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POTENTIAL HEALTHCARE SAVINGS FROM PLANT STEROL ENRICHED FOODS IN CANADA

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Abstract

Increased consumption of foods containing plant sterols has the potential to reduce the incidence of coronary heart disease (CHD) and thus reduce costs associated with treating that disease in a significant way. This paper reports the results of an investigation of the potential monetary benefits of allowing foods enriched with plant sterols to be marketed in Canada. The objective of this research was to estimate the annual savings that would accrue to Canada's single-payer publicly funded health care system if plant sterols were approved for use. If foods containing plant sterols are consumed at a sufficient rate, a reduction in CHD should follow. This research employs a variation of traditional cost-of-illness analysis entailing four steps: (i) estimation of a "success rate" (proportion of persons who would consume plant sterols at the necessary rate); (ii) presumption of blood cholesterol reduction due to plant sterol consumption; (iii) assumption of reduction in CHD that follows from blood cholesterol reduction; (iv) calculation of cost savings associated with reduced incidence of CHD. Calculations were carried out for four scenarios: ideal, optimistic, pessimistic, and very pessimistic. It was estimated that between \$38 million (very pessimistic scenario) and \$2.45 billion (ideal scenario) could be saved annually by Canada's health care system with plant sterol enriched food products being made available for sale.

Key Words: coronary heart disease, cost of illness analysis, health care costs, success rate

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1. Introduction

The potential health benefits gained from consuming plant sterol-enriched foods have been studied as early as the 1950s (1), with the preponderance of literature indicating that plant sterol and stanol enriched food can reduce blood cholesterol in humans (2,3,4,5). In 2006, new harmonised regulations were adopted in the EU regarding use of health/nutrition claims for food products; the new legislation requires clear scientific substantiation of all such claims. Recently the European Food Safety Authority approved the claim that "Plant sterols have been shown to lower/reduce blood cholesterol. Blood cholesterol lowering may reduce the risk of (coronary) heart disease" (6).

High blood cholesterol is a major risk factor for heart disease and stroke; individuals with high blood cholesterol have a greater likelihood of developing coronary heart disease (CHD). Thus, if consumption of foods containing plant sterols can reduce the number of individuals with high cholesterol, it follows that the consumption of plant sterols should lead to a corresponding decrease in the incidence of CHD. A 1998 Statistics Canada estimate of outlays for physician services, hospital costs, lost wages, decreased productivity, and other losses attributed to CHD in Canada was approximately \$18 billion (7). Accordingly, it is expect that a lowering of the incidence of heart disease will result in a reduction of some of the costs associated with treating CHD.

In Canada, as in other jurisdictions with publicly funded health-care systems, the rising costs of treating diseases and the economic production lost due to premature death and disability are a major concern. The potential economic impact of incorporating plant sterols into Canadians' diets can be calculated by determining the proportion of the estimated \$18 billion cost of CHD avoidable by allowing public consumption of plant sterols in Canada. Previous research has shown that consumption of plant sterol enriched margarine could result in significant benefits from the perspective of a European health insurer (8); however, no comparable research has been done in a Canadian context to date. A previous attempt to estimate the potential economic impact in Canada from the introduction of a trans fat-free canola oil showed a significant reduction in the costs associated with CHD (9). A similar approach could be taken with respect to plant sterol enriched food.

The purpose of this research is therefore to determine the potential economic savings associated with allowing plant sterol consumption in Canada. The process to establish the

potential value of these economic savings from the consumption of plant sterol containing-foods involves four steps: i) assessment of a "success" rate; ii) presumption of a possible blood cholesterol reduction due to consumption of foods containing plant sterols; iii) assumption of the reduction in the incidence of CHD due to the realized decrease in blood cholesterol levels; and iv) calculation of the reduction in costs associated with decreased prevalence of CHD. Results provide an early approximation of the potential health care savings associated with use of plant-sterol enriched foods; it is expected future research using more elaborate techniques will yield more refined estimates.

2. Methods

When attempting to measure potential health benefits, a number of methods are available including cost-benefit analysis, cost-effectiveness analysis, and cost-of-illness analysis. The selection of an appropriate method should be consistent with the available data and the phenomenon being studied. Cost-benefit analysis and cost-effectiveness analysis are both used for evaluation of two or more alternative treatments; these techniques require the costs associated with both the treatment and the alternatives to be well-known. The purpose of this research is to determine the potential benefits from allowing plant sterol enriched foods to be sold into a market where they are currently not available, not to compare plant sterol enriched foods to alternative treatments. Additionally, it is not possible to estimate the cost premium that would be attached to foods enriched with plant sterols in Canada as this market would need to evolve in order to establish a long-term price. As such, neither cost-effectiveness nor cost-benefit analysis is an appropriate tool for this analysis.

