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Primary care

Estimating the high risk group for cardiovascular disease in the Norwegian HUNT 2 population according to the 2003 European guidelines: modelling study

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Abstract

Objective To estimate the high risk group for cardiovascular disease in a well defined Norwegian population according to European guidelines and the systematic coronary risk evaluation system.
Design Modelling study.
Setting Nord-Tröndelag health study 1995-7 (HUNT 2), Norway.
Participants 5548 participants of the Nord-Tröndelag health study 1995-7, aged 40, 50, 55, 60, and 65.
Main outcome measures Distribution of risk categories for cardiovascular disease, with emphasis on the high risk group.
Main results At age 40, 22.5% (95% confidence interval 19.3% to 25.7%) of women and 85.9% (83.2% to 88.6%) of men were at high risk of cardiovascular disease. Corresponding numbers at age 50 were 39.5% (35.9% to 43.1%) and 88.7% (86.3% to 91.0%) and at age 65 were 84.0% (80.6% to 87.4%) and 91.6% (88.6% to 94.1%). At age 40, one out of 10 women and no men would be classified at low risk for cardiovascular disease.
Conclusion Implementation of the 2003 European guidelines on prevention of cardiovascular disease in clinical practice would classify most adult Norwegians at high risk for fatal cardiovascular disease.

Introduction

Mortality from cardiovascular disease has declined considerably in most European countries since the early 1970s.[1] Interventions to modify risk factors have long been shown to reduce mortality and morbidity from cardiovascular disease, in both people with previously unrecognised disease[2] and people with established disease.[3] Intervention in people at high risk is an accepted method for disease prevention. Since the first US Framingham model for predicting heart disease risk was published in 1991, it has become ever more widely recommended that doctors in primary care carry out risk assessment by combining several risk factors for cardiovascular disease using algorithms. Until recently most risk equations have been derived from the Framingham study, but these calculations tended to overestimate risk in the European context.[4] A new European risk scoring system for cardiovascular disease, based on the first phase of the systematic coronary risk evaluation (SCORE) project, was presented in 2003.[5] The system is based on a pooled dataset of cohort studies from 12 European countries, among these Norway, and offers a format for estimating fatal cardiovascular disease risk that is suitable for clinical practice.[5] The system is embedded in the current version of the European guidelines on prevention of cardiovascular disease, issued by the Third Joint Task Force of European and other Societies on Cardiovascular Disease Prevention in Clinical Practice in 2003.[6] The authoring body consists of eight European and international medical societies and experts. The guidelines aim to present all relevant evidence to facilitate clinical decision making in the primary and secondary prevention of cardiovascular disease, which can be adapted to different political, economic, social, and medical circumstances.[6]

The legal status of clinical guidelines for the prevention of disease is not fully established,[6] but authoritative recommendations contribute to expert and opinion leaders' definition of what constitutes good medical practice. Several studies have, however, shown clinicians' limited adherence to medical guidelines for asymptomatic conditions.[6–9] This is the case even in high risk situations, such as patients with angina pectoris or diabetes mellitus.[8] This phenomenon, termed "clinical inertia," has been partly attributed to too much work, too little time, and "soft reasons to avoid intensification of therapy."[7]

Population based data on risk factors for cardiovascular disease are available for many European regions.[10] The 2003 European guidelines, however, provide no estimates of the aggregated workload associated with implementation of the recommendations. We recently showed that implementation would result in three out of four Norwegians aged 20 or older being classed as in need of counselling because of high cholesterol or blood pressure levels.[11]

We estimated the high risk group in the Norwegian population participating in the Nord-Tröndelag health study 1995-7 (HUNT 2),[12] according to the 2003 European guidelines on prevention of cardiovascular disease.

Materials and methods

The 2003 European guidelines tackle the prevention of atherosclerotic disease in general (coronary heart disease, peripheral artery disease, and cerebrovascular atherosclerotic disease). Risk is defined in terms of the absolute probability of developing a fatal cardiovascular event within 10 years, and the threshold for high risk is defined as $\geq 5\%$.[6] The guidelines [6] specify a list of biomedical conditions that classify people at high risk (see box). These people require maximal clinical attention, with no further estimation of risk.[6] In remaining asymptomatic, apparently healthy people, risk estimation and counselling should be guided by the total risk level, as estimated from a chart produced by the systematic coronary risk evaluation project.

