APPENDIX C: EXPENDITURE MODEL FOR DIAGNOSIS AND TREATMENT OF hypercholesterolemia IN THE ELDERLY

In order to analyze the cost implications of a cholesterol screening benefit under Medicare, OTA developed a model to estimate annual total direct health care expenditures associated with screening and treatment of hypercholesterolemia in the elderly, This appendix describes the model. The text of the paper discusses the results of the analysis.

The Model

Several expert groups have recommended periodic screening for hypercholesterolemia. The most recent of these guide lines--formulated by the Adult Treatment Panel of the National Cholesterol Education Program (NCEP)--provides a suggested model for the detection and subsequent management of hypercholesterolemia. OTA has neither evaluated nor endorsed the protocol outlined by the Adult Treatment Panel. However, because of the protocol's wide dissemination throughout the medical community, it is the basis for estimating direct expenditures associated with cholesterol screening and treatment in the elderly.

The recommended protocol of NCEP is as follows (1 16):

- All adults should have their total serum cholesterol measured at least once every 5 years.
- If the cholesterol level is found to be less than 200 mg/dl, it is classified as "desirable, " and no specific management is required (educational materials about diet and cardiac risk factors should be provided).
- If the cholesterol level is at least 200 mg/dl, the cholesterol test is repeated. If the average of the two readings is between 200 and 239 mg/dl, it is classified as "borderline-high" cholesterol. If the average of the two readings is less than 200 mg/dl, further management is the same as for individuals with a desirable cholesterol level.

Table 8.--- NCEP Risk Factors for Coronary Heart Disease

- Male gender
- Family history of premature CHD (definite myocardial infarction or sudden death before age 55 in a parent or sibling)
- Cigarette smoking (currently >10 cigarettes per day)
- Hypertension[a]
- Diabetes mellitus[a]
- History of definite cerebrovascular disease (stroke) or occlusive peripheral disease
- Severe obesity (>30% overweight)
- Known history of low-HDL-cholesterol level (<35mg/dl confirmed by repeated measurement)

[a]NCEP does not specify the criteria for categorizing patients as diabetic or hypertensive.

ABBREVIATIONS: CHD=coronary heart disease; HDL = high density lipoprotein; NCEP = National Cholesterol Education Program.

SOURCE: Office of Technology Assessment, 1989.

- If the average of two readings is greater than 239 mg/dl, or if it is at least 200 mg/dl and the individual has either a history of coronary heart disease (CHD) (defined as prior myocardial infarction, or myocardial ischemia such as angina pectoris), or two other CHD risk factors, as shown in table 8, lipoprotein analysis is recommended. Lipoprotein analysis includes measurement of fasting total cholesterol, triglycerides, and high-density lipoproteins (HDL), and calculation of the low-density lipoprotein (LDL) level (from the Friedewald formula).
- For persons who receive lipoprotein analysis, further management is based on the calculated LDL level. If it is less than 130 mg/dl, the individual is considered to have "desirable LDL cholesterol," and no specific further management is required. Management of an LDL level above 130 mg/dl depends on the presence of other risk

factors. All patients are started on a dietary intervention for 6 months. If at the end of that time they have failed to achieve a desirable cholesterol level, medications may be added, depending on the LDL level, and the physician's discretion. These recommendations for testing and therapy are summarized in Figure 3.

Using an adaptation of this protocol, OTA performed an analysis of the likely health care expenditures associated with an ongoing cholesterol screening and treatment program for Medicare recipients. Because the costs of medications vary widely, expenditures for a range of medical regimens were estimated in 1988 prices.

Assumptions

The assumptions used in this analysis appear in table *9*. The basis for the assumptions is as follows:

Size of the population to be screened---The analysis uses the projected number of American men and women aged *65* and over in 1995 (113). The year *1995* was chosen because it would represent the first year in which full screening of the population could be anticipated under an every-5-year screening program.