A cost-of-illness analysis measures the direct and indirect costs of a specific disease--in this case CHD. A variation of a cost-of-illness analysis is to calculate the dollar savings associated with preventing or avoiding an illness. This variation has been used to calculate the economic benefit of drug abuse interventions (10), preventable drug related medical complications (11), and trans-fat free canola (9). A similar approach to the technique employed here was used previously by Malla, Hobbs, and Perger to estimate health care savings from trans fat free canola in Canada (12).

The economic benefit of consumption of plant sterol containing foods is evaluated using an economic simulation involving four steps, described below.

Step 1: Assessment of a "success rate"

In order to realize health benefits from plant sterols, an individual must consume between one and three grams per day. The proportion of the Canadian population that will consume a sufficient quantity of plant sterol enriched foods to reduce their cholesterol level is defined as the *success rate*. Plant sterols can feasibly be added to a number of food products such as orange juice, cheese, milk, yogurt, salad dressing, cereal products, cooking oils and margarine. The average Canadian consumption of these food categories is around nine servings per day according to Statistics Canada (13). It is thus reasonable to conclude that there is sufficient scope within the Canadian diet to accommodate an adequate dose of plant sterols without having to drastically alter food consumption patterns. It should be noted that all of the foods listed above may not be equally effective as delivery vehicles for plant sterols; it may also be the case that claims will be allowed for different foods containing plant sterols along different timelines.

Since the market for plant sterol enriched foods has not until very recently existed in Canada, estimating its size and characteristics is difficult. The overall Canadian functional food market, of which phytosterol fortified foods will become a subset, is still evolving and changing rapidly, thus available data are relatively sparse. Given the lack of available information, the best method for predicting how Canadians would respond to plant-sterol enriched food products is to examine the markets for similar functional foods in Canada and plant sterol enriched foods in other countries.

An activities, interests, and opinions (AIO) framework and cluster analysis was used to determine the potential markets for functional foods in Canada (14). Survey information from across Canada enabled a cluster analysis to determine attitudes, knowledge, and motivations combining to identify consumers likely to buy functional foods. It was discovered that a cluster representing approximately 47% of the adult Canadian population possesses the characteristics that would make them likely to purchase functional food products. Canadian survey data available to determine the acceptance of specific functional foods are limited when compared to larger markets; however, the acceptance of conjugated linoleic acid (CLA) fortified foods has been examined in Western Canada (15). It was found the percentage of survey respondents highly likely to purchase CLA-enriched dairy products, if available where they normally shop, ranged from 4 to 13 percent. Since many of these dairy products are similar to potential phytosterol fortified foods, it seems reasonable to extend these results to such products.

In Finland, a country which has allowed phytosterol/stanol fortified foods in the marketplace for quite some time, a survey found 17% of adults reported daily use of plant sterol enriched margarine, with another 20% reporting monthly use (16). An additional 7% indicated having occasionally used the product. For the purpose of this economic evaluation, the success rates shown in Table 1 were used in the various sensitivity analysis scenarios as an estimate of the success ratio.

Table 1: Estimated Plant Sterol Success Rates

	Plant Sterol Consumption			
Assumption	Rate	Source		
Full potential all consumers who are predisposed to purchase functional food	47%	Herath, Cranfield, & Henson (2008)		
Consumption level similar to Europe	17%	Niva (2006)		
Consumption level similar to CLA survey intentions	10%	Peng, West, & Wang (2006)		

Step 2: presumption of a possible blood cholesterol reduction due to consumption of foods containing plant sterols

The primary health benefit of consuming foods fortified with phytosterols is reduction in serum cholesterol levels. Approximating this reduction requires extrapolation from results of meta-analyses of available human phytosterol feeding studies. Since plant sterols are relatively well-established as functional food additives, several thorough meta-analyses exist (2,3,4,5). One of these was limited in scope to plant sterol enriched spreads and found a reduction in LDL-cholesterol of 8.4% (95% CI 6.6-10.0%) (3). Another included 23 plant sterol and stanol trials and found a serum cholesterol reduction ranging between 4.6% and 24.3% with a mean LDL-cholesterol reduction of 11.0% (4). Yet another used 21 published plant sterol studies in their meta-analysis and found that average dose of 2.3g of plant sterols per day yielded an average cholesterol reduction of 9.7% (95% CI 8.5%-10.8%) (2). The most recent meta-analysis examined the results of 59 studies and found that plant sterol containing products reduced LDL-cholesterol by 0.31 mmol/L, a significant reduction (5).

