Economic evaluation of prevention programs for cardiovascular diseases

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Economic evaluation of prevention programs for cardiovascular diseases

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Economic evaluation of prevention programs for cardiovascular diseases

PROEFSCHRIFT

Ter verkrijging van de graad van doctor
aan de Universiteit Maastricht,
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Prof G.P.M.F. Mols,
volgens het besluit van het College van Decanen,
in het openbaar te verdedigen
op 11 januari 2007

door

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1

General introduction

Introduction

The prevalence of cardiovascular diseases (CVDs) is very high in many countries who adapted the western life style.¹ In the western world, the lifetime risk of cardiovascular diseases at age forty is estimated to be one in two for men and one in three for women.² In the Netherlands, more than a million people suffer from CVDs.³ This represents 8 percent of the Dutch adult population. In addition to this – and this is also true for most other Western European countries - CVDs are the most important cause of death in the Netherlands: 35% of all deaths each year can be attributed to CVD.^{1 4} This means that reducing the prevalence of CVD has a large potential to improve public health. Because of their high prevalence, cardiovascular diseases lead to high costs. In the Netherlands, the 2003 medical costs for cardiovascular diseases were €5.3 billion,⁴ corresponding to almost 10% of the total Dutch health care costs. Improving risk factors for cardiovascular diseases might thus also reduce the burden that cardiovascular diseases impose on the health care budget.

Many interventions, both preventative and curative, are available for CVDs. However, insufficient resources are available to implement all effective interventions because of fixed healthcare budgets, so choices have to be made. The aim of this thesis is to gain more insight into the costs and the cost-effectiveness of the prevention of CVDs. The aim is twofold, namely, to gain more insight into the quality of cost-effectiveness analyses in this field that have been performed so far, and to calculate the cost-effectiveness of Hartsлаг Limburg (Limburg Heartbeat), a programme for preventing CVDs.

In this chapter, the concept of CVDs and their epidemiology will be discussed. Then we provide background information about economic evaluations and describe the Hartsлаг Limburg programme. We conclude the chapter with an outline of the thesis.

Types of cardiovascular diseases

According to the *International Classification of Diseases, 10th edition* (ICD-10), CVDs can be divided into several subgroups.⁵ The subgroups ischaemic heart diseases, cerebrovascular diseases, and other heart diseases account for almost 85% of all the cardiovascular mortality in the Netherlands.

Ischaemic heart diseases are caused by stenosis of the coronary arteries.⁶ Clinical presentations include angina pectoris, acute myocardial infarction and its complications, repeated myocardial infarction, and other ischaemic heart diseases.^{5 7} Ischaemic heart diseases caused 32.7% of all cardiovascular deaths in the Netherlands in the year 2002.⁸ The most frequently occurring ischaemic heart disease is acute myocardial infarction, which causes 70% of all ischaemic heart disease deaths.⁸

A quarter of the cardiovascular deaths can be attributed to cerebrovascular diseases.⁹ Cerebrovascular disease implies a disturbance of brain function due to insufficient blood supply.¹⁰ In most cerebrovascular diseases – almost 80% – insufficient blood supply is due to a closed blood vessel.¹⁰

Just like cerebrovascular diseases, the remaining category 'other heart diseases' accounts for a quarter of all cardiovascular deaths.⁹ Heart failure causes 50% of the deaths within this category.⁹ Heart failure is caused by insufficient pumping capacity of the heart, which is accompanied by complaints such as fatigue and shortness of breath.¹¹

Trends in cardiovascular health

In the Netherlands, trends in mortality due to CVDs are well documented. Fortunately, the mortality rate for CVDs has decreased in recent decades. The standardized mortality rate due to ischaemic heart diseases, cerebrovascular diseases, and other heart diseases decreased from 395 per 100,000 in the year 1980 to 253 per 100,000 in the year 2000 for men, and from 338 to 225 per 100,000 for women during the same period.⁹ This represents decreases of 33 to 36 percent.

Much less detailed data are available for trends in the incidence and prevalence of CVDs. Information about the incidence and the prevalence of CVD is not available for all subgroups of CVD, but only for specific disease types.

Information is available about changes in the incidence and prevalence of the most frequently occurring subtype of ischaemic heart disease, namely, acute myocardial infarction. During the period 1985–2000, the incidence of the acute myocardial infarction decreased from 4.5 to 3.5 per 1000 for men and from 3.2 to 2.3 per 1000 for women.^{12 13} The prevalence of the acute myocardial infarction rose during this period. The prevalence increased from 14 per 1000

men and 8 per 1000 women in the year 1985 to 22 per 1000 men and 13 per 1000 women in the year 2000.¹²

Although the mortality rate for cerebrovascular diseases has decreased in recent years, their incidence rates have remained constant (about 4 per 1000 for both men and women).^{12 13} The prevalence rate of cerebrovascular diseases increased by 30 percent: from 15 per 1000 in 1985 to 20 per 1000 in the year 2000.¹³

The prevalence of heart failure has increased by 40 percent during the last 20 years.^{13 14} The incidence of heart failure in men decreased slightly, from 2.7 per 1000 in 1985 to 2.4 per 1000 in the year 2000.^{12 13} For women, the incidence rate of heart failure during this period decreased from 3.5 per 1000 to 2 per 1000.

Although no strong evidence exists, previous research suggests that the decrease in CVD mortality can at least partly be explained by preventive measures.^{8 9 15 16 17}

The priority for the prevention of CVDs will continue to be high. In the Netherlands, the proportion of elderly people will increase excessively in the coming decades. The ageing population will cause the absolute cardiovascular mortality rate to increase to 40 percent within the next 20 years.^{18 19 20}

Risk factors for cardiovascular diseases

As is well known, behavioural factors (poor diet, low exercise rate, and smoking) lead to unfavourable profiles of biological risk factors for CVD, such as high blood pressure and high levels of cholesterol.^{13 21} The biological risk factors increase the risk of CVDs in a multiplicative way.²¹ The behavioural risk factors also exert direct negative effects on cardiovascular health. This is especially true for smoking. Figure 1 visualises the relationship between risk factors, CVDs, and mortality.

Although we focus on the effects of risk factors on CVDs, it should be mentioned that the risk factors also exert negative effects on other diseases. Smoking, for example, is an important risk factor for lung cancer.

In this section, we first describe the influence of behavioural risk factors on biomedical risk factors. Then we discuss the direct consequences of high blood pressure, high cholesterol levels, and smoking on CVDs. We conclude with

giving an indication about the potential health benefit gained by reducing risk factors for CVDs.

The influence of behavioural risk factors on biomedical risk factors

Poor diet, especially if it includes much saturated fat, leads to a high body mass index (BMI). The saturated fat consumption and the high BMI lead to increases in both blood pressure and cholesterol level (Figure 1).

Low exercise rates may also result in high BMI and high levels of blood pressure. Furthermore, exercise rate is related to high-density lipoprotein (HDL) cholesterol. The lower the rate of exercise, the lower the levels of this favourable cholesterol type will be (Figure 1).

Smoking exerts a negative effect of cardiovascular health because it increases the blood pressure (Figure 1). Smoking also exerts some direct effects on cardiovascular health. These are discussed in the following section.

Biomedical risk factors and cardiovascular diseases

The underlying process of most cardiovascular diseases is atherosclerosis of the arteries. Plaque formation in the arterial walls leads to stenosis and decreased blood supply. This process is mostly due to subintimal cholesterol accumulation. Instability of these plaques may lead to rupture of the covering cap, with eruption of cholesterol and subsequent thrombus formation.

Complete occlusion of the coronary arteries for example, leads to acute myocardial infarction. Atherosclerosis is a multifactorial disorder and many risk factors play a role. Some of these are reversible either by changing life style or by medical treatment. Most common reversible risk factors are hypertension, hypercholesterolaemia, nicotine, and overweight and sedentary life style.

The potential health benefit of reducing risk factors for cardiovascular diseases

Changing the risk profile of the population has a high potential for improving health. About 30 percent of the CVD mortality in the Netherlands can be ascribed to high blood pressure and 45 percent to smoking.^{22 23} Furthermore, research has shown that the prevalence of myocardial infarction would decrease by 17 percent for men and 4 percent for women if BMIs of 30 or more were prevented.¹³ Even relatively small reductions in risk factors may lead to considerable CVD health gain. For example, a cholesterol reduction of 1 percent causes a decrease in CVD mortality of 2 to 3 percent, and a reduction of diastolic blood pressure by 5 to 6 mmHg has been shown to effect a

reduction in the CVD risk of 14 percent.^{24 25} A combined reduction of several CVD risk factors, as is striven for within Hartslag Limburg, will lead to more favourable effects than the reduction of only one of the risk factors due to the multiplicative effects that the risk factors exert on CVD.^{21 25}

Figure 1. Risk factors for cardiovascular diseases

BMI, Body mass index; BP, blood pressure; CVD, cardiovascular disease; Chol, cholesterol; HDL, high-density lipoprotein; LDL, low-density lipoprotein.