Participation. --OTA estimated the cost. of full compliance with the NCEP protocols by all elderly people. Of course, not all Medicare recipients will avail themselves of the screening program or will comply with drug therapy. For example, one health maintenance organization that provided OTA with information on the use of preventive services reported that of members over *65* years old, 75 percent had their cholesterol measured at least once during a 5-year period (40). Consequently, the model was constructed to estimate costs under various assumptions about levels of compliance. Results are presented in the main body of this report indicating how costs would change if compliance with the NCEP screening and therapy guidelines were only 25 percent in the elderly.

Table 9--- Assumptions for Cholesterol Expenditure Model

	1995 Over-65 population (in thousands)
Men	13,441
Women	20,447

Fraction screened annually	0.2
Compliance with screening and therapy	0.25-1.00
Fraction with risk factors	0.3-0.7
Response to dietary therapy	10-15%
Fraction of drug expenditures incurred in the first year for persons who begin medication after failing to respond to dietary therapy	0.5

Cost assumptions	
Total cholesterol measurement	$ 6.79
LDL measurement	16.89
Annual costs of drug and monitor:	
low-cost medication (niacin)	525.00
high-cost medication (lovastatin)	1,678.00

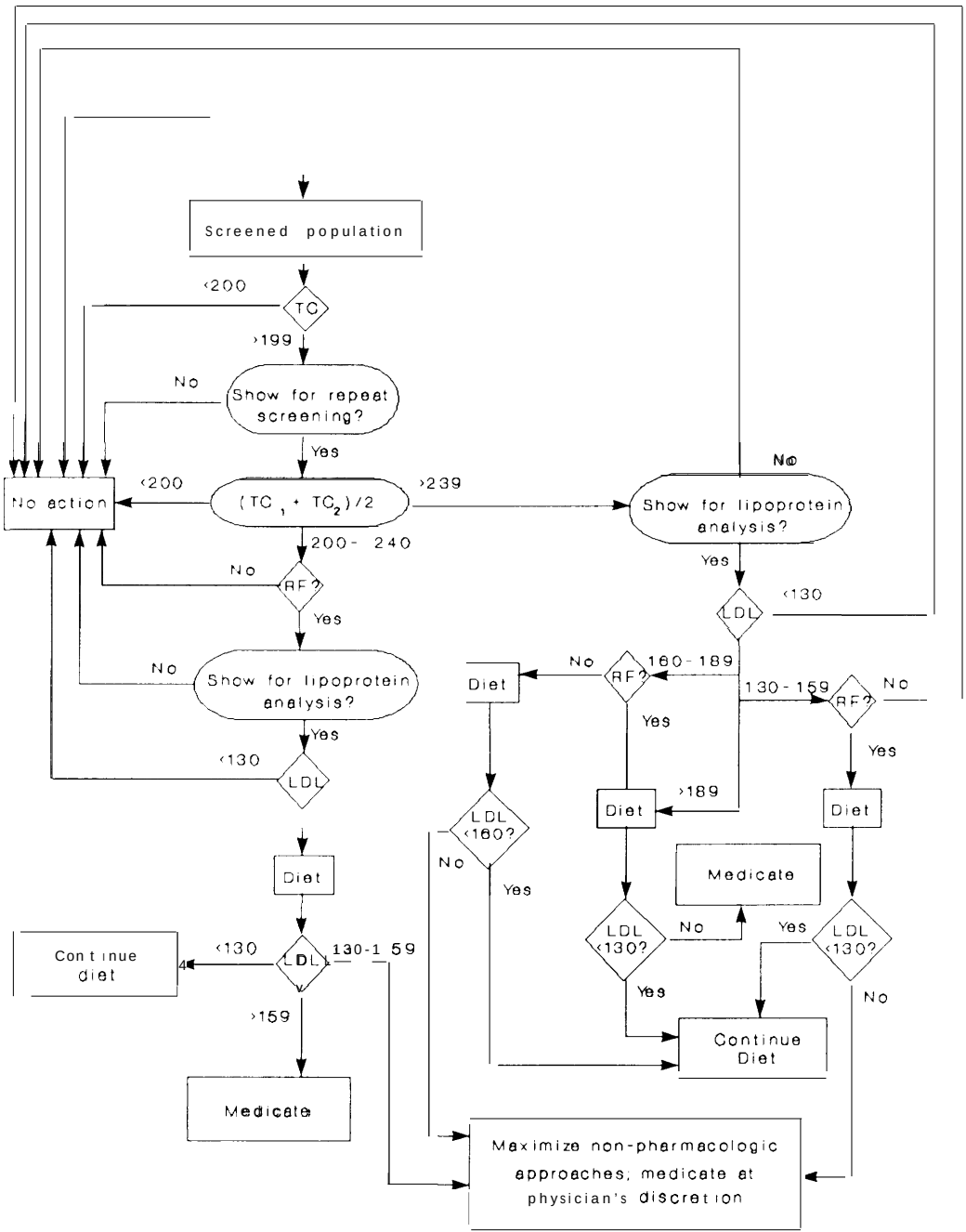
Lipid distributions	Men	Women
Total cholesterol (mg/dl)		
Mean	221.00	246.00
Standard deviation	62.33	60.21
LDL cholesterol (mg/dl)		
Mean	149.00	162.00
Standard deviation	40.00	44.00
Correlation, total and LDL cholesterol	0.84	0.88
Proportion with		
cholesterol under 200 (mg/dl)	0.37	0.22
cholesterol under 240 (mg/dl)	0.62	0.46

