Health claims policy

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Synergy between omega-3 fatty acids and cardiovascular drugs
Peter Howe; University of Adelaide and University of South Australia, Adelaide
Acting on risk factors such as hyperglycieridemia, hypertension, and dyslipidemia to improve compliance and endothelial dysfunction, 
$\alpha_3$ supplementation can both augment the efficacy of other cardiovascular drugs and provide broader risk benefit. It also reduces BP in hypertensives treated with diuretics or $\beta$-blockers and counters adverse effects of these drugs on lipids. Its hypotriglycerideremic effect can also complement the adverse effects of statins and offers a safer alternative to fibrates/statin combinations for treating mixed hyperlipidemia. Moreover, it may further reduce cholesterol in patients taking statins.

Apart from effects on BP and blood pressure, $\alpha_3$ counteracts arterial disease by enhancing endothelial function and inhibiting inflammatory mechanisms mediating target organ damage. There is increasing recognition that such mechanisms contribute to the efficacy of ACE inhibitors, angiotensin blockers and statins in reducing coronary outcomes. Hence prudent combination of $\alpha_3$ with these drugs may have potential effect on cardiac mortality which are independent of their effects on risk factor modulation. Serhan & others (J Exp Med. 2000; 192:1197?1203) have shown that, when combined with aspirin, $\alpha_3$ is converted to a new array of eicosanoids with potent anti-inflammatory effects in blood vessels. Such $\alpha_3$-drug synergies may contribute to the benefits of use of cardio protective strategies unseparated with $\alpha_3$ supplementation of drug treated subjects in recent secondary intervention trials. Therapeutic applications of nutrients may be more than beneficial to nutritional roles, but their exploitation requires more rigorous, hence costly, substantiation. This may be justified in the case of $\alpha_3$ supplementation, especially if one considers its potential as an adjunct therapy.

Topic: Regulatory update

Proposed trial of omega-3 fatty acids in coronary heart disease prevention
Trevor Mori and Peter Howe

An international workshop entitled Omega-3 fatty Acid and Primary Prevention of coronary heart disease was held in November 2002 to consider evidence relating omega-3 fatty acids to cardiovascular disease and, if the evidence indicated that they were efficacious, the feasibility of mounting a randomized primary prevention trial of omega-3 fatty acids in a high-risk population, with prevention of cardiovascular disease as an end point.

There is evidence from secondary prevention trials that dietary omega-3 fatty acid supplementation in healthy people reduces BP to a lesser extent than in patients with established cardiovascular disease. However, omega-3 fatty acids may reduce the risk of CHD.

been established for the general population. In February 2001, the US Food and Drug Administration issued a Qualified Health Claims for omega-3 fatty acids and CHD: "...the scientific evidence indicates that taking omega-3 fatty acids may reduce the risk of CHD, but not conclusive... It is not known what effect omega-3 fatty acids may have or may not have on the risk of CHD in the general population."

The workshop's panel of experts in omega-3 fatty acids and/or clinical trials concluded that in order to assess any possible benefit, a primary prevention trial was needed which would:
1. provide more data directly linking omega-3 fatty acids to CHD risk reduction
2. be carried out in patients at high-risk of, but without, clinized, CHD
3. include clinical endpoints and well-recognised surrogates of CHD risk, and
4. demonstrate efficacy of a dose of omega-3 fatty acids that is within reach of dietary recommendations.

If an international trial is initiated through an NIH grant, Australia would have an opportunity to participate.

Regulation of LPCUFA: sources and claims
Janine Lewis; Food Standards Australia New Zealand, Canberra

FSANZ recently approved specifications for food ingredients that contain high proportions of LPCUFA, including oils derived from sources such as fungal or marine organisms that need to be novel. These ingredients are in the form of oils and powders.

Criteria for omega claims were introduced as Standard 1.2.8 of Volume 2 of the Food Standards Code in December 2002 to expand the range of permitted claims for polyunsaturated fats in response to the increased use of 'omega' in food labelling. Positive and negative criteria were set on the basis of amounts of particular nutrients in foods, since no official reference daily intakes were available.

For omega-3 claims, all foods, except fish with added saturated fat, must contain less than 28% total fatty acids in saturated and trans form or no more than 15% saturated and trans fatty acids/100g food. Also, for source' claims, the food must contain at least: 200 mg ALA/serving, or 30 mg EPA + DHA/serving, for 'good source' claims at least 60 mg EPA + DHA/serving.

For omega-6,-9 claims, all foods must contain no more than 28% of total fatty acids in saturated and trans form and no more than 40% total fatty acid as the claimed fatty acid.

Fatty acid declarations in the nutrition information panel are arranged in nested order according to specificity. For example, an 'omega-3' claim would require the declaration of fat and types of fatty acids to four levels; fat, polyunsaturated (as well as saturated, monounsaturated and saturated); omega-3, and individual fatty acids, eg EPA and DHA.

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The review of the regulation of health claims, and of nutrition labelling and education, underway in Australia and New Zealand for several years. With the creation of the new food regulatory arrangements in Australia, the Ministry of Health requested the development of policy guidelines to inform the development of regulations in this area. The policy guidelines are currently being developed by the Food Regulation Working Group, which is a working group chair by the Food Policy Unit of the Commonwealth Department of Health and Aging. The Policy Guidelines will be considered by the Ministerial Council in November 2002. The guidelines will incorporate principles agreed in May 2002 and a ‘watchdog’ to monitor the use of health and related claims.

Regulatory update – European position
Peter Weber; Rolf Wachter, Ltd, Switzerland

In Europe, nutritional-grade oils as well as natural vegetable oils obtained by conventional oil processing are considered components of natural food and can be added to food without any registration as long as the food standards for fats, oils and related products are met. Food supplements containing natural marine omega-3 oils are subject to the novel food regulations in the different member states of the European Community (EC). Products derived from microorganisms (eg algae) as well as concentrated oils are regarded as Novel Food within the EC. It should be noted that EC has harmonised EC Novel Food Regulation (EC No. 258/97). Omega-3 oils for use in infant formula are regulated in separate Directives (EC 91/528 EC 96/4). For products containing erthyl esters, different regulations apply in the various member states of the EC. Regarding health claims related issues, the EC currently does not allow health claims to be included in foods, but it is being considered, and the EC is intending to harmonise health claims on foods. A draft proposal has been published.

Intakes and food sources of omega-6 and omega-3 PUFA

Estimates of the omega-6 and omega-3 PUFA intakes and food sources in the Australian diet were assessed using food records from 10 891 adults in the 1995 Australian National Nutrition Survey. The composition data on 1690 foods taken from the Supplement to NUTTAB05 was used together with new intake distribution benefit to estimate the fatty acid content and the food sources.

A daily average intake of linoleic, arachidonic, total omega-6 PUFA's, eicosapentaenoic (LNA), EPA, DPA, DHA, very