The European guidelines' clinical priority list

The clinical priority list in the European guidelines on cardiovascular disease prevention in clinical practice (pocket version). Individuals who fulfill criteria 1 or 2, or both are defined as at high risk

Priorities of cardiovascular disease prevention in clinical practice
1) Patients with established coronary heart disease, peripheral artery disease and cerebrovascular atherosclerotic disease
2) Asymptomatic individuals who are at high risk of developing atherosclerotic cardiovascular disease because of:
 a) Multiple risk factors resulting in a 10 year risk of ≥5% now (or if extrapolated to age 60) for developing a fatal cardiovascular event
 b) Markedly raised levels of single risk factors: cholesterol ≥8 mmol/l (320 mg/dl), LDL cholesterol ≥6 mmol/l (240 mg/dl), blood pressure ≥180/110 mmHg
 c) Diabetes Type 2 and diabetes Type 1 with microalbuminuria
3) Close relatives (first degree relatives) of:
 a) Patients with early-onset atherosclerotic cardiovascular disease
 b) Asymptomatic individuals at particularly high risk
4) Other individuals met in connection with ordinary clinical practice

Source: De Backer et al [6]

The chart comprises a table of the parameters sex, smoking status, systolic blood pressure, total cholesterol (or ratio of total cholesterol to high density lipoprotein), and age (40, 50, 55, 60, and 65 years). Risk is estimated by rounding a person's age to the nearest one shown on the chart, their cholesterol level to the nearest whole unit, and their blood pressure to the nearest multiple of 20 mm Hg.[5] The guidelines specifically recommend extrapolation of the risk estimate to 60 years when counselling people in the younger age groups. We calculated risk distribution both with and without extrapolation to evaluate its effect on the high risk group.

The chart is designed in two versions, for use in high or low risk populations. As the guidelines state that Norway is a high risk region, we analysed data using the high risk chart.

The guidelines encourage people with increased risk for cardiovascular disease to change their lifestyle.[6] To facilitate communication of risk, a person's combined risk estimate is visualised by "traffic light" colours. High risk is illustrated by increasingly dark shades of red. Intermediate risk (2%-4% risk of a fatal event within 10 years) is illustrated by yellow-orange, and low risk (≤ 1%) by green.

The Nord-Tröndelag health study 1995-7

Our population data were derived from the Nord-Tröndelag health study 1995-7, a large Norwegian population study that was designed to investigate the importance of biomedical risk factors. Its design and methods are described elsewhere.[12] Data were obtained from 66 140 participants. The study population has been considered fairly representative of the Norwegian population for demography, socioeconomic factors, morbidity, and mortality.[12]

To apply the guidelines' recommendations as precisely as possible, we included in the present analysis only people of the ages shown in the chart. The analysis is based on participants from the Nord-Tröndelag health study aged 40, 50, 55, 60, and 65 years, totalling 5548 people (2841 women, 2707 men). These participants answered two questionnaires; one sent by post before screening and the other presented at screening. A range of health topics was covered.[12] Of relevance to our study were questions about cardiovascular disease, diabetes mellitus, and smoking habits. For our analysis we define smoking as daily consumption of cigarettes, cigars, or a pipe.

In the Nord-Tröndelag health study, blood pressure was measured in seated participants by specially trained staff using a Dinamap 845XT based on oscillometry.[12] In our analysis we record blood pressure as the mean values of the second and third of three measurements carried out consecutively at the same visit. Blood sampling was carried out whenever the participants attended—that is, in the non-fasting state. Fresh serum was analysed on a Hitachi 91 autoanalyser. Total cholesterol and high density lipoprotein cholesterol were measured by an enzymatic colorimetric cholesterolesterase method.[12] Height was measured to the nearest 1.0 cm and weight to the nearest 0.5 kg. Body mass index was calculated.

Projection of the guidelines to the study population

We established the proportion of participants at high risk of cardiovascular disease in a stepwise manner, in accordance with the guidelines. We calculated the age and sex specific proportions that should be assigned to the high risk category on the basis of criteria 1 and 2b-c of the priority list (see box). We used the chart to estimate risk in the remaining participants. As the chart does not give exact cut-off points for systolic blood pressure and total cholesterol, we applied the following limits: systolic blood pressure (mm Hg) ≤ 119, 120-139, 140-159, and 160-179; total cholesterol (mmol/l) ≤ 3.9, 4.0-4.9, 5.0-5.9, 6.0-6.9, and 7.0-7.9.