ABBREVIATION: LDL = low-density lipoprotein.

SOURCE: Office of Technology Assessment, 1989.

Prevalence of risk factors.--The NCEP protocol for determining lipoprotein fractions and treatment depends not only on the serum cholesterol but also on the presence of other risk factors. A high-risk individual is identified as one with 2 or more of the risk factors. Information is unavailable about the prevalence of other risk factors in relation to the cholesterol level in the elderly. It seems likely that a substantial number of Medicare recipients will either have a history of CHD or have two of the risk factors: about 20 percent of men and 15 percent of women

Figure 3--- Protocol for Cholesterol Screening in the Elderly



ABBREVIATIONS: LDL = low-density lipoprotein; RF = risk factors; TC = total cholesterol.

SOURCE: Office of Technology Assessment, 1989. Adapted from Adult Treatment Panel, National Cholesterol Education Program, National Institutes of Health, U.S. Department of Health and Human Services, "National Cholesterol Education Program Expert Panel on Detection, Evaluation, and Treatment of High Blood Cholesterol in Adults," Arch. Intern. Med. 148:36-69, 1988.

aged 65 and over are current smokers (122), nearly 14 percent report that they have CHD, and one half of Americans aged 65 to 74 have definite hypertension (121).

Because the precise number of elderly individuals who have CHD or two other risk factors is unknown, the analysis includes calculations for three different assumptions:

- the low-prevalence estimates assume that 30 percent of the Medicare recipients are high-risk based on a history of CHD or two risk factors for CHD (other than hypercholesterolemia),
- the middle-prevalence estimates assume that 50 percent have the risk factors, and
- the high-prevalence estimates assume that 70 percent have risk factors.

OTA assumed that the prevalence of the risk factors is not correlated with the cholesterol level; this assumption probably leads to an underestimate of the number of persons who will need treatment, since it is likely that the risk factors are more common among individuals whose cholesterol levels are elevated than among those whose cholesterol levels fall below 200 mg/dl. Given that male sex is a risk factor according to the NCEP framework, the high-prevalence assumption (70 percent) may be the most likely value for men over 65 years old.

Number of participants requiring further testing or treatment .--The analysis assumes that the repeat cholesterol assay will give the same result as the initial assay. This assumption will underestimate screening expenditures because it does not count the costs of repeat total cholesterol screening for those people whose initial readings are greater than 199 mg/dl, but who receive no further management on the basis of the second screening. The magnitude of this effect should be slight but depends on the accuracy and precision of the screening tests.[1]

The number of people in alternative treatment groups (e.g., those who do not have a history of CHD or two other CHD risk factors, but do have a cholesterol level in excess of 200 mg/dl and an LDL cholesterol level above 190 mg/dl) is calculated by assuming that the total cholesterol and the LDL - cholesterol level have a joint bivariate normal distribution.

