously. I apologize for the flight of ideas approach.

I am intrigued by the idea of Vitamin A as a model, particularly since Vitamin A, vitamins in general, antioxidants in particular, and deficiencies especially, have now so much broader meanings than when deficiency diseases were first discovered and RDAs first recommended. Crazy ol' Linus was probably more right than we knew when he early on developed the evolutionary biology concept of human adaptations (to high ascorbate intake during the major stages of evolution). Nowadays others may be right in their consideration that relative deficiency of antioxidants occurs often in our current environment so high in oxidizing potential from smoking, alcohol, pollution, etc. I assume that these old-new concepts will enter interestingly into the picture.

I wonder whether the more direct counterpart of the Vitamin A model (and maybe even the more relevant carotene model?) would be saturated fatty acids rather than dietary fat or cardiovascular diseases. The quantity and quality of dietary fat greatly complicates discussion of the biology, the epidemiology, and of policy. In contrast, the effects of saturated fatty acids are more precise and knowledge is more complete. Would not dietary fat be a closer equivalent of all vitamins or all anti-oxidant vitamins?

If cardiovascular diseases are the model, what is the counterpart Vitamin A disease model?

For example, we have found the remarkable phenomenon of very low cardiovascular disease rates in populations with quite high proportions of total fat in their diets--when those diets are low in saturated fatty acids (Greek Islands of the '60s and '70s). Consideration of total fat brings into play all the complex biology of relative calorie excess, obesity, glucose and insulin metabolism, etc., plus the complications of cancer relationships. We might be considerably more focused dealing only with the metabolic aspects of saturated fatty acids, or so it seems to me.

On your larger charge, to develop "general principles which should guide the implementation of knowledge as nutrition policy", the agenda leads to that beautifully, but does it also hold the potential hazard of major preoccupation with areas where we are all most experienced and comfortable, that is, evaluating the scientific evidence. In regard to Koch's postulates, and their counterparts in epidemiological criteria for causal inference, are these not already pretty well worked out? I suspect we don't need to dwell on them and in fact it wouldn't be much fun to go over all that old territory in respect to Vitamin A and disease and dietary fat and disease. I guess I am just wondering then, in passing, whether the "case studies" and extensive reviews of the "basic biology" are likely to lead us down that old path and where I am sure you would not like to have us bog down.

In fact, the real problem you seek to address is principles of application and dissemination when the scientific evidence is in place and "acceptably" strong, of course, always in the presence of some uncertainty. I have unsuccessfully wrestled, as you will see in these enclosures, with a major issue that in my view is responsible for most of the controversy in nutrition and among the public about nutrition, and which I suspect is responsible for most of the scientific and public confusion and controversy, that is, the difference in criteria, principles and recommendations appropriate to a) the individual case or patient; and b) the population, al, or targeted adults, etc. I have traced out in a number of fields the failure to address individual and population applications and recommendations separately that have led to the confusion, contradictions and controversy. I also tried rather weakly to get that point across in Chapter 28 of the National Research Council's Diet and Health Report.

Finally, it was George Beaton's expert WHO Report that hit the nail on the head about separate consideration of individual and population recommendations and I have marked out where I have quoted that in the enclosed larger editorial diatribe. George, himself, might be a helpful participant.

As I mentioned to you over the 'phone, I was very ambitious in that NRC Report to arrive at the same ends you are seeking, that is, criteria for translating "established" science into public policy. I brought this issue to a brilliant thinker and statistician on our panel, John Bailar III, formerly statistician for the New England Journal of Medicine and at the National Cancer Institute. We didn't come up entirely empty-handed, but really found it quite beyond our ability to develop Koch's postulates for the translation of scientific evidence to policy.

I will enjoy revisiting these issues, but perhaps we need to consider whether we are gathering the experts to help us in this thinking. Certainly few of us in the worlds of medicine and nutrition or epidemiology, have the experience or the skills to do more than to discuss the components of this problem. I will attempt to find personal notes on this issue that are probably more revealing that the little we got into the Diet and Health Report, but that will have to be after my return to my office

in February.