Types of interventions for changing behaviour

Several types of intervention have been carried out in order to increase healthy behaviour; for example: individual behavioural counselling, group counselling, quit-smoking contests, community programmes and - in the case of smoking – nicotine replacement therapy. In this thesis, we focus on individual counselling strategies and community programmes.

Counselling programmes are generally directed towards people with increased risks of CVDs or towards people with an established cardiovascular event. A health counsellor educates people about healthy behaviour and helps change unhealthy behaviour to more healthy behaviour.

Community programmes can be very diverse and aim to change the exercise pattern, dietary habits, smoking, or a combination of these factors within the whole community. Mass media campaigns are often part of a community

programme to prevent CVDs. Furthermore, activities can be organized in which people can actively participate to change their behaviour. Examples are exercise groups, cooking courses, and quit-smoking contests. Sometimes, even screening for cardiovascular risk factors followed by advice from healthcare personnel is included.

Economic evaluation of preventive interventions

The basic idea of economic evaluation is to compare the costs of different treatment alternatives with their various consequences, in order to determine whether a treatment offers 'good value for money'. The consequences are preferably measured in terms of years of life saved (yols) or quality adjusted life years (qaly), as to facilitate comparison between the cost-effectiveness of interventions from different medical disciplines. As already mentioned in the first section of this chapter, not all interventions that effectively improve health can be provided; this is due to budgetary constraints. Choices have to be made about the interventions to be implemented. In order to assist policy-makers in managing this implementation problem, economic evaluation studies are being carried out more and more often.

Because of the increased interest in evidence-based medicine, the interest in cost-effectiveness analyses over the whole field of healthcare – including those of preventive interventions – have increased in recent years. In spite of this, few studies have been published in this field to date.^{26 27 28} There are two important reasons for this. The main reason is that guidelines for economic evaluation were initially designed for medical interventions, such as those for drug therapy and surgery.^{29 30} The application of these techniques to the field of health promotion is not straightforward and leads to certain difficulties that must be overcome.^{26 31}

The application of the economic evaluation guidelines to the field of health promotion is problematic on several levels. The guidelines can neither be used directly for determining the outcome nor for calculating the costs. Furthermore, some general techniques of economic evaluation lead to difficulties when they are used in health promotion.

Determining the outcome

Health economists prefer outcome measures such as years of lives saved or quality-adjusted life years.³⁰ Because preventive interventions will only result in

changes in the incidence of diseases in the distant future, intermediate end-terms (such as changes in intention to change behaviour, behavioural changes or biological parameters) are frequently used as a starting point to calculate yols or qalys.

The first challenge in economic evaluation research is to achieve reliable intermediate measures of effects. This is more difficult than in the field of medicine because applying the RCT, which is regarded as the gold standard in effect research, is difficult and sometimes even impossible in public health research.^{27 31}

When intermediate outcomes are available, models have to be used to extrapolate intermediate end terms into the number of yols.^{26 27} Constructing such a model requires detailed information about risk factors, relative risks, and the incidence and prevalence of the disease. Only when sufficient data are available can such a model be built. Constructing such a model is not always necessary in the field of medicine. And if necessary, it is often more difficult to construct a reliable model in the field of health promotion than in the field of medicine. The reason for this is that in the field of health promotion intermediate outcome measures like intention to change behaviour and behavioural change are frequently used instead of biological parameters. For constructing the model, this means that, besides information about the influence of biological parameters on diseases, information is necessary about the effects of behavioural change on biological parameters and in some cases even about the intention to change behaviour on behavioural change. Clearly, this results in less reliable estimations of the yols. In the present health promotion study, changes in biological parameters were measured to obtain most reliable effects. However, it should be kept in mind that all models are based on assumptions to some extent. They will thus never be able to fully represent the reality.

Cost calculation

The calculation of the intervention costs takes much more planning and effort than is the case for medical interventions. This is especially true for large-scale, multifactor, community interventions because intervention costs can be very complex. A prospective and detailed follow-up is needed to ensure that all relevant costs are incorporated while irrelevant costs are excluded. Until now, the most usual way to calculate the costs of a community programme has been to use the actual expenditures derived from the financial records as an estimation of the programme costs.

General economic evaluation techniques

Another aspect of the guidelines for economic evaluation that brings about some difficulties when they are applied to health promotion is the concept of discounting. Discounting is intended to adjust for any difference in timing of costs and benefits.^{29 30} However, because the benefits of health promotion usually will only be observed in the distant future, discounting the future benefits is argued to be unfavourable for health promotion programmes when they are compared to medical interventions.^{27 31}

Current situation

Community programmes

Although not in all,^{32 33} most community programmes for preventing CVDs reported favourable effects on lifestyle, biological risk factors and cardiovascular mortality.^{34 35 36 37 38 39 40 41}

Some cost-effectiveness evaluations of community programmes for CVDs have been performed because of these positive results.^{42 43 44 45 46 47 48 49 50 51}

The reported cost-effectiveness ratio within the studies reviewed ranged from €24 to €6700.^{46 50}

Guidelines for economic evaluations, however, have been neglected in many studies.

Individual counselling

The evidence of the effectiveness (in terms of changes in lifestyle or biological risk factors) of individual counselling sessions in secondary care is contradictory. Although some studies report favourable and long-term effects,⁵² or even favourable cost-effectiveness ratios,^{53 54} others report only small or short-term effects,^{55 56 57 58} or even no effects at all. The same is true for counselling in primary care. The effectiveness has been proven in some studies,^{59 60 61 62 63 64} and cost-effectiveness was reported,^{65 66 67} but some studies were not cost-effective in spite of being effective,⁶⁸ and some studies found no effects at all.^{69 70}

Hartslag Limburg

Hartslag Limburg (Dutch for Heartbeat Limburg) is a large-scale project consisting of a community programme and a high-risk programme. Its purpose was to reduce the prevalence and incidence of CVD in the southern part of Limburg in the Netherlands.⁷¹ The programme was carried out in this specific region because of its relatively high prevalence of risk factors and CVD morbidity and mortality.^{71 72}

The community programme

The Hartslag Limburg community programme aims at health promotion among all inhabitants of the intervention region of Maastricht and four adjacent municipalities ($n = 180,000$). It can thus be regarded as a primary preventive intervention. The programme is based on a unique design through implementation by a network of organizations. While the Regional Public Health Institute of Maastricht coordinated the programme, many other agencies, including health promotion agencies, the local hospital, general practitioners (GPs), welfare services, and local authorities, joined the project. The many participating organizations made it possible to implement a multiple intervention strategy and to reach inhabitants of the region in a variety of ways.

Special attention was paid to inhabitants of four low socio-economic status (LSES) neighbourhoods ($n = 20,000$), in which 50% of the interventions took place.

The community-based health promotion campaign within Hartslag Limburg was realized through nine local health committees: one in each of the five municipalities and one in each of the four LSES areas. Each committee consists of employees of the Regional Public Health Institute and of welfare services, civil servants, and individuals from the target populations themselves. The committees approach individuals and groups within the target populations by means of health promotion projects and activities.

The participation of community members in the local health committees is essential to facilitate the recruitment and participation of inhabitants. This is especially true for the LSES regions because people with a LSES are difficult to reach for general health-promoting activities.

The participation of civil servants is important to make policy changes happen, and health promotion activities are partially financed by city councils.

The high-risk programme

The high-risk programme was carried out among GPs' patients who were at increased cardiovascular risk (secondary prevention) and among patients having recently suffered from a cardiovascular event, who visited the outpatient cardiology clinic of University Hospital Maastricht (tertiary prevention). Both trials were evaluated separately.

The intended intervention of the high-risk programme consisted of two parts, namely, individual health counselling and optimisation of individual cardiovascular drug treatment. Nurses or dieticians who had special counselling education provided the health counselling. The counselling focussed on quitting smoking, improving the dietary pattern, and increasing the exercise rate. The patients and the counsellor decided together which lifestyle factors would be included in the counselling.

Optimization of individual drug treatment was also intended to be an important aspect of the intervention. On the basis of a computerized absolute cardiovascular risk-factor profile, individual treatment was to be improved by adjusting the medication to recent guidelines.

Outline of the thesis

The first aim of this thesis was to gain insight into the quality of economic evaluation studies in the field of prevention of CVDs. To obtain more information about this subject, Chapter 2 reviews the quality of cost-effectiveness studies concerning the treatment of tobacco dependence as an example.

