A CHALLENGE TO NUTRITION COMMUNICATORS: SOME MISMATCH BETWEEN FOOD LABEL CLAIMS AND HEART HEALTH 'ROUND TABLE' MESSAGES

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The trouble with listing and bullet-pointing information is that it is difficult to wean the reader away from the impression that there is meaning to the order of information, because order usually imparts emphasis and significance.

The latest list that food industry decision-makers and communicators are all checking (for emphasis and significance), is the EU register on nutrition and health claims (7). But to what extent do the EU authorised health claims relating to diet and heart health match the dietary messages that nutrition communicators are giving to the public?

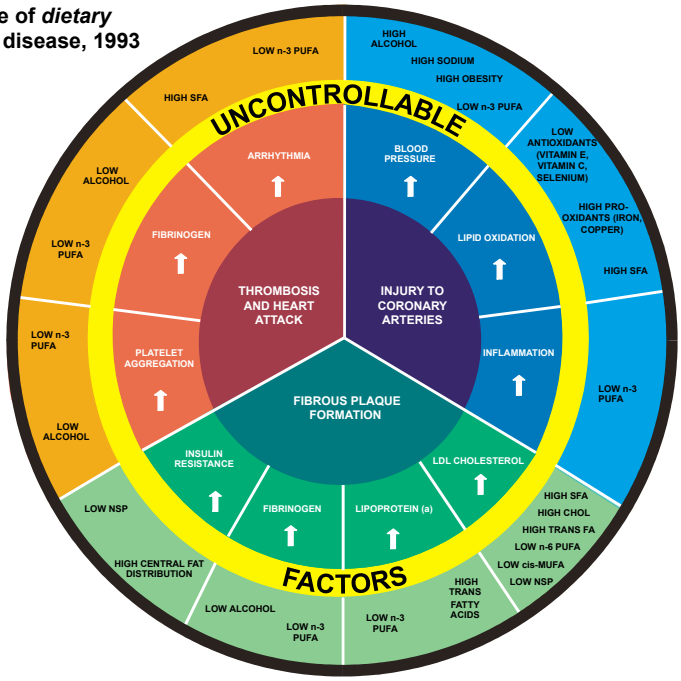
THE 1993 ROUND TABLE MODEL OF DIET AND HEART DISEASE

More than 20 years ago, the British Nutrition Foundation challenged one of the authors (MA) to find a model to communicate the complexities of the many dietary factors known to influence the risk of coronary heart disease. A moment of inspiration lead to the 'Round Table' model. We all know that King Arthur placed his knights at a round table so that no one knight could declare superiority over another. So if you want to present many factors, without ranking significance, you place them at a round table.

This Round Table model (rather than lists and boxes of information) allowed the inclusion of the many dietary factors that had beneficial (or adverse) effects on the principal physiological risk factors which impacted upon pathological events. The model also gave clarity to the fact that multi-component parts of the diet influenced different aspects of risk. It was not possible 20 years ago and still remains the case, to provide precise rank orderings of food/nutrient components relating to the risk of coronary heart disease. The positioning of the individual physiological and dietary factors in the Round Table avoided the communication of any time-sequencing or hierarchy and the format of the model allowed for the insertion (or removal) of factors over time (see Figure 1).

When the report was first published (1), the model was welcomed by many health and industry professionals as an 'aide memoire' and as a pragmatic tool in the discussion and communication of this complicated topic. Its popularity led to an extended and updated second edition (2) and, later, three variant models with three alternative 'outer rings' to detail obesity related factors, activity-related factors and pharmacological factors (4).

Figure 1: A Round Table of *dietary* factors related to heart disease, 1993



Abbreviations
- SFA saturated fatty acids;
- MUFA monounsaturated fatty acids;
- Chol Cholesterol;
- PUFA polyunsaturated fatty acids;
- NSP, non-starch polysaccharides

THE 2013 ROUND TABLE MODEL OF DIET AND HEART HEALTH

We have taken the opportunity to update the Round Table model of diet related factors, making its name more positive in doing so (see Figure 2). So what are the differences in the factors portrayed in the original Round Table model, published in 1993, compared with the updated version?