Overall, 283 women (10% of the total) and 186 men (6.9%) were unclassifiable according to the chart owing to missing data, mostly on smoking habits. We included all participants in the denominator when we determined the distribution of risk categories.

We adapted the priority list on the basis of the data from the Nord-Tröndelag health study. Under criterion 1 we included only participants with a history of myocardial infarction or stroke. We did not calculate low density lipoprotein, as application of the Friedewald formula is unreliable in non-fasting people. We included participants who reported receiving treatment for hypertension and all people with diabetes mellitus in the high risk category.

We display graphically the risk distribution for cardiovascular disease among the Nord-Tröndelag health study population in two versions; one based on extrapolation to age 60 as recommended in the guidelines, the other based on the participants' age. In doing so we applied the colour system, without differentiating between shades of the same colour. Shaded red indicates people who are defined as at high risk on the basis of criteria 1 and 2b-c. Unshaded red indicates high risk according to the chart (criterion 2a). We used SPSS version 12.0 to analyse frequencies.

Results

Table 1 gives an overview of participants from the Nord-Tröndelag health study included in the present analysis. The participation rate varied from 70% to 89%. Table 2 shows the proportion of people categorised as at high risk on the basis of noticeably raised levels of single risk factors (see box) and the distribution of the combined risk categories, according to the chart of the systematic coronary risk evaluation project.

If all recommendations including extrapolation of risk to 60 years are applied, 22.5% (95% confidence interval 19.3% to 25.7%) of women and 85.9% (83.2% to 88.6%) of men aged 40 are classified as at high risk for fatal cardiovascular disease (fig 1 and table 2). Only 8.5% (6.5% to 10.9%) of women and no men aged 40 are classified as at low risk. By age 50, the high risk group includes 39.5% (35.9% to 43.1%) of women and 88.7% (86.3% to 91.0%) of men and by age 65, 84.0% (80.6% to 87.4%) of women and 91.6% (88.6% to 94.1%) of men.

Table 1 Participation rates, means, and prevalence of relevant risk factors among participants in Nord-Tröndelag health study 1995-7 (HUNT 2), Norway. Values are percentages (numbers) unless stated otherwise

	40 years		50 years		55 years		60 years		65 years	
Variable	**Women**	**Men**	**Women**	**Men**	**Women**	**Men**	**Women**	**Men**	**Women**	**Men**
No of participants (participation rate)	657 (80.8)	624 (69.6)	709 (84.1)	698 (76.0)	554 (85.9)	555 (79.9)	471 (88.9)	411 (80.4)	450 (85.1)	419 (81.7)
Mean (SD) systolic blood pressure	124.0 (14.5)	133.6 (13.1)	133.1 (19.1)	137.5 (16.9)	138.8 (19.8)	140.6 (17.9)	144.6 (21.1)	144.9 (20.6)	150.7 (23.5)	148.4 (20.4)
Mean (SD) diastolic blood pressure	76.1 (9.8)	80.8 (9.9)	80.8 (11.2)	85.4 (10.9)	82.8 (11.4)	85.4 (10.8)	82.9 (11.6)	87.0 (11.4)	84.5 (13.0)	86.2 (12.1)
Mean (SD) total cholesterol concentration	5.4 (1.0)	5.7 (1.1)	6.1 (1.1)	6.1 (1.1)	6.5 (1.2)	6.2 (1.2)	6.8 (1.3)	6.1 (1.1)	6.8 (1.2)	6.2 (1.1)
Mean (SD) body mass index	25.4 (4.1)	26.3 (3.4)	26.5 (4.4)	27.0 (3.4)	27.1 (4.4)	27.1 (3.5)	27.8 (5.0)	27.1 (3.3)	27.5 (4.7)	27.1 (3.3)
Smokers	46.1 (281/610)	34.8 (204/586)	38.9 (240/617)	34.1 (220/646)	33.7 (157/466)	32.9 (166/505)	32.5 (123/379)	32.7 (118/361)	32.8 (114/348)	33.9 (122/360)
Total cholesterol ≥5 mmol/l	65.7 (430/654)	76.4 (475/622)	86.7 (615/709)	86.2 (600/696)	91.7 (508/554)	88.6 (491/554)	94.1 (443/471)	86.6 (355/410)	95.3 (429/450)	86.9 (364/419)
Blood pressure ≥140/90 mm Hg and untreated	15.2 (102/657)	36.0 (224/623)	29.8 (211/709)	41.7 (290/696)	37.3 (206/552)	44.8 (248/554)	42.2 (198/469)	52.1 (214/411)	43.8 (196/448)	46.8 (195/417)
Angina without myocardial infarction	0.2 (1/657)	0.0 (0/624)	1.3 (9/708)	2.1 (15/698)	1.1 (6/549)	2.5 (14/553)	3.8 (18/469)	4.9 (20/411)	4.5 (20/447)	7.5 (31/414)
First degree relatives with myocardial infarction before age 60	15.8 (92/581)	20.7 (105/508)	20.6 (132/640)	17.9 (104/582)	21.8 (108/495)	18.5 (86/464)	19.4 (86/444)	17.7 (63/356)	17.8 (76/426)	18.8 (71/377)