Because the results were disappointing in that the guidelines for economic evaluation were not very well adhered to, a second study was performed. It recalculates the cost-effectiveness ratios of the original studies reviewed in Chapter 1 in order to gain insight into the magnitude of the error that may arise due to guideline nonadherence (Chapter 3).

The subject of the following chapters is the Hartslag Limburg programme. Chapter 4 investigates the hypothesis, that focusing a community programme on people with a LSES status is more efficient than focusing on groups with high socioeconomic status or on the general population. Chapter 5 presents the effects in terms of the quality of life of the participants in the high-risk programme of Hartslag Limburg. Chapter 6 describes the evaluation of a health promotion intervention carried out within Hartslag Limburg, which was

established in a public-private partnership. In Chapter 7, the costs of the Hartslag Limburg community project are calculated in a detailed way. The method also allows the costs to be generalized to other regions. Chapter 8 is closely related to Chapter 7 as it describes the cost-effectiveness of the Hartslag Limburg community programme. Finally, Chapter 9 draws conclusions and presents a general discussion of the research carried out within this thesis.

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Cost-effectiveness of treatment for tobacco dependence - a systematic review of the evidence

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Abstract

Good decisions on which health interventions to invest can be facilitated by high quality evaluations of its cost-effectiveness. Although there are several reviews on the evaluations of the cost-effectiveness of smoking cessation programs, the reviews did not give information about the quality of the studies. The present study tries to fill this gap by thoroughly evaluating the quality of economic evaluations of interventions to reduce tobacco consumption. First, the general characteristics of all the studies reviewed are described, and then the quality of epidemiological characteristics and of the economic evaluation is analysed, using a criteria list proposed by Drummond et al. (1997). It is found that the quality of many aspects of many of the studies leaves much to be desired. However, the studies do consistently conclude that stop-smoking interventions are cost-effective, and this conclusion is robust when sensitivity analyses are performed. The cost-effectiveness ratios estimated by the studies for smoking cessation interventions are much lower than most other health care treatments. The study concludes that the broad conclusion that treatments to reduce the number of smokers are cost-effective at least in relative terms, is likely to be true, despite the concerns expressed about the quality of the economic evaluations. The implication for policymakers is that smoking cessation interventions are worthwhile.

Introduction

Smoking is one of the biggest health threats facing society today. At present trends, an estimated 500 million of the five billion people alive in 2000 will die as a result of tobacco consumption.¹ Reducing tobacco consumption has enormous potential to improve public health.

During the last two decades, there has been much progress in identifying effective interventions in many areas of health care, including in reducing tobacco use. There are now a variety of proven, effective interventions and treatments to reduce tobacco use including, but not limited to, smoking cessation interventions.^{2,3}

Limited health care budgets imply that choices have to be made about which interventions to implement. Good decisions are facilitated by information about the cost-effectiveness of interventions. This information comes from careful economic evaluations. A number of cost-effectiveness studies have been carried out in the field of treatments for tobacco dependence, and there are several reviews of the results.⁴⁻⁷

In general, authors of these reviews conclude that interventions to make people stop smoking are cost-effective. However, although the quality of studies is of paramount importance to reach reliable conclusions,⁸ thorough evaluations the quality of the individual studies reviewed were not carried out. The main objective of the reviews was to identify the principle findings of the studies evaluated. Sensitivity analysis was used to decide on the reliability of the cost-effectiveness estimates of the interventions. Brown and Garber (1998, 2000) tried to increase reliability of their conclusion by limiting the studies for review when possible, to those that (1) presented outcome in terms of years of life saved, (2) performed the analysis from a societal perspective, (3) discounted costs and effects in a consistent way, and (4) gave a description of the age and gender of the study population.^{4,5} Although their main goal was to review a large and diverse set of different interventions and populations, many of the studies did not meet their inclusion criteria. This short overview of existing reviews concludes that the quality of studies on the cost-effectiveness of smoking cessation interventions has not been of primary concern up to now.

Careful evaluation in other fields of health care, however, indicates that the majority of studies is not of sufficient quality.⁹ Because an accurate evaluation

on quality has not yet been performed in the field of smoking cessation, a knowledge gap exists on this subject. The present study tries to fill this gap by thoroughly evaluating the quality of economic evaluations of interventions to reduce tobacco consumption. First, the general characteristics of all the studies reviewed are described, and then the quality of epidemiological characteristics and of the economic evaluation is analysed, using a criteria list proposed by Drummond et al. (1997).⁸ The results of the analysis, both from a scientific perspective and the perspective of practical information, are discussed in the last section of this paper.

Methods

Literature search

An extensive search of the literature was performed from the year 1966 until the year 2000, using the following databases: Medline, Embase, Dare, NHS EED, HTA, Cochrane, Psychlit, EconLit. The *Istahc* journal was searched also.

Data bases which included a thesaurus function were searched as follows:

- (Costs and cost analysis) and smoking cessation
- Cost and smoking cessation

Data bases without a thesaurus function were searched using the following searches:

- (Cost* or economic*) in title or abstract and (smoking and cessation) in title or abstract
- (Cost* or economic*) and smok*
- (Cost* in ti or economic* in ti) and smok* in ti

The *Istahc* journal was searched with the following terms:

- Economic in ti
- Smoking in ti
- Costs in ti
- Cost in ti
- Cost effectiveness in ti
- Cost-effectiveness in ti

Additional literature was selected using citation tracking. Only English language articles were included. Letters, editorials and reviews were excluded from our review.

Assessing the quality of the studies

The guidelines of economic evaluation proposed by Drummond et al (1997) were used to assess the quality of the individual studies.⁸ These guidelines incorporate the following aspects: general, measurement of effect, measurement of costs, and issues such as discounting and sensitivity analysis. All interventions mentioned in the reviewed studies are reviewed for all aspects covered in the guidelines.

The study of Parrott et al. (1998)⁷ is treated slightly different than other studies. The study includes cost-effectiveness analysis of a number of interventions. However, because the community interventions and related cost-effectiveness analyses were not clearly described, they are excluded from the present review.

Results

After excluding letters, editorials and reviews, 22 full economic evaluations were identified. All studies identified were cost-effectiveness studies. In 14 studies cost-effectiveness was defined as costs per life years saved.^{7 10-23} One study also included cost utility in its outcome, and presented costs per quality adjusted life years (qaly).²³ The remaining seven studies define cost-effectiveness in terms of costs per quitter.²⁴⁻³⁰ Twelve of the identified studies were carried out in the United States.^{11 12 14-16 20 22-25 27 29 30} Six studies were performed in the United Kingdom.^{7 10 13 18 19 21} The three remaining studies were done in the Netherlands,²⁸ Finland,²⁶ and Spain.¹⁷

General characteristics

The general characteristics of the studies do not necessarily influence their quality, but definitely affect the way in which results can be interpreted. Important general characteristics are described in the following sections. Attention is paid to the viewpoint of the analysis, the interventions performed and alternative interventions, and to the study population.

Viewpoint of the analysis

Studies can be performed from different points of view, and these differences greatly affect the interpretation of the results. Therefore, a study's viewpoint should be mentioned explicitly in economic evaluation studies. This, however, is the case in only 11 of the 22 studies.^{7 12 13 15 17 20 21 23 27 28 30}

Drummond et al.'s economic guidelines recommend that economic evaluations take a societal perspective to prevent decisions being based solely on costs and effects for a specific organization or population. But only four of the studies explicitly mention having performed cost-effectiveness analysis from a societal perspective.^{7 12 17 28} An organisational perspective is also used,^{15 20 28 30} as well as the perspective of the NHS,^{13 21} the medical payer,²⁸ the health authority,⁷ and the participants.²⁸

Interventions performed

Literature on the cost-effectiveness of smoking cessation covers a wide range of interventions (table 1). Interventions include self-help programs,^{7 24 25 28-30} counselling,^{7 12 14 15 17 18 25 28} quit-smoking contests,^{7 24 26} nicotine replacement therapy,^{7 10 16 17 21-23} community health education programs,^{7 13 19 20} counselling combined with behavioural therapy²⁷ and other combinations of interventions. Interventions are compared with placebo therapy,^{10 16 21 27} counselling,^{7 14 23} physicians' advice,^{17 18 22} a school education program,¹⁹ and usual care.^{7 11-15 19 24-26 28-30} The most frequent comparison is between counselling and usual care.

Three studies compare self-help and usual care.

Unfortunately, the studied interventions and alternative interventions to which they are compared are too heterogeneous to allow cost-effectiveness ratios of different studies to be compared.

