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[The task force replies:]

Criticism of the task force's initiative has focused on the process used. Dr. Horlick feels that there was inadequate consultation with experts in lipid disorders and too little "consensus". We did consult international experts in the field, including Dr. Alan Garber, Dr. Scott Grundy, Dr. Thomas Kottke and, indeed, Dr. Horlick, as chairman of the CCCC. Opinions among these experts differed, so that not all their recommendations could be included in the report. Producing practical guidelines for optimal practice patterns called for a group trained in evaluation of medical data rather than a group of experts in various aspects of lipid metabolism. The guidelines were intended to provide Ontario physicians with a practical guide for deciding who should be tested and who should be treated that is based on the best analysis of the best current scientific evidence.

This exercise represents a major advance in collaborative efforts to develop therapeutic recommendations that are based on impartial and critical review of all scientific evidence available in the hope of reducing inappropriate use of drugs or techniques. The Ontario Ministry of Health must be commended for endorsing the recommendations and accepting the fact that the implementation of these guidelines will substantially increase the costs of the diagnosis and treatment of asymptomatic hypercholesterolemia over present levels. The expected benefit will come from avoidance of the excessive or unnecessary testing and drug use that might result if not constrained by coherent scientific recommendations.

The OMA also endorsed the guidelines, signalling its willingness to cooperate with government in initiatives aimed at improving the quality of health care. The task force recommendations do advocate some restraint in testing and treatment of hypercholesterolemia, but these are based on clinical considerations that balance the adverse effects of medical intervention with the benefits expected. Like any guidelines supported by the OMA these are voluntary, flexible and subject to immediate modification when new evidence appears.

The members of the task force confirm their support for the policy document, which we believe provides guidance for physicians based on complex data analysis that would be beyond the capabilities of virtually any individual physician. We did not expect that the report would be universally accepted, and we welcome debate both on its scientific conclusions and on the development of better methodology with which to address similar problems in the future.

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[The working group replies:]

The mandate of the Toronto Working Group on Cholesterol Policy was to review the evidence concerning the potential benefits, side effects and costs of detecting and treating elevated serum cholesterol levels in the diverse adult subpopulations at risk for CHD. We were also required to weigh the respective roles of community-wide health promotion strategies and individualized medical strategies. These tasks are not within the usual domain of either bench research in lipid biochemistry or subspecialty referral practice in lipid disorders.

As case-finding becomes commonplace, testing and treatment of asymptomatic persons for elevated serum cholesterol levels will take place almost exclusively in the offices of those engaged in adult primary care. Indeed, when Blue Cross-Blue Shield in the United States sought an external review of the cholesterol testing conundrum it turned to a group not unlike ours — ambulatory care practitioners with expertise in clinical epidemiology and health economics.[1]

The important point is a willingness to appraise the relevant evidence critically. Dr. Horlick, for example, claims that the NDHS showed an "average 10% reduction in cholesterol levels" with a diet similar to the AHA level 1 recommendations.[2] The treatment group actually followed diets much higher in polyunsaturated fats than recommended for the AHA level 1 diet. The average decreases of 8.4% and 9.3% were observed relative to a control group consuming prepared foods with high saturated fat and low polyunsaturated fat contents. The NDHS subjects were a self-selected volunteer group comprising only 11% of all those asked to participate. More important still, the subjects were randomized to obtaining one of three varieties of all fat-containing foods *at study distribution centres*. The difference in the decrease in cholesterol levels over 1 year between the single cohort randomized to dietary instruction, who obtained their food on the open market, and the "control" group in the same city, who obtained fatty foods at a distribution centre, was less than 4% averaged over the last 40 weeks of the year and 2% at the end of the year. We suggest that such analyses are not "gloomy" but a realistic prerequisite to policy formulation.

Horlick misrepresents the Ontario policy. The poster mailed to Ontario physicians states: "Regardless of whether serum cholesterol is measured, practitioners should encourage all patients to

follow a healthy diet." Our background report[3] strongly supports promulgation of national dietary guidelines, promotion of a "prudent" diet at every opportunity by practitioners and implementation of a major campaign to drive home the need for community-wide dietary change. We particularly emphasized the multifactorial pathogenesis of CHD and the need to consider risk factors in the context of medical screening and treatment.

In effect, the working group recommended a true high-risk approach for the medical component of the preventive campaign against CHD, coupled with a strong population-based program to promote community-wide dietary and lifestyle changes that are already credited with reducing the burden of CHD in North America. In our suggested program, persons with serum cholesterol levels between 5.2 and 6.2 mmol/L would obviously be candidates to receive brief dietary advice and printed materials that we hope practitioners would make available in their offices. On the other hand, we find no evidence to support the proposition that such persons should receive the same individualized attention that is warranted for those with higher cholesterol levels.

Our case-finding suggestions are in line with those of the British Cardiac Society,[4] the Canadian Task Force on the Periodic Health Examination[5] and other authorities.[6-8] The final report of the CCC also states that persons with CHD risk factors should be the priority for case-finding.[9] As to cut-off points, even the British Hyperlipidaemia Association,[10] which represents physicians in lipid referral clinics, reserved "clinical care" for persons with total cholesterol levels above 6.5 mmol/L.

Horlick and one of the CCCC organizers, Dr. Alick Little, have already acknowledged the potential pitfalls of their ultimate program. In a recent *CMAJ* editorial[11] they forecast that the medical strategy favoured by the CCCC would cause 50% of the adult population to "enter the health care system as patients", 25% as candidates for lifelong drug therapy. They deemed the latter "not reasonable" and "unacceptable". However, they also claimed that the serum cholesterol cut-off point of 5.2 mmol/L should not be changed because it is based on "firm epidemiologic evidence".