The results from the meta-analysis based on 21 published plant sterol studies (2) will be adopted for the majority of the scenarios in the sensitivity analysis. This work included the

largest number of trials limited exclusively to plant sterol enriched foods and did not include plant stanol enriched foods. As a result, this data-set was judged as best representing the relationship between plant sterol consumption and serum LDL-cholesterol level reduction in humans.

Step 3: assumption of the reduction in the incidence of CHD due to decrease in blood cholesterol levels

Since no long-term studies have directly tracked the relationship between phytosterol consumption and heart disease in humans, it was necessary to make assumptions regarding the rate at which lower cholesterol levels due to plant sterol consumption will reduce the incidence of CHD. A meta-analysis of cholesterol-reducing treatment studies found a 13% to 14% reduction in CHD mortality for every 10-percentage-point net reduction in serum cholesterol levels (17). In a similar examination of studies concerning the relationship between cholesterol levels and ischemic heart disease, it was found that a 10% cholesterol reduction would lead to a 25% to 30% reduction in mortality from ischemic heart disease over the long-term (18). As both those studies focused on reductions in CHD mortality; it seems likely that the non-fatal incidence of CHD would decrease in a similar fashion if serum cholesterol was reduced across the population.

In an economic evaluation of the health benefits associated with trans-fat free canola oil, a ratio of a 1% reduction of cholesterol corresponding to 2-3% reduction in the incidence of CHD was utilized (9). This result is consistent with the findings of previous research (17,18) and was therefore used as the assumption regarding the reduction in the incidence of CHD due to decreased blood cholesterol levels resulting from plant sterol consumption in the majority of the sensitivity analysis scenarios.

Step 4: calculation of the reduction in costs associated with CHD due to a reduction in the overall incidence of CHD

The final stage of the model quantifies the economic benefit resulting from introducing plant sterol enriched food to the Canadian market. Health Canada has estimated the cost of CHD in Canada (7); even though the data are more than a decade old, they are still the most recent and comprehensive available. Since the 1998 data are in nominal dollar amounts but health care costs are subject to inflation, the 1998 amounts require adjustment to more current monetary terms. This adjustment is made using Statistics Canada's consumer price index for health and personal

care (19). Adjustment of the 1998 estimate of \$18.472 billion to 2007 levels yields a new approximation of \$21.176 billion as the assumed economic cost of CHD in Canada.

The economic cost of disease is generally broken down into direct and indirect components; the former are incurred directly by the health care system with the goal of improving and/or preventing a patient's health status from deteriorating. In the case of heart disease, direct costs include hospital care, drug costs, physician expenses, and other miscellaneous items. Indirect costs are those incurred due to the loss of production arising from disease and include loss of production due to mortality and morbidity costs arising from long and short-term disability. Table 2 provides a summary of direct and indirect costs attributable to CHD in Canada in both 1998 and inflation-adjusted 2007 dollars. While it seems obvious that a reduction in the level of CHD will lower related costs, is the extent to which these costs will be lowered is less clear. Previous work utilized a directly proportional relationship and assumed that a 1% reduction in CHD would result in a 1% reduction in CHD related costs (9). This type of assumption may oversimplify the health care process and could thus result in an overstatement of the potential cost reduction.

Table 2: Summery of Costs Attributed to Coronary Heart Disease in Canada (\$ millions)

Cost Category	1998	2007
Direct Costs		
Hospital	4 161.8	4 771.0
Drugs	1 772.8	2 032.3
Physician Care	822.3	942.7
Other Direct	61.2	70.2
Total Direct Costs	6 818.1	7 816.0
Indirect Costs		
Mortality	8 250.0	9 457.5
Long-term Disability	3 151.5	3 612.8
Short-term Disability	253.3	290.4
Total Indirect Costs	11 654.8	13 360.7
Total CHD Costs	18 472.9	21 176.7

Source: Health Canada (1998)

Rather than assuming a proportional cost reduction, it is appropriate to more closely examine the structure of specific cost categories. For example, hospitalization expenditures related to CHD include a sizeable fixed cost component—the costs of operating a hospital will be incurred regardless of the number of heart attack patients treated at the hospital. Research conducted with respect to the fixed cost variable cost breakdown in hospitals found that hospital costs are approximately 84% fixed and 16% variable (20). Accordingly, it is assumed that a reduction in CHD will not result in a reduction in fixed costs of hospitalization, but will cause a proportional reduction in variable hospitalization costs.