Study population

Not only do the studies compare a wide variety of interventions, the study populations differ in characteristics as well. For example smoking habits among study populations of different studies are not equal. Furthermore, some interventions were available for all smokers,^{7 11-13 15 17-20 24-31} while in other studies interventions were provided to heavy smokers only.^{10 21 22}

In addition to this, in contrast to preventing healthy people from stopping smoking, some studies were designed to promote non-smoking among patient populations.^{14 15 18 20}

The age and sex distribution of the study population is also relevant to determining whether the results of a specific study can be generalized. Eleven studies explicitly mentioned the age- and sex distribution of the population receiving the intervention.^{12 16 17 19 20 22 25 27 28} Five of these studies calculated age- and sex-specific cost-effectiveness ratio,^{12 16 17 22 23} while the other remaining six studies simply reported age and sex characteristics of the population.

Table 1: General characteristics of cost-effectiveness studies performed in the field of smoking cessation

first author	main outcome measure	country	perspective	intervention	alternative intervention	study population	results (\$)
1	costs per quitter	US	not stated	Counselling, self-help, contest	usual care	all smokers	235 - 399 22 - 144 129 - 236
2	costs per quitter	US	not stated	Counselling, self-help	usual care	all smokers	150 150
3	costs per quitter	Finland	not stated	Contest, tv	usual care	all smokers	24
4	costs per quitter	US	not stated	NRT, behavioural therapy	placebo	all smokers	567 - 1699
5	costs per quitter	NL	Society organisation	Counselling, self-help	usual care	all smokers	648 - 1297
			Participants	Counselling self-help			200 - 411 37 - 66
6	costs per quitter	US	not stated	Self-help	usual care	all smokers	686 - 1412 89 - 160
7	costs per quitter	US	organisation	Counselling, self-help	usual care	pregnant women	90 - 352
8	costs per yols	UK	society	Brief advice	usual care	all UK smokers	51 - 118
				brief advice + self-help	briefadvice	all UK smokers	300
				brief advice + self-help + NRT	briefadvice + self-help	all UK smokers	567
				brief advice + self-help + NRT + specialist help	briefadvice + self-help + NRT	all UK smokers	5950
			health authority	brief advice	usual care	all UK smokers	1515
				brief advice + self-help	briefadvice	all UK smokers	247
				brief advice + self-help + NRT	briefadvice + self-help	all UK smokers	513
							935

Table 1: continued

first author	main outcome measure	country	perspective	intervention	alternative intervention	study population	results (\$)
				brief advice + self-help + NRT + specialist help	brief advice + self-help + NRT	all UK smokers	171
9	costs per yols	UK	not stated	counselling	placebo	heavy smokers (h)**	1430
10	costs per yols	US	not stated	variety of interventions	usual care	all smokers	1094 – 6828
11	costs per yols	US	society	counselling	usual care	all smokers (h)	705 – 2058
12	costs per yols	UK	NHS	community health education	usual care	all smokers (h)	cost saving
13	costs per yols	US	not stated	counselling	usual care	MI-survivors	80 - 19000
14	costs per yols	US	organisation	counselling	usual care	hospital patients	1691 - 7444
15	costs per yols	US	not stated	NRT*	placebo	all smokers (h)	4113 - 9473
16	costs per yols	Sp	society	NRT	medical advice	all smokers (h)	2608 - 8058
17	costs per yols	UK	not stated	counselling	medical advice	hospital patients	480 - 600
18	costs per yols	UK	not stated	community health education	usual care	all smokers	431 - 930
19	costs per yols	US	organisation	community health education	school program	children	445 - 1269
20	costs per yols	UK	NHS	counselling, NRT	placebo	heavy smokers	407 - 733
21	costs per yols	US	not stated	NRT	Counselling	heavy smokers (h)	965 - 4391
22	costs per qaly	US	medical payer	counselling, NRT	Counselling	all smokers (h)	4390 - 10943

* NRT = nicotine replacement therapy, ** (h) = hypothetical cohort

1	Altman, 1987	12	Haycox, 1994
2	Bertera, 1990	13	Krumholz, 1993
3	Korhonen, 1992	14	Meenan, 1998
4	Miller, 1996	15	Oster, 1986
5	Mudde, 1996]	16	Plans-Rubio, 1998
6	Nelson, 1989	17	Prathiba, 1998
7	Windsor, 1988	18	Ratcliffe, 1997]
8	Parrot, 1998	19	Secker-Wal-ker, 1997
9	Akehurst, 1994	20	Stapleton, 1999]
10	Croghan, 1997	21	Wasley, 1997
11	Cummings, 1989	22	Fiscella, 1996

The mean age of the population in these studies varied from 38 years of age to 48 years of age. The percentage of male participants ranged from 0 percent in a self-help group for pregnant women to 73 percent in a combined intervention using nicotine replacement therapy and behavioural therapy, performed among active duty service members.

Eleven studies did not explicitly mention the age and sex distribution of the research sample.^{7 10 11 13-15 18 21 26 29 30} Three of these studies are cost-effectiveness analyses of previous performed effectiveness analyses.^{10 14 15} The population for the study performed by Haycox (1994) consisted of the entire population of South-West of England.¹³ Parrot et al. (1998) estimated cost effectiveness of the entire population of the United Kingdom⁷

Effectiveness of programs

There are two relevant questions concerning effectiveness of programs. The first question concerns the way how consequences are identified and measured. The second question is whether effectiveness was established before or during the period of economic evaluation. Economic evaluation is useful only when effectiveness has been proven. These aspects are addressed below.

Identification and measurement of consequences

Consequences can be divided into short-term consequences and long-term consequences. Long-term health effects are preferred above short-term consequences, because the aim of preventive interventions is to improve health during future life years. Long-term health effects can be expressed either in life years saved or in quality adjusted life years.

Identifying consequences in terms of quality adjusted life years is the most preferred option. It includes long-term effects and takes into account aspects of

quality of life. Changes in quality of life are difficult to measure for two reasons. First, no consensus exists about methods to measure quality of life. Second quality of life changes take place in the future, which means that modelling is necessary. Because of these difficulties, only one study explicitly attempted to use quality adjusted life years as measure of effect.²³

The next best measure of effect is life years saved. Using information about prevalence of smoking-related deaths and modelling techniques, an estimate of the years of life saved can be made based on the number of quitters. If costs per years of life saved are available, it allows policy makers to compare non-smoking interventions not only with each other, but also with other health care interventions with respect to their life-saving effects. Fifteen studies used years of life saved as outcome measure.^{7 10-23}

The least favourable outcome measure in economic perspective is the number of quitters, because of its short-term scope. This measure of effect in itself provides no information about changes in health, and studies using costs per quitter as outcome measure cannot be compared to anything other than other smoking cessation interventions. Yet, seven studies provide effects only in terms of number of quitters.²⁴⁻³⁰

In short, the majority of economic evaluations reviewed are cost-effectiveness studies. Several studies provided outcome in the less preferred costs per number of quitters and only 1 study estimated the most favoured outcome, namely cost-utility.

Was effectiveness established?

When performing a cost-effectiveness analysis, it is important that reliable estimates of effectiveness are made. As is mentioned in the previous section, a large number of studies calculated effects in terms of life years saved. To estimate long term-effects, modelling techniques are used. No tools are available to check the quality or validity of models that are being used to extrapolate the number of quitters to years of life saved. For this reason, the quality of the models will not be discussed. When reviewing studies on effectiveness, analysis is restricted to establishing effectiveness of non-smoking programs in terms of number of quitters.

Attention is paid to the source of the information about the effectiveness (empirical data, secondary data), to the kind of effectiveness evaluation performed (randomised or observational), to study period, and to the way relapse and unaided cessation are dealt with. Table 2 summarises these results.