Figure 2 shows the distribution of risk categories without extrapolation to age 60. Extrapolation explains 86.0% of the high risk group after evaluation using the chart among women aged 55. The values for men are 64.4% at age 50 and 18.7% at age 55.

Discussion

Implementation of the 2003 European guidelines on prevention of cardiovascular disease in a well defined Norwegian population would class four out of 10 women and nine out of 10 men aged

Table 2 Percentages (numbers) of women and men at high risk for cardiovascular disease according to criteria 1 and 2b-c in priority list (see box), distribution of combined risk categories for cardiovascular disease among remaining individuals according to systematic coronary risk evaluation (SCORE) chart

	40 years		50 years		55 years		60 years		65 years	
	Women	**Men**	**Women**	**Men**	**Women**	**Men**	**Women**	**Men**	**Women**	**Men**
Priority list:										
Established myocardial infarction or stroke	0.3 (2/657)	0.3 (2/624)	1.4 (10/708)	4.3 (30/698)	1.6 (9/549)	8.2 (45/552)	2.6 (12/467)	9.7 (40/411)	5.9 (26/444)	12.8 (53/415)
Systolic blood pressure ≥180 mm Hg or diastolic blood pressure ≥110 mm Hg	0.5 (3/657)	0.5 (3/624)	2.4 (17/709)	2.1 (15/698)	4.7 (26/553)	2.9 (16/554)	7.2 (34/470)	7.3 (30/411)	14.0 (63/449)	6.2 (26/418)
Cholesterol ≥8 mmol/l	1.1 (7/654)	3.5 (22/622)	6.3 (45/709)	5.5 (38/696)	13.0 (72/554)	5.6 (31/554)	17.8 (84/471)	5.4 (22/410)	16.2 (73/450)	6.2 (26/419)
Diabetes	0.3 (2/657)	1.3 (8/616)	2.3 (16/708)	1.6 (11/696)	2.4 (13/551)	3.8 (21/552)	2.8 (13/468)	4.6 (19/410)	3.8 (17/446)	4.6 (19/415)
Receiving treatment for hypertension	1.8 (12/655)	1.8 (11/621)	8.1 (57/708)	9.3 (65/696)	14.3 (79/551)	14.4 (80/554)	16.8 (79/469)	17.3 (71/411)	28.3 (127/448)	26.9 (112/417)
Sum high risk*	3.8 (25/657)	7.2 (45/624)	17.8 (126/709)	19.5 (136/698)	29.2 (162/554)	26.7 (148/555)	36.7 (173/471)	33.8 (139/411)	51.1 (230/450)	43.4 (182/419)
SCORE chart for combined risk among remaining individuals with extrapolation†:										
Unclassifiable‡	7.0 (46)	6.4 (40)	10.7 (76)	6.6 (46)	11.7 (65)	5.8 (32)	11.9 (56)	8.0 (33)	8.9 (40)	8.4 (35)
High risk	18.7 (123)	78.7 (491)	21.7 (154)	69.2 (483)	19.3 (107)	64.7 (359)	20.6 (97)	55.7 (229)	32.9 (148)	48.2 (202)
Intermediate risk	61.9 (407)	7.7 (48)	46.5 (330)	4.7 (33)	38.6 (214)	2.9 (16)	30.6 (144)	2.4 (10)	7.1 (32)	0 (0)
Low risk	8.5 (56)	0 (0)	3.2 (23)	0 (0)	1.1 (6)	0 (0)	0.2 (1)	0 (0)	0 (0)	0 (0)
Total sum of high risk group, according to priority list and SCORE chart	22.5 (148/657)	85.9 (536/624)	39.5 (280/709)	88.7 (619/698)	48.6 (269/554)	91.4 (507/555)	57.3 (270/471)	89.5 (368/411)	84.0 (378/450)	91.6 (384/419)

*One or more of following criteria present: myocardial infarction, stroke, antihypertensive treatment, diabetes, cholesterol ≥8 mmol/l, systolic blood pressure ≥180 mm Hg, diastolic blood pressure ≥110 mm Hg.
†Extrapolation to 60 years for ages 40, 50, and 55 (denominator is number of individuals in each cohort).
‡Mostly explained by missing data on smoking habits.