I certainly agree with you that we need to know the biology and its complexities to arrive eventually at rational public policy. But I have the impression that this agenda might mire us in the biological complexities to the detriment of the policy issues. One of the reasons for this, beyond inexperience in medical science, is that we are always faced, and will forever be faced, with the issue of making policy decisions and nutritional recommendations in the presence of incomplete knowledge, in the certainty that new knowledge is always around the corner, and thus, making decisions and recommendations for individuals and populations from a base of perpetual uncertainty. What we need is principles for recommendations in the face of uncertainty, such as how much benefit at a given time is likely, at what cost, and at what potential harm.

I suppose that in an ideal world scientific conclusions and decision-making would best be based on congruent scientific evidence from biology, clinic and epidemiology, whereas conclusions on individual and population interventions are best based on evidence of cost-benefit. In the latter, of course, we are dependent on economists with a very primitive science, using highly simplistic and incomplete models, and in a field in which few, if any, nutrition types are competent.

So where does that leave us? I guess I am running over the idea that we are in danger of reinventing scientific wheels that already exist, versus the danger of seeking principles of translation in which we are all without foundation or experience. We need to recognize that the principles of evaluating scientific evidence already exist and decide whether we can improve on them. We may need the deliberate decision that this working conference would mainly involve educating those of us interested in these matters through discussion of the elements that should enter into translation of scientific evidence into policy, and consider whether this can be carried off in the presence of public health, policy and economist types to provide the framework that none of us really has.

In these terms, I think of a few people in addition to John Bailar, Mervin Susser as a distinguished intellect, now editor of the Am J. of Public Health; Milton Terris, a long-term public health thinker; another man whose name I am blocking on, at Duke, one of the more advanced health economists with sophisticated models to translate scientific evidence into estimated public health effects. And people who are, or who have been, at policy levels and understand these issues, such as Mark Hegsted and perhaps Michael McGinnis and perhaps that interesting women, Carol (blocking again) who was deputy in the Department of Agriculture and worked with Mark Hegsted on the Joint HHS/USDA Committee that saw to it that health issues were considered in agricultural policy during a brief but enlightened period. Those two were really responsible for the Dietary Guidelines for Americans. Don't we really need those kind of types, over and above investigators?

Now, after that long and pontifical monologue, I am reading through the whole

agenda and commenting on specifics, on the fly:

Session I
You mention interventions "at the level of the individual and community". I suggest that subsequent discussions be permanently dichotomized along your idea, to explore the often separate issues in the biology, potential harm, economic impact, etc., of individual and population recommendations.
I do see the value of the case histories and the synthesis of principles from them. I am simply mainly concerned that we will get too deep in the first sessions.

I am a little unsure, for the poor synthesizer, what actually are the general principles to be exemplified here. Are these biological principles or are they principles of evaluation, and how do these in turn relate to recommendations for the individual (I) or population (P)? I assume you mean primarily biological principles, such as the need to consider dose- effects, interactions, etc. Again, I ask whether these principles are already pretty well known.

Session II
I am a little wondering about the term "biology of interventions" or how such things as fortification are "biological issues". Nevertheless, I find points a through d most appealing and very effective take-off places for discussions of criteria and procedures for intervention. But most of these seem to me different issues than "the biological nature of the zone of uncertainty" required here from the synthesizer. Again, there is a huge burden on the synthesizer.

I am quite sure we will all enjoy discussing "ideal nutriture" and "frank excess", particularly if we put it in the I versus P orientation. For example, I have just returned from Japan where I have been involved with their changes in nutrition over the last 35 years. Our Japanese colleagues are actually claiming (bragging) that Japan now has "ideal nutriture": their total death rate is lower than anywhere, their longevity is greater than anywhere, their stroke rates are plummeting, and their coronary deaths are low and falling. Some cancers, such as stomach, are going away. But what an illusion is their idea of ideal nutriture?! By my reckoning, they are only a decade or so away from an unbelievable epidemic of coronary disease and lung cancer, because of the 10 and 20 year lagtimes in the development of these diseases after mass lifestyle changes. So we must clearly consider adding "the direction of change" in nutrition and eating patterns, the "rate of change" and the "lagtime" to development of disease, in our concepts of ideal nutriture.

Session III
This session looks very much to the point, but do we have an expert representative on mass behaviors, on cultural mores, on marketing and communications? Should we not stringently avoid getting bogged down in the psychology of individual eating and exercise behavior?