That "epidemiologic evidence", far from being "firm", is complex and open to disagreement. The arguments are documented in detail in our report,[3] but two points bear repetition here. First, caution is warranted since there is no evidence that lowering the serum cholesterol level in primary prevention affects all-cause mortality, either in individual trials or in all the trials combined by meta-analysis. Second, focusing only on CHD, two major drug trials in high-risk middle-aged men required about 350 patient-years of treatment to avert one fatal or nonfatal CHD event.[12,13] Considering males and females of all risk brackets together, for a serum cholesterol level of 5.2 mmol/L it would take more than a millenium of dietary manipulation to achieve similar effects. Such effort-yield ratios are the place of community-wide health promotion, not individualized medical treatment.

Horlick and Little also defend the ultimate CCCC program by suggesting that a population-based strategy would, over time, lower the average serum cholesterol level in Canadian society and thereby reduce the number of patients with levels above the 5.2 mmol/L cut-off point. What do they propose should be done in the intervening decades while we are awaiting substantial population shifts in this and other CHD risk factors? If we follow the interim suggestions of the CCCC we find a list of risk factors for testing priorities with no mention of cigarette smoking, no guidance to interpret the interplay of those risk factors with each other and with gender, and no indication of how risk factors should affect treatment decisions. Meanwhile, Horlick charges that the Ontario policy has sown "confusion".

Surely common sense demands an explicit short-range policy with a clear commitment to ongoing revision as mandated by changing resources, research evidence and constructive criticism. That is exactly what has been offered. At stake here are millions of patient-years of treatment, countless hours of work by physicians, dietitians and laboratory personnel, and hundreds of millions of health care dollars. Under the circumstances, we believe that a responsible debate should focus not on political processes, professional credentials and personal biases but, rather, on the scientific evidence as derived from a careful and critical review of the relevant studies. We welcome responses of that nature from Horlick and others who have contributed materially to the development of Canadian lipidology and the current campaign for cholesterol lowering.

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The recent circulation of the Ontario Ministry of Health and OMA task force recommendations on the detection and management of asymptomatic hypercholesterolemia illustrates, I believe, a trend in which the delineation of health by authority may be counterproductive.

For effectiveness, even "with middle-aged male patients with clearly elevated total cholesterol levels, about fifty persons must be treated for five to ten years to prevent one fatal or non-fatal heart attack". Given perfect compliance, this means that 98% of this select population would be subjecting themselves to an intervention that, statistically, would prevent "heart attacks" in 2% of them.

Apart from the immeasurable discomfort associated with individuals' introspection about personal health, extrapolated from their perceptions of public hygiene, the preventive medicine fashion seems to be approaching an unsustainable position of a pound of prevention being worth an ounce of cure. As a profession we must ensure that the public and the news media are given a clear sense of proportion, the better to hold reasonable health expectations at the individual and group level, especially when resources are to be used to maximum efficiency.

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The recently published final report of the CCCC[1] was marred by the Ontario task force report on the detection and management of asymptomatic hypercholesterolemia.[2] The circulation of the executive summary of the task force report to all Ontario physicians may be counterproductive and obscures the CCCC's important and comprehensive proposals. The medical profession is now unsure what strategy to adopt for the detection and management of asymptomatic hypercholesterolemia. There will undoubtedly be rancorous reverberations in the profession and, worse, division among lipid experts. One of the most predictable conclusions is that new guidelines are needed.

The task force report states that laboratory standards are almost certainly inadequate to provide ideal support for "high risk" detection and management programs. Despite the difficulty in obtaining reliable cholesterol laboratory measurements[3] the report does not recommend a provincial lipoprotein standardization laboratory or any source of reference material necessary to standardize cholesterol assays and thereby ensure accurate measurements. A Canadian lipoprotein standardization laboratory has been established in Vancouver, but this organization has received no federal or provincial funding. In the United States such reference materials are available from the National Bureau of Standards, Centers for Disease Control and the College of American Pathologists.

The report refers to laboratories but not to physicians' private offices, where cholesterol measurements are also performed. The executive summary does not advise, recommend or caution physicians on quality control in their offices. The task force report discusses desktop analysers, but none of the information was communicated to physicians in the executive summary. No major organization has endorsed desktop analysers; rough analysis indicates a false-positive screening rate of about 12% in detecting a threshold level of 6.2 mmol/L.

Accurate and precise cholesterol measurements are needed because a 10% reduction in cholesterol levels may not be detected by measurement systems with poor precision, and the total blood cholesterol level is reduced by 10% to 15% through dietary therapy.[3] The level can be estimated in outpatients on a fasting or nonfasting basis, but the use of hospital inpatient lipid values to evaluate cardiovascular risk is not recommended. Studies indicate that prolonged fasting induces ketosis and a rise in the serum cholesterol level; a partial fast, in which no fat is ingested and carbohydrate is the only source of energy, induces a fall in the cholesterol level.[4]

There are also two apparent contradictions in the task force publications. The report states that no evidence was found from randomized controlled trials that reduction of the total serum cholesterol level through dietary measures or drug therapy can lower the risk of CHD in women and men under 35 or over 60 years of age. This refers to patients with markedly elevated levels combined with other risk factors. By contrast, under the protocol for testing the report states that physicians should test for the total serum cholesterol level in men aged 20 to 34 and 60 to 69 and women aged 20 to 69 who have two or more risk factors. Does the explanation lie later in the report in the statement that there is nonexperimental evidence suggesting that intervention may be effective in reducing the incidence of CHD in this group?

The report states that, in the absence of other risk factors, routine testing of young men and women, premenopausal women