Thirteen studies empirically established the effectiveness of non-smoking interventions.^{11 15 18-21 24-30} In other studies effectiveness estimates were based on secondary literature.^{7 10 12-14 16 17 22 23} Most of the studies using secondary data, performed a review of studies closely related to the intervention under study.^{7 12 16 22 23} Two studies based effectiveness data on one study only.^{10 14} One study did not clearly explain the source of the effectiveness data.¹³ Most studies used observational designs to establish effectiveness.^{11 14 17-20 24-29} Effectiveness was based on randomised controlled trials in 6 cases only.^{10 12 15 16 21 30} In four articles the design used is not clear or both designs are used.^{7 13 22 23}

Table 2: characteristics of the underlying effectiveness data

first author	source effect-data	design effect study	study period (in months)	taken account of relapse
Altman, 1987	empirical	observational	<3	yes*
Bertera, 1990	empirical	observational	18	n/a
Korhonen, 1992	empirical	observational	6	no
Miller, 1996	empirical	observational	6	no
Mudde, 1996	empirical	observational	6	no
Nelson, 1989	empirical	observational	<3	no
Windsor, 1988	empirical	RCT	9	no
Akehurst, 1994	secondary, 1 study	RCT	12	yes*
Croghan, 1997	empirical	observational	12	yes
Cummings, 1989	secondary, review	RCT	>12	yes
Haycox, 1994	?	?	?	no
Krumholz, 1993	empirical	observational	12	n/a
Meenan, 1998	empirical	RCT	12	n/a
Oster, 1986	secondary, review	RCT	>12	yes
Plans-Rubio, 1998	empirical	?	12	n/a
Prathiba, 1998	empirical	observational	12	n/a
Ratcliffe, 1997	empirical	observational	12	n/a
Secker-Walker, 1997	empirical	observational	12	n/a
Stapleton, 1999	secondary, review	RCT	12	yes
Wasley, 1997	secondary, 1 study	?	12	yes
Fiscella, 1996	secondary, review	?	12	yes

* in sensitivity analysis

Other important features to take into account when interpreting effectiveness data are study period and relapse. Relapse is common among smokers attempting to quit. Follow-up should thus be long enough to be able to exclude excessive relapse. When the follow-up period is relatively short (less than 12 months) data will be more reliable when corrected for future relapse.

All but one study defining cost-effectiveness as costs per yols had a follow-up period for at least 1 year.^{10 11 23 7 12 14-19 21 22} Haycox (1994) was not clear about study duration.¹³

Among the studies using number of quitters as final outcome, only one study reported a study-duration of 12 months.²⁵ Six- or nine-month follow-up of patients was used in the studies of Korhonen et al. (1990), Miller et al. (1996), Mudde et al. (1996) and Windsor et al. (1986).^{26-28 30} Two studies assessed smoking status one to three months after the program had been ended.^{2 4 29} Only one of the studies defining cost-effectiveness as costs per quitter examined effects of relapse in the sensitivity analysis.²⁴

In summary, this means that there were only five published cost-effectiveness studies that performed a randomised controlled trial and took account of relapse.^{10 12 15 16 21}

Economic quality of studies

When performing cost-analysis, health care costs as well as non health care cost (both direct and indirect) might be of interest.

Direct health care costs include costs for prevention, diagnosis, therapy and care related to the disease or risk factor of interest. Overhead costs - like equipment, space, and telephone etceteras - are part of direct health care costs. Indirect health care costs include general medical costs that are generated during the life years gained by smoking cessation.³²

The most important direct cost outside the health care sector is the value of the time of the patient and the family. Indirect non health-care costs mainly consist of the costs associated with loss of work due to sick leave and lower productivity costs.³²

There are several ways in which costs can be identified, measured and valued. Drummond et al. (1997) recommend about how to handle in all three stages to assure the quality of economic evaluation. Their advice is described below. It should be noted, however, when trying to make judgements about quality of the economic evaluation, that these three aspects are closely related.

Identification of costs

As mentioned before, according to guidelines of Drummond et al. (1997), for a study to be internally valid, costs included in the analysis have to be in concordance with the viewpoint of the analysis that the study uses.⁸ Intervention costs, changes in health care costs due to changes in smoking related disease,

changes in costs due to changes in lifetime health care costs, costs due to productivity changes and participants' costs can be regarded as relevant cost components, depending on the perspective.

Economic evaluations are performed to facilitate future decision-making. Therefore, economic evaluations should exclude costs that are irrelevant for future performance. For intervention costs, this means that costs of intervention development should not be included into the cost analysis. The same is true for research costs. Implementation costs might have to be made in future, but only once. It is therefore preferable not to incorporate these costs into the cost-effectiveness analysis; they offer more useful information when mentioned separately. When estimating intervention costs it is also important to consider contributions from third parties. The total costs of the intervention should be reported, independent of the way the costs are financed.

When calculating intervention costs, the important costs to consider are performance and overhead (e.g. electric power, cleaning and administration). Overhead costs can be identified either explicitly or implicitly. Costs can be estimated using an input oriented approach, which means that all cost components are identified separately. Summing up the costs components of the intervention that are identified provides an estimate of the total intervention costs. A number of studies, especially those evaluating counselling or NRT, make use of service units instead of an input oriented approach when estimating costs. Service units are aggregated cost a unit, such as hospital visits or visits to a general practitioner. Although not explicitly mentioned, these costs include overhead costs.

The question of whether cost identification is done in concordance with the perspective mentioned in the study is discussed below. When there is no perspective mentioned in the study, a description of the identified cost categories is given.

Societal perspective

The studies performed by Mudde et al. (1996), Cummings et al. (1989), and Plans-Rubio (1998) and Parrot et al. (1998) were the only studies that explicitly mention that the study was performed from the preferred societal perspective.⁷

^{12 17 28} However, careful evaluation of the studies showed that none of the studies included all cost categories relevant for a societal perspective. Mudde et al (1996) failed to include decreases in health care consumption of smoking related diseases due to the intervention.²⁸ Also not mentioned in the study were health care costs during additional life years, and declines in productivity losses

due to absence from work of smokers. In addition, intervention costs were not measured in an adequate way, as they contained development costs and implementation costs. Chapter 7 of this thesis elaborates on this. The other studies mentioning a societal perspective did not perform the analysis completely from a societal view either. In the study of Plans-Rubio (1998), only the direct health care costs were assessed.¹⁷ Cummings et al. (1989) faultlessly identified program costs, and they further identified future health care costs related to smoking and health care costs in additional years of life.¹² Productivity changes were excluded. Parrot et al. (1998) identified program costs and patient costs correctly, but they did not include future health care costs and productivity changes.⁷

Perspective of the organisation

When the analysis is performed from the perspective of the organisation, program costs should be assessed. All five studies performing the study from an organisational perspective indeed did include program costs only.^{15 20 27 28 30} However program costs were not defined correctly. Development and implementation costs were included in intervention costs in one study.²⁸ Another study incorporated development and research costs into the analysis, while ignoring overhead costs.²⁰ The other three studies that performed cost-effectiveness analysis from the perspective of the organisation did not take account of overhead costs.^{15 27 30}

When the organisation is a medical one, which is the case in the study of Meenan et al. (1998), future medical costs related to the organisation should have been measured also.¹⁵ This was neglected.

Perspective of the National Health Service

Some studies have been performed from the viewpoint of the National Health Service (NHS). Direct and indirect health care costs are relevant costs to consider. One study considered both cost-aspects.¹³ Unfortunately, overhead costs were not incorporated into the analysis. The other study reported program costs only.²¹

Perspective of the medical payer

The perspective of the medical payer was used by one study. In line with the perspective used, non-medical costs were not included.²³ Consistent with the above-mentioned aim of economic evaluations, intervention costs were taken to include performance costs and overhead costs only.

Perspective of the health authority

Parrot et al. (1998) used this perspective. Only program costs were included. These program costs were correctly identified.

Perspective of the program participants

One study calculated cost-effectiveness from the viewpoint of the participants.²⁸ In this study telephone costs for participants were identified, as were charges for the program, time required for participants, transportation costs, and savings caused by not smoking or reduced smoking. These costs appear to cover the costs made by the program consumers.

Perspective not mentioned

Seven of the 11 studies that did not explicitly reported the perspective of the studies identified intervention costs only.^{11 18 19 22 25 26 29} Three of these studies included relevant, and excluded irrelevant components.^{11 18 22} Calculation of intervention costs in the other four studies was unsatisfactory. Altman et al. (1987) identified program costs and patient costs.²⁴ Program costs were not appropriate to the decision making process: research costs and implementation costs were included into the analysis. Akehurst and Piercy (1994) rightly identified intervention costs, and they also used smoking related disease costs in their analysis.¹⁰ Intervention costs (unfortunately lacking overhead costs) and changes in costs due to changes in lifetime health care costs, were identified by Krumholz et al. (1993).¹⁴ Finally, Oster et al. (1986) used adequate program costs in the analysis together with future smoking related and non-smoking related disease costs.¹⁶

In short, when focussing on the internal validity of cost-estimation it is observed that costs included do better represent the perspective used, when a narrow perspective is adopted. However, intervention costs did often not include the recommended cost components.

Therefore, it can be concluded that there is only one study that identifies costs according to perspective stated,²³ and that identifies intervention costs in an accurate way.

Measurement and valuation of costs

In the reviewed studies there was a tendency to make use of service units (e.g. provider visits) when possible. An input oriented approach was used more often when interventions were complex or could not be defined as services.