The pathological events remain broadly the same (injury to coronary arteries, atheroma and fibrous plaque formation and vulnerability, and thrombosis). Among the physiological risk factors, additions include increased plasma homocysteine, impaired endothelial function and procoagulant state. Of particular note is the fact that factors such as LDL cholesterol and lipoprotein(a)

have been incorporated into a composite risk factor, 'the atherogenic profile'.

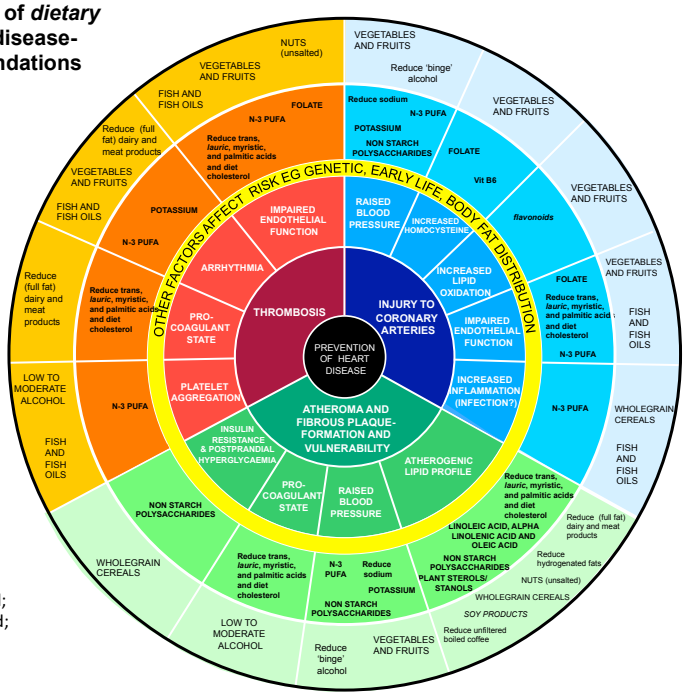
A general yellow ring described as 'uncontrollable factors' was part of the original model, positioned between physiological and dietary factors, to indicate the differences observed between people in relation to genetic and other variation. In the 2013 model, the yellow ring now also includes factors described as 'less controllable': early life factors (5) and the distribution of body fat (3) have joined the role of genetic factors (10).

The main criticism of the model in the 1990s was that the dietary components were placed on the model purely on pragmatic decisions on the best scientific consensus, rather than based on any authoritative expert report. The publication of the WHO report in 2003 (11) has since given us a firmer scientific basis on which to update the placement of the diet factors on the model. Although this report is 10 years old, it still represents the most comprehensive and authoritative review of the impact of dietary factors on heart health and is still used as the basis for healthy eating advice given by many health professionals.

Table 10 of the WHO report summarised the strength of the evidence of factors (foods and food components/nutrients) contributing risk for developing cardiovascular diseases in terms of 'convincing', 'probable' and 'possible'. This has allowed us to add a new outer ring to include foods and drinks in contrast to specific nutrients and food components which remain in their own ring. We have included all grades of evidence here and only distinguished between 'convincing and probable' and 'possible'. Furthermore, as the WHO report does not specify mechanisms of action for all components, we have used our knowledge of accepted links with physiology and pathology to allocate some food components to sections in the Round Table.

Figure 2 shows that all the nutrients and food components from the 1993 model remain, but others have been added, such as plant sterol esters and flavonoids. The newly added outer ring includes foods such as fish and fish oils, wholegrain cereals and fruit and vegetables.

Figure 2: A Round Table of *dietary* factors related to heart disease-incorporating recommendations of WHO, 2003



Key
- Foods and food components to increase in black CAPITALS
- Foods and food components to reduce in black lower case
- WHO convincing or probable evidence in regular case; possible evidence in italics

Abbreviations
- EPA, eicosapentaenoic acid;
- DHA, docosahexaenoic acid;

EU AUTHORISED HEALTH CLAIMS IN THE FIELD OF HEART HEALTH

One of the major advances in the field of nutrition and health in the last 20 years has been the schemes devised in various countries and finally the EU, to decide which health claims should be allowed for foods and drinks. Some of these claims, reviewed by the European Food Safety Authority (EFSA), have now been authorised by the EU for public communication (via food labelling, in advertising and other forms of commercial communication). These are listed on the EU Register on nutrition and health claims (7).