Followup testing. --In order to calculate how many individuals will have repeat cholesterol determinations, lipoprotein fractionation, and recommendations for testing, OTA used data from the National Health and Nutrition Examination Survey, reproduced in the NCEP report. The analysis assumes that the total cholesterol level and the LDL - cholesterol level have a bivariate normal distribution in the Medicare population, and use the published figures for the mean and standard deviation of cholesterol and LDL for the 65 to 74 year-old age group. The correlation between LDL cholesterol and total cholesterol is assumed to be 0.84 for men, and 0.88 for women, based on the Framingham Heart Study, as shown in table 2. The predicted number of people whose cholesterol is less than 200 mg/dl or less than 240 mg/dl is consistent with the percentiles noted in table 1.

Response to diet. --The model assumes that individuals treated with diet will uni -

1 While the accuracy and precision of cholesterol measurement is important i n eva 1 uat i ng the **effectiveness** of a screening benefit, it is of less importance in estimating the **health care expenditures** associated with such a benefit. Hence, OTA did not build into its model more sophisticated mechanisms for model linghowwell the various screening technologies work.

formly achieve a 10-percent reduction in LDL. This is an optimistic assumption regarding the effectiveness of dietary interventions in lowering LDL levels. The Multiple Risk Factor Intervention Trial of middle-aged men led to a 7-percent reduction in LDL with diet. Even in the subset of participants with "best adherence," LDL fell by 8.6 percent (32).

Although the effectiveness of diet control interventions appears to be limited, if a way were found to reduce LDL levels more dramatically through diet alone, the estimated cost of the NCEP program would be greatly reduced. Therefore, OTA also calculated how costs might change if a 15 percent reduction in LDL could be expected from diet.

Costs of testing. --The marginal cost of performing lipoprotein analyses is uncertain. Laboratory and physician charges for cholesterol determinations are highly variable. For this analysis, total cholesterol measurements were assumed to cost $6.79 per determination (which includes drawing the blood and performing the analysis), the Medicare average allowed charge in 1986 inflated to 1988 prices by the Medicare Economic Index (87,94). This is more expensive than the retail price of fingerstick cholesterol determinations (47). The analysis assumes that fractionation (measurement of HDL, triglycerides, and total cholesterol, with a calculated value of LDL) costs $16.89, the average allowed Medicare charge in 1988 dollars.

As is discussed in greater detail in the text, the model does not include the cost of a physician visit in estimating expenditures for screening. It assumes that cholesterol screening either would take place in a community setting or would occur as part of a patient's visit to the physician for some other purpose. It is possible, however, that the introduction of a cholesterol screening benefit would increase the number of physician office visits for Medicare beneficiaries and the health care costs of the program would rise accordingly.

Costs of treatment protocols. --The analysis assumes that diet imposes no direct health care costs. This assumption underestimates treatment expenditures, since most patients participating in dietary therapy require counseling with physicians or dietitians in the establishment and monitoring of their diets. The NCEP protocol recommends that people on dietary therapy have a "complete clinical evaluation. " The costs of such an evaluation are not included in the model.

Under certain conditions, if improvement in LDL levels with diet is totally inadequate, the NCEP protocol leaves it at the physician's discretion whether to continue with diet or to initiate therapy with medication. The model assumes that physicians will always be conservative in decisions and will not initiate medication. Thus, the model is extremely conservative in estimating the number of elderly people who would end up on medication and the costs of their treatment.

For medications, OTA calculated the estimated annual expenditures in 1988 dollars for a low cost regimen of $525 per patient per year for niacin, and a high cost regimen of $1,687 for lovastatin, including the costs of followup testing. The figures are obtained from table 4, and the text of the paper describes how they were derived.