Approximating the reduction in drug costs due to CHD assumes that fewer individuals with CHD will require less medication to treat CHD. Since 49.6% of drug costs resulting from CHD are for the treatment of hypertension (7), a condition not normally improved as a result of cholesterol reduction, these costs are not reduced in the calculations. The remaining 50.4% of drug costs associated with CHD are reduced proportionally to the reduction in the overall rate of CHD. Physician care costs associated with CHD are based on physician billings which in turn are derived from patient visits to doctors' offices. It is assumed that if fewer people are afflicted with CHD, fewer visits to physicians for CHD treatment will occur, resulting in less numerous billings and lower health care costs. As such, a 1% reduction in CHD is assumed to lead to a 1% reduction in CHD related physician costs.

A large component of the miscellaneous CHD related expenditures has been categorized by Health Canada (7) as services provided by "other health providers." For this analysis, the cost of chiropractors (0.8%), dental (26.2%), and vision (9.6%) health professionals were excluded, as such costs are unlikely to be reduced due to a reduction in heart disease. However, the cost of physiotherapists (1%) and "all other health professionals" (4.7%) would be reduced in proportion to the overall CHD reduction. Also ignored in this analysis are costs which are largely fixed and therefore unlikely to decrease with the rate of CHD: expenditures on health research (4.4%), administration (6.5%), and public health (20.2%). By contrast, costs that will likely be reduced by a reduction in CHD include ambulance (4.2%), home care (6.2%), and "all other health expenditures" (7.2%). The final result is that a 1% decrease in the incidence of CHD is expected to result in a 0.23% reduction in miscellaneous CHD related costs.

Mortality, short-term disability and long-term disability costs were taken to have a directly proportional CHD reduction to reduction in cost relationship. Since the incidence of

CHD will decline, it was deemed reasonable to assume the number of people who will die or become disabled as a result of CHD will decline proportionately. As a consequence, the loss of human capital that would ordinarily be incurred as a result of CHD related death and disability, would not take place; this reduction results in an economic saving. Table 3 summarizes the proportion of cost reductions that could be achieved by a reduction in the incidence of CHD.

Table 3: Summary of Coronary Heart Disease Cost Reduction Corresponding to a 1% Decrease in Incidence of Coronary Heart Disease

Cost Category	Reduction in Cost
Hospital	0.16%
Drugs	0.50%
Physician Care	1.00%
Other Direct	0.23%
Mortality	1.00%
Long-term Disability	1.00%
Short-term Disability	1.00%

A number of assumptions are required to approximate the potential reduction in the cost of CHD from introducing phytosterol fortified foods to the Canadian market. Though these assumptions are based on a review of the peer-reviewed scientific literature, it could be misleading to suggest a single number as best representing the exact economic cost savings. As such, results are reported as a sensitivity analysis; as this approach allowed the effects of varying model assumptions within the simulation to be gauged. To make the numbers as robust as possible, four scenarios were examined; a description of the sensitivity analysis scenarios is provided below with a summary of the assumptions shown in Table 4.

Table 4: Summary of Sensitivity Analysis Scenario Assumptions

		Scenario Very		
Assumption	Ideal	Optimistic	Pessimistic	Pessimistic
Success Rate	47%	17%	10%	5%
Cholesterol Reduction Due to Plant Sterol Consumption CHD Reduction Due to 1%	10.8%	9.7%	8.5%	5.0%
Reduction in Serum LDL-cholesterol	3.0%	2.5%	2.0%	1.0%
CHD Reduction Due to Plant Sterol Consumption	32.4%	24.3%	17.0%	5.0%

3. Results and Discussion

The "ideal" scenario, in which the most positive assumptions are used, is calculated as the greatest possible economic benefit of allowing consumption of plant sterol enriched food in Canada. It is unlikely that this scenario is achievable in the short-term; however, over the long-term this estimate provides an index of the full potential of the economic savings resulting from the consumption of plant sterol enriched foods in Canada. The "optimistic" and "pessimistic" scenarios make more reasonable assumptions and represent a medium-to-short-term estimate of the potential economic savings possible through plant sterol consumption. The "very pessimistic" scenario is included to determine the impact on the cost estimations under a worst-case scenario. This scenario could be considered appropriate if the acceptance of phytosterol fortified foods is very low and the efficacy of plant sterols in reducing cholesterol and the health benefits of cholesterol reduction are considerably below normal expectations.