The initiative for consideration of the scientific validity of health claims has been the submission of a dossier/supporting references by a food company, or ingredient or product sector group (9). Therefore, the underlying basis for the authorised nutrition and health claims for food labelling is the positive outcome of the critical assessment of three key aspects of health claims:

(i) adequate characterisation of the food or food component;

(ii) the claimed effect represents a beneficial physiological effect (general function claims), or an independent risk factor for development of a disease (reduction of disease risk claims) and

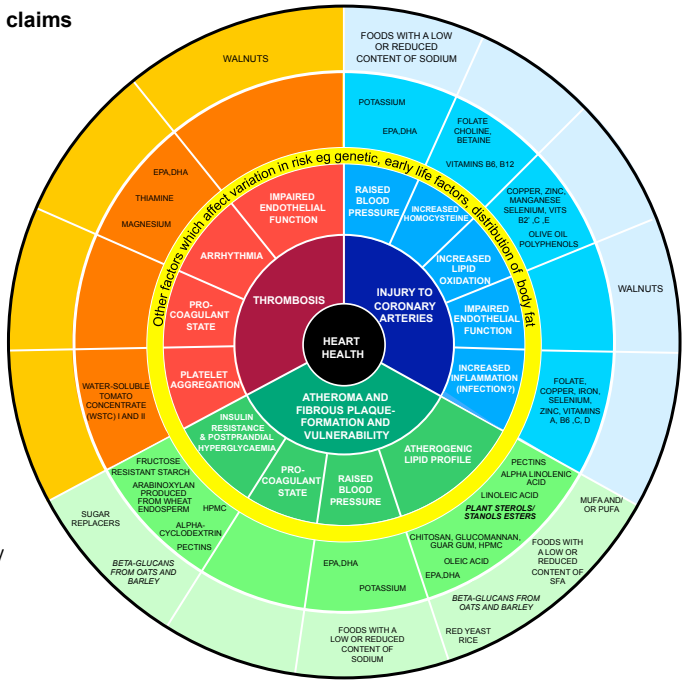
(iii) that the scientific evidence base for the claim demonstrates a cause and effect relationship (EFSA 2011).

This contrasts with the approach used by WHO as discussed above. Although the main impetus for the EU regulations on nutrition and health claims was the protection of the consumer from unwarranted claims, there are varying views on the extent to which health claims should also assist consumers in choosing a healthy diet.

In order to illustrate the possible differences in emphasis that are the outcomes of the two contrasting approaches, the authorised EU health claims for nutrient/foods related to beneficial physiological effects or to independent risk factors for heart disease have been put onto the 2013 Round Table model (see Figure 3).

It should, however, be noted that the health claims Regulation (8) makes an important distinction between general function health claims (Article 13.1) and reduction of disease risk claims (Article 14.1a). The former are based on beneficial physiological effects, while the latter must demonstrate the ben-

Figure 3: EU authorised claims related to heart health



Key
- EU article 13.1 or 13.5 claims in regular case
- EU Article 14.1 claims in italics

Abbreviations
- SFA saturated fatty acids;
- MUFA monounsaturated fatty acids;
- PUFA polyunsaturated fatty acids;
- HPMC Hydroxypropyl methylcellulose

eficial alteration of a risk factor for the disease in question.

EFSA has defined a risk factor as an independent predictor of disease risk supported by a biologically plausible mechanism (6). Very few risk factors are supported by sufficiently strong evidence for this purpose - raised blood LDL cholesterol is one such factor. However, low blood HDL-cholesterol, elevated blood concentration of triglycerides and elevated blood homocysteine concentration, for example, though associated with an increased risk of CHD, have not been generally shown to reduce the risk of CHD on modification. To be awarded disease risk reduction claims, such risk factors would need to be supported by human studies validating their association with the risk of CHD in the context of the particular nutritional intervention that is the subject of the claim. Hence EFSA's determination of physiological risk factors is particularly strict.