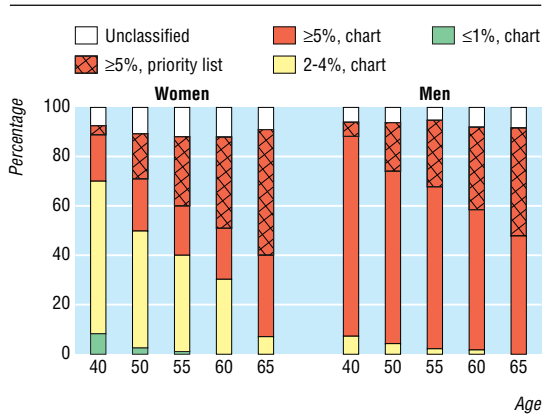

Fig 1 Distribution of risk categories for cardiovascular disease when risk is extrapolated to 60 years, as recommended by the 2003 European guidelines

50 as at high risk for fatal disease. No men aged 40 or older would be classified as at low risk.

Strengths and limitations of the study

The population of the Nord-Tröndelag health study 1995-7 (HUNT 2) is well defined, considered fairly representative of Norway, a country which contributed substantial amounts of data to the systematic coronary risk evaluation project.[5] Compared with other European high risk regions included in the systematic coronary risk evaluation project or the monitoring trends and determinants in cardiovascular disease (MONICA) project (third phase, 1992-4),[10] the population did not differ significantly for cholesterol levels and smoking habits. Blood pressure levels were higher in the Nord-Tröndelag population than in most comparable countries, but lower than in Finland.

The adjustments we made to adapt the data from the Nord-Tröndelag health study to the priority list of the European guidelines, should not significantly affect our main results. People with self reported angina, peripheral artery disease, and high levels of low density lipoprotein cholesterol were not automatically assigned to the high risk group. This contributes to a conservative estimate of the group before evaluation using the chart. Patients with diabetes type 1 without microalbuminuria, however, were included, as were patients receiving treatment for hypertension, irrespective of blood pressure levels. However, all patients with diabetes type 1 and people receiving antihypertensive treatment require a level of attention similar to that of people recently diagnosed as at high risk. We have no specific information on the use of lipid lowering drugs among the participants of the Nord-Tröndelag health study. To the extent that our population may have included patients receiving such treatment, this would contribute to a conservative estimate of the high risk population.

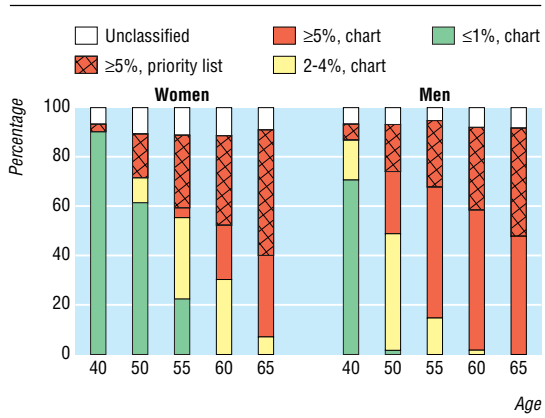

Fig 2 Distribution of risk categories for cardiovascular disease with reference to person's age (not extrapolated)

Applicability of 2003 European guidelines

Our findings can be discussed with regard to three explicit objectives of the guidelines—that is, the development of a risk estimation system intended for adaptation at national or even local level; a tool for prioritising patients; and an aid to individual risk communication and counselling.

Adaptation at national level

A paramount aim of the systematic coronary risk evaluation project was to encourage development of national guidelines on prevention of cardiovascular disease.[5 6] Applying the Framingham risk equation to European countries overestimated the risk of cardiovascular disease.[4 5] This highlights the importance of evaluating risk scoring systems against epidemiological data from the population to be screened before implementation in clinical practice.[13] In addition, a country can show regional differences in morbidity and mortality.[4] A dichotomisation of Europe into high risk and low risk regions may maintain the earlier introduced imprecision of the risk assessment. Whether the high risk chart applies to Norway has yet to be investigated.