Table 5 shows the range of values reasonable to assume as representative of the economic savings to Canada from allowing plant sterols in the diet of Canadians. Each of the direct and indirect cost components is represented for the ideal, optimistic, pessimistic, and very pessimistic scenarios described above. Under even the most pessimistic set of assumptions, substantial cost savings would be realized to Canada's publicly funded single-payer health system. Under more reasonable assumptions (the optimistic and pessimistic scenarios), the savings become increasingly significant. Although it is unlikely the ideal scenario would be achieved in the short

term, it is evident that under a very optimistic set of assumptions, the potential savings become substantial.

Table 5: Reduction in Coronary Heart Disease Cost due to Consumption of Plant Sterol Enriched Foods (\$ millions)

Cost Category	ф иниона)	Scena	nrio	
Direct Costs	Ideal	Optimistic	Pessimistic	Very Pessimistic
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Hospital	116.2	31.5	12.9	1.9
Drugs	155.9	42.2	17.4	2.6
Physician Care	143.5	5.9	0.1	nil*
Other Direct	2.4	nil*	nil*	nil*
Total Direct				
Costs	418.0	79.6	30.4	4.5
Indirect Costs				
Mortality	1 440.2	389.9	160.8	23.6
Long-term				
Disability	550.2	148.9	61.4	9.0
Short-term				
Disability	44.2	12.0	4.9	0.7
T 1 1 1				
Total Indirect	2.024.6	550.0	227.1	22.2
Costs	2 034.6	550.8	227.1	33.3
Total CHD				
Costs	2 452.6	630.4	257.5	37.8
	2 132.0	030.1	231.3	37.0

^{*} denotes non-zero amounts too small for inclusion

The dynamic process from the point in time when plant sterol enriched foods are introduced to the market and the point in time at which the savings predicted in the various scenarios will occur is difficult to model with certainty. The scenarios presented in this report represent a static picture at some point the future; but how quickly the product is adopted will determine the speed with which that point is reached. The very optimistic scenario with a high success rate is more likely to occur at a point in time that is further into the future than the optimistic or pessimistic scenarios which have lower success rates built into their models. While a specific timeline cannot be predicted with certainty, the optimistic scenario requires that Canadians adopt phytosterol fortified foods in a manner similar to that of Finland, which does not seem unreasonable. Based on the introduction pattern of plant sterol enriched foods in

Finland over the 1990s of 17%, it would be reasonable to conclude that the impact of introducing plant sterol fortified foods into the Canadian market could be realized in a period of 5-10 years.

4. General Discussion and Conclusions

The results of the simulation indicate that substantial economic savings can result from introducing plant sterol enriched foods into the Canadian market. The rising costs of health care exist as a growing concern globally; especially in countries such as Canada where direct costs of treating disease are borne largely by the public health care systems. It has also been found that the cholesterol-lowering effects of plant sterols are additive to other cholesterol lowering strategies such as diet (21) and statin treatment (22). As such, phytosterol enhanced foods can work in concert with lifestyle changes and medication to lower the economic cost of CHD. A possible direction for future research would be to explore the cost effectiveness of reducing CHD through plant sterols in food products compared to statins, which currently enjoy a cost advantage over sterols.

When considering the cost savings presented in this analysis it should be noted that the cost premiums associated with plant sterol enriched foods has not been accounted for in this valuation. The costs of phytosterol fortified foods will fall outside of the medical system in Canada and thus represent a benefit to the publicly funded health care system. An excessive price premium would result in a lower economic benefit of plant sterol enriched foods. As the market for phytosterol fortified foods develops and more is known about possible price premiums, this issue should be revisited with a cost-benefit or cost-effectiveness study.

CHD is a substantial component of the economic burden of illness in Canada and high serum cholesterol is a major risk factor in developing CHD. Functional foods such as those which contain plant sterols have the potential to "demedicalize" and reduce significant portion of the economic costs associated with CHD in Canada, which in turn would allow health care funds to be allocated more efficiently.

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