Counselling and nicotine replacement therapy are interventions that can easily be defined into multidimensional units. As a result, they were often identified, measured and valued this way in the studies. Nicotine replacement therapy is

measured in terms of doses and duration of nicotine replacement intervention.¹⁶
^{17 21-23 7 11} Valuation is based on retail prices in four cases.^{7 16 17 22 23} Stapleton (1999) valued costs of nicotine patches in terms of manufacturers' wholesale prices.²¹

Physician counselling was often measured in number of minutes of physician time needed, and valuation occurs based on charges for physician visit.^{10 12 17 21}
²³ When counselling was not provided by physicians, but by nurses or other qualified persons, input data are used to estimate costs.^{14 18 25 23} The amount of time input was registered, and valuation was based either on actual wages^{18 23} or on an estimation of the average wage rate.^{14 30} Although it was assumed that general practitioners provided the counselling, Parrot et al. (1998) used the method of cost measurement and cost valuation as described above.⁷ Because of failures in the identification phase, only personnel costs but no overhead costs are measured and valued in three of the four input oriented counselling based studies.^{14 25 30} Prathiba (1998) included overhead costs, but the methods for measuring and valuating these costs are not clear.¹⁸

If interventions become more complex, measurement and valuation of costs become less straightforward. A variety of quit smoking interventions other than counselling and nicotine replacement therapy were economically evaluated.

Altman (1987) evaluated three interventions: a self-help kit, a contest and a smoking-cessation class.²⁴ The only cost-aspect for which measurement was explicitly mentioned was participants' time input. It is valued at \$10, but the reason for assigning this value was not explained. Measurement and valuation of other aspects is not clear. Reading between the lines, it seems that actual costs made during the program were used, including staff and staff benefits, overhead, rents, supplies and materials, travel and data-analysis.

More or less the same procedure seems to have been followed by Mudde et al. (1996).²⁸ Costs of the program are primarily based on financial records. Hourly wages of trainers are based on the national average wage, time input of participants was valued based on figures in literature, and transportation costs are measured and valued separately.

Costs of the community health educational program by Secker-Walker et al. (1997) were estimated from project records only.²⁰

In another community health education project all aspects of the campaign were measured separately.¹⁹ Time input is measured and valued as a proportion of individual gross salary. Overhead was assumed to involve the same proportion. Media costs were divided into buying and advertising time. These units are

valued using recorded data. Costs of self-help booklets were also measured and valued using recorded data.

In the study by Croghan et al. (1997) quit smoking therapies provided by the Mayo clinic to all of their clients were evaluated.¹¹ Costs of this large variety of interventions were determined by total operating costs of the Mayo clinic over over year. These costs were projected over the total study period.

Miller et al. (1996) combined behavioural modification with nicotine replacement therapy and provided educational material to subjects.²⁷ Costs of behavioural modification is estimated by measuring time input of trainers, valuing time input as the average wage. Nicotine replacement therapy was measured in duration and dosage of therapy. It was valued by using the costs at which the company acquired the products. The costs of educational materials were estimated as the *actual costs per pamphlet, multiplied by the number of pamphlets*.

Recruitment strategy for a quit-smoking contest was the main intervention in the study by Nelson et al. (1989).²⁹ Costs were measured as time input of the persons involved, and were valued at average wage. Volunteer time was not valued. Costs for promotional and educational materials were taken from project records.

Two studies are very inaccurate in measuring and valuing costs of the intervention program. Haycox used a hypothetical community intervention.¹³ Determination of intervention costs was not explained at all. Korhonen gave only rough estimates of costs made by the organisation. Costs incurred by other partners were not valued at all.²⁶

Reductions in costs due to decrease in smoking related disease together with an increase in costs due to increase in routine medical costs in additional life years were referred to by 4 studies.^{12 13 16 23} Three studies decided not to measure these costs because literature suggest that the benefits that arise from reductions in smoking related diseases are of the same magnitude as the increase in health care costs during the additional life years.^{12 16 23} Haycox et al. (1994) used current figures about smoking related health care and health care costs together with modelling to estimate effects on total health care costs.¹³ The result was a net cost saving in health care expenditure. Only one study included a reduction in costs due to fewer smoking related diseases.¹⁷ Costs were determined by gaining advice from an expert panel. Finally, one study examined the effects of an increase in lifetime medical care costs in sensitivity analysis.¹⁴ Costs were based on published data.

General quality aspects

Incremental analysis

For a meaningful comparison of alternatives, additional costs and effects of one program over another program need to be explored.⁸ All reviewed studies were full economic evaluations, which means that a comparison between alternatives is made when estimating cost-effectiveness. A cost-effectiveness ratio is most informative when relevant alternatives are compared. Appropriate alternatives of a new program are prevailing interventions or best care. Studies are reviewed with respect to the incremental analysis in this section. Information about incremental analysis is summarised in table 3 also.

Half of the studies performed a precise incremental analysis that was well described in the article.^{7 12 14-18 20-23} Most of these studies analysed the additional cost-effectiveness of nicotine replacement plus counselling versus the relevant alternative of counselling alone.^{16 17 21 23} Three studies assessed incremental cost-effectiveness of counselling compared to routine physicians' advice,^{14 15 18} which is also an adequate comparison. One study looked at the additional value of follow up visits as an extra service to counselling.¹² Again, the interventions compared are relevant in determining reliable cost effectiveness ratios. Parrott et al. (1998) compared brief advice with usual care, and brief advice plus a self-help kit was compared with brief advice alone. Nicotine replacement therapy in addition to brief physicians advice and self-help material was compared with brief advice and self-help material. Finally, an intervention using specialist smoking cessation services in addition to brief advice, self-help and nicotine replacement was compared with the same packet of care, excluding specialist smoking cessation service.⁷ All these comparisons are useful. In another study, the incremental cost-effectiveness of a mass media campaign in addition to a school program was subject of research.²⁰ Two studies compared the smoking cessation rate at the end of the intervention with the estimated smoking cessation rate in the general population.^{11 12} Only seven studies compared the smoking rate at the end of the program with the smoking rate at the start of the program.^{20 24 25 26 28 29 30} By using this kind of comparison, the authors implicitly suggest that usual care or 'doing nothing' is the best alternative available. Although in principle, this is often a good choice for the alternative comparator intervention, the authors of these articles wrongly assumed that there would be no quitters when the intervention under research were not performed.

In short, there are differences observed in the quality of incremental analysis performed.

Discounting

The process of discounting is strongly related to the concept of time preference. People prefer incurring costs in future rather than today, and they favour benefits today rather than in the future. This means that they prefer to spend money in future rather than in the short term. Drummond et al. (1997) gave some explanations for this phenomenon:⁸ it can be explained partly because the value of an amount of money will decrease over time, and partly because it provides people with more flexibility; giving them more options.

Time preference is not restricted to monetary values. People also favour health benefits today rather than tomorrow. Drummond et al. (1997) provide reasons for this.⁸ One reason might be that the future is uncertain. Therefore, when the health benefits of a specific intervention will only be felt after 20 years of time people give less value to it because many other bad things can happen to them during that time period. Furthermore, people simply may have a short-term view of life. Because of the importance of time preferences - especially in preventive interventions - it is incorporated in the analysis via the process of discounting of costs and effects.

Time preferences will only play a role when the costs or the health effects occur in the future. Seven of the reviewed studies in the field of cost-effectiveness of non-smoking interventions defined cost-effectiveness in terms of costs per quitter.²⁴⁻³⁰ In most cases, the costs involved are short term program costs only. This makes discounting unnecessary. In two studies, the intervention lasted more than one year and the costs were discounted.^{24 29} Effects expressed in number of quitters, does not include future health benefits. Therefore, there is no need for discounting either (table 3).

The remaining studies expressed cost-effectiveness in terms of costs per yols.^{7 10-15 18-23 31 33} Cost-utility is determined by Fiscella et al. (1996).²³ These studies expanded outcome to future health benefits and should therefore have discounted the effects. All but one study indeed discounted effects (table 3). The most commonly used discount rate was 5%.^{11 12 14-17 22} Discount rates of 1.5%,⁷ 1.75%,²¹ 3%,^{20 23} and 6%,^{10 13 19} are used also.

Discounting of costs was necessary only when future costs are incorporated (table 3). Future costs were identified in seven studies, and were included in the analysis in three of them.^{13 16 17} In concordance with the guidelines, these three studies indeed discounted future costs at a rate of 5% or 6%. When future costs

were identified but not measured, based on literature, the assumption of a zero net effect was made.