You have rightly focused I think on such concerns as agri-business, education,

commerce, etc.

Session IV

As with the "biology of interventions", I have a little problem with the term "epidemiology of interventions". Again I see the synthesizer in deep trouble to consider both the principles of evaluation of the epidemiological evidence and the, perhaps, rather distantly related "criteria -- related to interventions --".

Again, the question here is whether the counterpart to reduce Vitamin A deficiency is reduced saturated fatty acid excess rather than cardiovascular diseases?

I am intrigued, but wondering, about the speakers presenting "predictors of benefit from the intervention". I have the impression that that might be one of the major jobs of the whole conference, to consider such predictors that would weigh the strength of the associations, the dose- effect in experiments, and the toxicity issues with those of feasibility and cost of implementation, etc. Again, of course, each of these factors, and the predictive profile, are different, or at least separate for the individual and population benefit.

Again, the synthesizer has the monster problem to "generalize criteria which -- apply -- to interventions", when, in fact, such criteria may not exist and are what the conference needs to develop. This might best be done as a working group rather than a series of presenters and synthesizers(but clearly we must try your agenda, not mine!)

Session V

Happily, you here specifically, if only parenthetically, indicate that the real model is saturated fatty acids and we agree. In this session which seems very straightforward, feasibility, trials and demonstrations, training, etc. are all excellent issues and it needs only the issue of individual strategies (medical and professional) versus population strategies (health, agriculture, industry, food purveyors). I guess that there is no special problem about program coming prior to policy in the discussions since obviously we have a lot more experience with program than with policy.

Session VI

This, of course, is the exciting session. I guess I think we require good thinkers at high policy levels on these issues. Again, I think of Mark Hegsted and Carol ____ who could surely help us. They have the nutritional background and the policy experience to know whereof they speak. I certainly don't have the experience or background to synthesize here; these issues are quite beyond me.

It may be symbolic that your charge to the speakers in this session is so broad and non-specific, indicating that this is the area of greatest need and least expertise. It probably deserves a workshop unto itself with nutrition types serving mainly as consultants.

It all looks like fun. I suppose I would come under Session IV if you still think after this barrage of uncertainty and ambiguity that I belong in the conference at all! I truly would be happy to be involved and am hoping that there might be a focus to enlist expert colleagues who would help us on the criteria for translating forever uncertain scientific evidence into policy, for the individual, as medical policy, and policy for the population at large, public policy. If you consider, based on these thoughts, that I would be more disruptive than constructive, I will understand.

Cordially,

Henry Blackburn (nb)

Henry Blackburn, MD
Mayo Professor of Public Health
and Professor of Medicine

Enclosures
(sent with mailed copy only)

nb

pc: T. Pearson

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Suite 300
1300 South Second Street
Minneapolis, MN 55454-1015
612-624-1818
Fax: 612-624-0315

February 1, 1994

Cutberto Garza, MD, PhD
Director and Professor
Cornell University
Division of Nutritional Sciences
Office of the Director
127 Savage Hall
Ithaca, NY 14853-6301

Dear Dr. Garza:

If "epidemiology of interventions" (a new concept to me) means a critical review of diet saturated fat-lowering clinical trials and their disease effects, there are any number of competent folks:

Jacques Rossouw - NHLBI
Lew Kuller - University of Pittsburgh
John Farquhar - Stanford University
Jeremiah Stamler - Northwestern University
Henry McGill - Southwestern Institute
John LaRosa - Georgetown

If your term means rather a review of metabolic ward-type experiments of saturated fat-lowering effects on blood lipoprotein levels, the field is more limited.

The best is Mark Hegsted, who I have already strongly suggested to you also as the #1 person on agricultural policy and who would be a great guiding hand at the Conference.

The most active worker in feeding studies nowadays, of course, is Scott Grundy at Southwestern in Dallas.

Again, I continue to wonder that this approach sounds like formal plowing in the old ground of research rather than examining the new and difficult issues, in a thoughtful workshop, of transferring scientific evidence to policy. But then I have not seen a revised program or list of participants, or had any response from you to my excessively long, but sincerely intended memorandum of January 12th. Good luck.

Regards,

Henry Blackburn, MD
Mayo Professor of Public Health