Though we have retained the 'physiological risk factor' ring, many of the items presented in the ring devoted to physiological risk factors in Figure 3 (such as increased homocysteine) do not have sufficiently strong evidence to be considered as independent risk factors by EFSA and thus represent beneficial physiological effects as distinct from risk factors. Therefore Article 14.1a claims have been distinguished from Article 13.1 and 13.5 claims in Figure 3.

WHAT IS THE MATCH BETWEEN GENERAL PRUDENT DIET RECOMMENDATIONS AND EU AUTHORISED CLAIMS DEMONSTRATED BY THE ROUND TABLE MODEL OF HEART HEALTH?

Differences

A basic difference, arising from the way the evidence was collected, is that all the EU authorised claims are for components and foods with beneficial effects on heart health, while Figure 2, based on the WHO report, also includes factors with adverse effects.

At the core of the model, the pathological events form three anchor points for discussion of dietary risk factors of heart disease. In contrast to Figure 2, which is based on WHO advice, nearly all of the EU authorised claims in Figure 3 relate to the pathologies of injury to coronary arteries and atheroma and fibrous plaque formation and vulnerability; there are fewer claims that relate to reducing the risks of thrombosis. Thus Figure 3 gives a more restricted impression of the dietary factors which affect heart health than that given in Figure 2.

Similarities

Of the claims relating to the maintenance of normal cholesterol levels (included in the atherogenic lipid profile), there are three common nutrient/diet factors cited in both the WHO Model (Figure 2) and the EU Claims Register (Figure 3). These are linoleic acid (n-6 PUFA), alpha linolenic acid and plant sterols/stanols. Another health benefit, the reduction of elevated homocysteine, is associated with folate in both information sources.

Omissions

Perhaps the most surprising omissions in the food ring of Figure 3 are wholegrain cereals and fruit and vegetables. Submissions were made, but these claims were rejected on the grounds that these food groups were not sufficiently characterised. Further, EFSA requires evidence of cause and effect and did not accept epidemiological evidence alone as sufficient to substantiate a health claim. Further, the EU Claims Register does not permit any health claims for some food components that are mainstays of many functional foods, such as soy protein. Submissions were made, but the claims were not authorised.

Additions

Beta glucans from oats and barley and sugar replacers were not included in the WHO report, but are included in the EU register. Perhaps the research evidence has become more convincing since 2003?

Unfamiliar food components and foods

Some of the items with authorised EU health claims are for food ingredients that will not be familiar to consumers, and that can be consumed only as components of specifically formulated functional foods or as food supplements (for example betaine, choline, chitosan and pectins). These items will come as a surprise to most nutrition communicators too, as will the inclusion of foods/food supplements such as walnuts, red yeast rice (a traditional Chinese food fermented with Monascus purpureus which contains the active ingredient monacolin K) and water soluble tomato concentrate.

CONCLUSIONS

Our comparison of the dietary components which are included in the WHO Round Table Model of Heart Health (Figure 2) and those which have EU authorised health claims (Figure 3) has shown many differences because of the different approaches used to generate them. Although consumers might not be aware that claims for wholegrain cereals and fruit and vegetables were not authorised, the lack of such claims is likely to result in more specific claims based on their nutrient content rather than potentil health benefits of the foods in their entirety.

Health professionals will have to communicate the key messages on the links between diet and heart health at the same time that consumers will be receiving the specific and sometimes diverse messages on their food and drink products. So, has the whole claims approval process led to useful diet/health messages from the consumers' perspective? Will it help with achieving beneficial dietary changes? This mismatch between general prudent diet recommendations and authorised claims will generate new demands on health professionals. We hope that our latest Round Table models in Figures 2 and 3, which highlight the differences, will be helpful as an 'aide memoire' to those who need to know about the relationship between food and food components and heart health, including nutrition communicators and food industry personnel.

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