Sensitivity analysis

Every economic evaluation contains some degree of uncertainty. Because of the long-term scope, this is especially true for economic evaluations of preventive interventions. The effect data used in the study may not accurately represent the actual quit rates that result from the interventions. Based on one or more effectiveness or even efficacy studies, assumptions are made about quit rates, relapse rates, compliance, and other factors that determine the effect of the intervention. It might be clear that elimination of uncertainty in effect data can never be fully achieved. This is also true for costs used in economic evaluation. The degree of uncertainty of the data will influence the reliability of the established cost-effectiveness ratio. It is important for authors and reviewers of cost-effectiveness studies to be aware of this. The guidelines recommend that researchers explore the possible variability in outcome. Sensitivity analysis is the most frequent used tool in investigating robustness of outcomes. Five studies did not perform sensitivity analysis or any other form of investigating variability in outcome at all.^{7 19 25 26 29} The remaining seventeen studies all performed sensitivity analysis (table 3).

The results of sensitivity analysis have to be explored very well. Many researchers and policy makers consider only estimates of cost-effectiveness ratios that have high certainty to be of value. This may result in performing conservative sensitivity analysis by limiting the number of parameters varied or by defining unrealistic small sensitivity ranges. It is important to use realistic sensitivity ranges when performing sensitivity analysis and to explain explicitly the choice of the ranges.

In nine studies an explanation is given for the sensitivity range chosen.^{11 15 16 20-23 27 28} Confidence intervals (90% or 95%) were most often used to define a sensitivity range.^{15 16 20 21 23 27 28} Estimates of lower and higher bounds were based on literature in three studies.^{11 16 22} Table 3 summarises use of sensitivity-analysis in studies.

Table 3: Characteristics from the cost analysis and from general aspects of economic evaluation

first author year	relevant intervention costs		non-relevant intervention costs			smoking related disease costs	health care costs in ex- tra life years	pro- duc- tivity costs	pa- tient costs	dis- coun- ting costs	dis- coun- ting ef- fects	sensi- tivity ana- lysis	range sensi- tivity analysis explai- ned	incre- mental ana- lysis
	perfor- mance	over- head	develop- ment	re- search	imple- ment- tation									
1	y	y	(y)	y	y	n	n	n	y	y	n/a	y	n	n
2	y	n	n	n	n	n	n	n	n	n/a	n/a	n	n/a	n
3	y	n	n	n	n	n	n	n	n	n/a	n/a	n	n/a	n
4	y	n	n	n	n	n	n	n	n	n/a	n/a	y	y	n
5	y	n	y	n	y	n	n	n	y	n/a	n/a	y	y	n
6	y	n	n	n	n	n	n	n	n	y	n/a	n	n/a	n
7	y	n	n	n	n	n	n	n	(y)	n/a	n/a	y	n	n
8	y	y	n	n	n	n	n	n	y	n/a	y	n	n/a	y
9	y	y*	n	y	y	y	n	n	n	n/a	y	y	n	?
10	y	y	n	n	n	n	n	n	n	n/a	y	y	y	n
11	y	y*	n	n	n	y	y	n	y	n/a	y	y	n	y
12	y	n	n	n	n	y	y	n	n	y	y	y	n	n
13	y	n	n	n	n	n	y**	n	n	n/a	y	y	n	y
14	y	n	n	n	n	n	n	n	n	n/a	y	y	y	y
15	y	y*	n	n	n	y**	y**	n	n	y	y	y	y	y
16	y	y*	n	n	n	y	n	n	n	y	y	y	n	y
17	y	y	n	n	n	n	n	n	n	n/a	n	y	n	y
18	y	y	y	y	n	n	n	n	n	n	y	n	n/a	n
19	y	n	y	y	n	n	n	n	n	?	y	y	y	y
20	y	y*	n	n	n	n	n	n	n	n/a	y	y	y	y
21	y	y*	n	n	n	n	n	n	n	n/a	y	y	y	y
22	y	y*	n	n	n	y	y	n	n	n/a	y	y	y	y

* implicitly measured, ** in sensitivity analysis

1	Altman, 1987 [25]	12	Haycox, 1994 [14]
2	Bertera, 1990 [26]	13	Krumholz, 1993 [15]
3	Korhonen, 1992 [27]	14	Meenan, 1998 [16]
4	Miller, 1996 [28]	15	Oster, 1986 [17]
5	Mudde, 1996 [29]	16	Plans-Rubio, 1998 [18]
6	Nelson, 1989 [30]	17	Prathiba, 1998 [19]
7	Windsor, 1988 [31]	18	Ratcliffe, 1997 [20]
8	Parrot, 1998 [7]	19	Secker-Wal-ker, 1997 [21]
9	Akehurst, 1994 [11]	20	Stapleton, 1999 [22]
10	Croghan, 1997 [12]	21	Wasley, 1997 [23]
11	Cummings, 1989 [13]	22	Fiscella, 1996 [24]

Summary

This article reports on a review of 22 economic evaluations in the field of treatment for tobacco-dependence. The articles were quite diverse in terms of interventions performed, alternative interventions considered and study populations. This indicates that cost-effectiveness ratios and cost utility ratios of different studies could not be compared directly. However, differences in the general features of studies were not problematic for the current study because our interest was in the quality of the economic evaluation of individual studies. The checklist proposed by Drummond et al (1997) was used as a guide to perform a quality assessment of economic evaluations in the field of treatment for tobacco dependence.⁸

Scientific studies should start with providing a well-defined research question. In the case of economic evaluation, an important aspect of the research question is the perspective from which the analysis is performed. The perspective is mentioned in only 13 studies.

In terms of the economic evaluation itself, the first condition to provide reliable outcome-data in economic evaluation is to make use of qualitatively good effect data. There were only 5 published cost-effectiveness studies that used effectiveness data which were obtained with a randomised controlled trial and which took notion of relapse when necessary. This indicates that many economic evaluation studies might not be based on qualitatively good effectiveness data. In other words, although there is evidence that stop-smoking interventions are effective in general, the estimates of the magnitude of the effect in specific studies might not be reliable.

When reviewing cost-analysis, there was only one study that adequately identified cost-categories in concordance with the viewpoint taken by the study.

Contrary to identification of costs, measurement of the identified cost-categories is performed adequately by the majority of studies.

In addition to quality of effect data and quality of cost-analysis, there are some general aspects that influence quality of the economic evaluation studies. Discounting is one of these aspects. In most of the studies reviewed, discounting is performed when necessary, and many studies used the same discount rate.

Sensitivity analysis was performed by 17 of the 22 studies evaluated. An explanation for the width of sensitivity ranges is provided by only half of the studies. Sensitivity ranges were determined using confidence intervals and/or secondary literature. These methods seem to result in reasonable and appropriate sensitivity ranges.

In summary it can be said that, in general the guidelines were not followed very well. This conclusion raises the important question of whether the quality of the studies in general is low, or whether there are large differences in quality of economic evaluation between studies. There was no study that accurately handled effectiveness data and faultlessly identified relevant costs in concordance with the perspective stated. The study of Fiscella et al. (1997),²³ performed from the perspective of the medical payer, is most performed in accordance to the guidelines of Drummond et al (1997).⁸ Fiscella et al. (1996) identified costs in concordance with the perspective mentioned, and discounting and sensitivity analysis were carried out and the choices for sensitivity ranges were explained.²³ Effects were estimated on the basis of a review study. An important issue, however, is that this study was performed from the fairly narrow perspective of the medical payer. This perspective includes only a few cost categories, which means that the study is easier to perform than cost-effectiveness analyses performed from broader points of view. In addition, having not performed the study according to societal perspective makes the study inadequate for decision-making at the macro level. This will be discussed in the following section.

Conclusions and discussion

Overall it can be concluded that economic evaluation studies in the field of tobacco cessation as in other fields of research do not follow guidelines for economic evaluation very well. Authors often falsely assume that effectiveness

studies are of high quality. This study indicates that more attention has to be paid to the quality of the sources of effectiveness data. Furthermore, it is shown that the first step in the economic evaluation of smoking cessation interventions, namely identifying costs, was performed according to guidelines only in a few cases. It is of great concern that the basis of the determination of costs is frequently subject to inaccuracies.

The observation that sensitivity analysis often is performed in a non-scientific way is also of concern. Sensitivity analysis is the only part of the study in which the assumptions used to generate the cost-effectiveness ratio or cost utility ratio can be varied to test the robustness of the outcome ratio. This part of the evaluation has to be carried out very carefully.

In addition to the poor scientific quality of the studies, there is another caveat worth mentioning. To achieve information about costs per life years saved resulting from preventive interventions within a limited time frame, it is necessary to make use of modelling. In economic evaluation of quit-smoking interventions a diversity of models has been used to extrapolate the number of quitters to the numbers of life years saved. Studies based on modelling techniques are subject to a number of frequently raised concerns. Some frequently mentioned concerns are an inappropriate use of clinical data, concerns about bias in observational data, concerns about the validity of models, and concerns about difficulties in extrapolation.³⁴ Especially concerns with the validity of the models is very problematic. As a result of this, the quality of the models cannot be judged.