Tool for prioritising patients

The 2003 European guidelines seem to be intended as a tool to define the priorities to be set, given limited resources. We found that the guidelines are unlikely to serve as an effective tool for prioritising Norwegians, as they classify an unreasonable number of people as at high risk. Extrapolation of risk to 60 years contributes strongly to this and implies that no men aged 40 or older and only a few women can be considered as at low risk for cardiovascular disease. Absence of extrapolation, however, makes it theoretically impossible for someone aged 40 to be classified as at high risk on the basis of the systematic coronary risk evaluation chart. So whereas extrapolation of risk leads to an overwhelmingly large high risk group, lack of extrapolation may lead to down prioritising of younger people who might benefit from early intervention.

Tool for counselling in clinical practice

The vision of the Third Joint Task Force was to make the guidelines (or adapted ones) part of standard daily clinical practice throughout Europe.[6] The European Society of Cardiology encourages visitors to its website (www.escardio.org) to include these guidelines in their handheld digital systems. The guidelines are therefore clearly recommended for direct use in counselling in clinical practice. Several ethical dilemmas may be linked to implementation of the guidelines in clinical practice. These arise from the likelihood of overestimating someone's true risk for cardiovascular disease. People who contributed data to the systematic coronary risk evaluation project were mostly recruited in the 1970s and 80s (Norway, 1974-8). Since the beginning of the 1970s, mortality from cardiovascular disease has decreased by 30%-50% in western Europe.[1] Lifestyle and body composition in the Norwegian population has also undergone important changes.[14] A given combination of the relevant risk factors for cardiovascular disease is likely to predict a lower mortality risk today than 25 years ago. The systematic coronary risk evaluation project[5] does not discuss the problem of retrospective risk bias.[4 13] A Norwegian group on cardiovascular disease has

What is already known on this topic

Clinicians are urged to implement clinical guidelines in everyday practice

Clinicians show limited adherence to medical guidelines that target asymptomatic conditions

What this study adds

Implementation of European guidelines to prevent cardiovascular disease would label most people in an unselected Norwegian population at high risk of fatal disease from age 40

The validity of the evidence base of the guidelines is questionable and predicts practical and ethical dilemmas related to resource allocation and clinical counselling

The size of the population at risk should be estimated before clinical guidelines are issued

suggested that a 5% risk for mortality in 1985 may correspond to a 2.5% risk in 2003.[15] We question whether it was scientifically justifiable to include the risk charts of the systematic coronary risk evaluation project[5] in guidelines intended for implementation in a clinical setting[6] before validation in a contemporary context.

Any overestimation of a person's risk for cardiovascular disease can have important implications. Apart from causing unnecessary concern, it undermines the patient's informed choice for intervention. It is also likely to increase prescribing costs and affect life insurance premiums.[4 16] As yet little scientific knowledge is available on how the communication of this kind of risk affects people's understanding of themselves, their bodies, and their lives.[11 17 18]

Process for development of guidelines

When guidelines class most adults in one of the world's longest living and healthiest populations[19] as at high risk and therefore in need of maximal clinical attention and follow-up, it raises several scientific and ethical questions.[20] The finding predicts major dilemmas related to workload and resource allocation,[21] even in Norway where the political, economic, social, and medical circumstances[6] reflect excellent access to health care by international comparison,[19] and the per capita expenditure on health is among the highest in the world.[19] It may be time to reconsider the aims and means of prevention of cardiovascular disease and the process of developing guidelines.[22]

Methods for the development of guidelines for prevention of disease should be scientifically consistent so as to ensure that concordance with guidelines is practically feasible and likely to result in the desired outcomes.[23] Evidence from biomedical research has limited meaning in isolation; it must be regarded in light of the overall vision, values, strategies, and resources that exist in the area of preventive medicine, both nationally and internationally.[22–24] Despite the contribution of numerous experts and professional societies, it seems that authoritative clinical guidelines on the basis of the systematic coronary risk evaluation project may be an example of premature application of medical technology in routine clinical practice.

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Competing interests: None declared.

Ethical approval: Surveys in the Nord-Trøndelag health study were approved by the Norwegian data inspectorate and the regional committee for ethics in medical research.

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