Studies that did not make use of models present the outcome in terms of cost per quitter. The main problem with these studies is that cost-effectiveness ratio cannot be compared to health care interventions presenting outcome in costs per years of life saved. This does not necessarily mean that studies in which the costs per quitter is the only outcome measure mentioned are not useful. When more insight into modelling is gained, costs per quitter might be translated easily by economists into costs per life years saved and/or costs per qaly. Retaining these studies from analysis offers a broader view on costs and effects of smoking cessation interventions.

Because the studies are not of high quality scientifically, and because there is uncertainty about the validity of models, we are left with the question as to whether the economic evaluation studies in the field of smoking cessation are of practical use. The costs per life years saved presented in the studies are low (\$220 to \$19000), but because of the poor qualities of the studies, no firm

conclusions can be drawn about the cost-effectiveness of smoking cessation interventions. However, there is a very high consistency between the studies in concluding that stop smoking interventions are cost-effective, and the results stay favourable after having performed sensitivity analyses. Furthermore, although there are many biases observed in most of the studies, it is highly unlikely that the biases observed in many of the studies all modify the results in favour of the non-smoking interventions. Finally, cost-effectiveness ratios presented in studies about smoking cessation interventions are much lower than other already accepted health care treatments. So, in spite of the generally low quality of economic evaluations in the field of smoking cessation, the conclusion from other reviewers,^{4 6} namely that treatments to reduce the number of smokers are cost-effective at least in relative terms, is likely to be true.

This is important information for policymakers, who thus are advised to continue smoking cessation interventions, at least until better insight is gained into the cost-effectiveness of interventions to reduce tobacco consumption.

More robust scientific evidence can be gathered using a model that has the potential to modify all aspects relevant for estimating the cost-effectiveness of smoking cessation interventions. Developing such a model might be a challenge for researchers in order to solve the problem of cost-effectiveness of smoking cessation, and it may even be helpful in clarifying cost-effectiveness issues of other health care interventions.

Such a model might also solve another issue of importance, namely that of the external validity of the studies. Medical technology assessment is a research area that builds a bridge between science and policy. It is aimed at facilitating decision-making about implementation of health care interventions at a macro-level. To be able to make these decisions, studies have to be performed from the societal perspective, which very few of the reviewed studies used. Development of a meta-model in which all aspects of economic analysis can be simulated would increase the usefulness of the large number of economic evaluations performed from a non-societal perspective.

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3

Systematic review of economic
evaluations of smoking cessation -
standardizing the cost-effectiveness

Based on: Ronckers ET, Groot W, Ament AJHA. Systematic review of economic evaluations of smoking cessation: standardizing the cost-effectiveness. MDM 2005, 25: 437-448.

Abstract

This study was performed in order to render cost-effectiveness studies on smoking cessation therapies performed until now more comparable and more useful for policy-making. For this aim, the cost-effectiveness ratios reported by the studies were recalculated using a societal perspective and guidelines for economic evaluation. It was observed that the costs of individual interventions generally increased as a result of the standardisation procedure, while the effect size decreased. This resulted in increases in the cost-effectiveness ratios for individual studies ranging from 120% to 5600%. This means that not following guidelines when calculating cost-effectiveness ratios can result in large errors. Despite the fact that the standardised cost-effectiveness ratios of smoking interventions were higher than the non-standardised cost-effectiveness ratios, interventions aimed at reducing the prevalence of smoking are cost-effective.

Introduction

During the last two decades, major increases in medical and technical knowledge have resulted in a large increase in the number of effective interventions and treatments available for almost any disease.¹ Because of fixed health care budgets, however, insufficient resources are available to implement all effective interventions. This means that choices have to be made about interventions to be implemented, and these are often based on cost-effectiveness (CE) studies providing information about the costs per unit of health gain (e.g. years of life saved (yols)). When performed adequately and in a uniform way, cost-effectiveness studies within the entire field of health care can be compared, which greatly facilitates decision-making at the macro level.

Meta-studies and systematic reviews can facilitate the process of decision-making at macro-level, because they combine information from a number of studies in one analysis. Until recently, however, no such review had been produced for the field of smoking cessation therapies. Hence, the previous chapter of this thesis presents a review of all cost-effectiveness studies on smoking cessation in a systematic review. The review revealed considerable differences in methodology and in the way effects and costs were measured. First, only two studies had been performed from the societal perspective, the preferred method for analyses to be used at the macro level. Second, measures of effectiveness differed. Some studies measured the effect size in terms of numbers of quitters, while others defined effectiveness in terms of years of life saved or quality adjusted life years. Furthermore, studies differed in length of follow-up, relapse rates and unaided cessation rates, factors that can influence the effect size. Among the latter group, studies used a variety of models to extrapolate the effect size in term of quitters to the effect size in terms of years of life saved. Finally, costs had not been calculated in a uniform way and guidelines for cost determination had frequently been ignored. These differences in methodology make using their results in policy-making problematic.

The studies also differed with respect to more general characteristics, such as intervention, comparative interventions, outcome measure, study population and country and year of study, which also hampers the decision-making process. For example, the choice within a study of an intervention and a

comparative intervention often represents an implicit choice between an incremental and an average cost-effectiveness analysis. For the purpose of policy making, incremental analyses are much more informative.^{2 3} Furthermore, recruitment of the study population might influence the cost-effectiveness ratio. The effect size of an intervention will be much higher if only highly motivated persons are included than if a general sample of the smoking population under study is included. This might also influence the cost-effectiveness ratio.

Because of this large diversity in methodological and general characteristics of studies on the cost-effectiveness of smoking cessation interventions, no firm conclusions can be drawn about the cost-effectiveness of such interventions, which means that the studies were not very informative from the point of view of policy making.

The aim of the present study was to standardise the cost-effectiveness (CEA) ratios in order to improve their value for policy making.

Methods

We recalculated the cost-effectiveness ratios reported by the individual studies by using a societal perspective and the guidelines proposed by Drummond et al.,² together with information from the individual studies. These adjusted results were expected to make studies more comparable and therefore more useful.

Differences in CE ratios among studies can be caused by various factors, including the use of different perspectives, differences in calculating the costs of the interventions, differences in determining effect sizes and differences in extrapolating effect sizes in terms of quitters to effect sizes in terms of years of life saved. This section describes the methods we used to standardise these factors.

First, however, a short description is provided on the exclusion and inclusion of studies.

For practical reasons, some studies from our previous review were not included in the present analysis, viz. the studies by Croghan et al. (1997), Haycox (1994), Korhonen et al. (1992), Miller et al. (1996), Nelson et al. (1989), Ratcliffe et al. (1997) and Secker-Walker et al. (1997).^{4 5 6 7 8 9 10} The main reason was that it was impossible to recalculate the cost-effectiveness reported in these studies using our standardisation procedure. Five of the excluded studies reported on community interventions.^{5 6 8 9 10} This means that the results of the

present study will only be applicable to non-community intervention studies aimed at reducing the prevalence of smoking. The remaining 14 studies did allow for standardization. In order to facilitate the analysis, the comparisons included in the studies that did allow standardization were divided into subgroups, as shown in table 1. Individual studies could be assigned to more than one category, if they involved more than one comparison. The present analysis thus included 14 studies, covering 26 comparisons.^{11 12 13 14 15 16 17 18 19 20 21 22 23 24} In addition, some studies provided data allowing analyses that had not been performed in the original studies.^{12 17 23 24} For example, some studies provided cost-effectiveness analyses of self-help versus usual care and counselling versus usual care within one study,^{7 12 17 24} without attempting to analyse the incremental cost-effectiveness ratio of counselling versus self-help. The present review tried to fill these gaps.

Table 1: Intervention components relevant for the cost-calculation per subgroup of intervention and comparative intervention

	1	2	3	4	5	6	7
Counsellor's counselling time	x				x		
Study material	x				x		
Room rent	x				x		
Counsellor's travel time	x				x		
Counsellor's travel costs	x				x		
Patient counselling time	x				x		
Patients' travel time	x				x	x	
Patients' travel costs	x				x	x	
Self-help manual	x	x					
Other self-help assistance	x	x					
Distribution	x	x					
Patient time	x	x					
Extra costs specific manual			x				
Physician's time follow-up visit						x	
Gum/patch/nasal spray							x
Costs of counselling							
Minus costs of self-help				x			

1

coun-selling/self-help versus usual care

2

self-help versus usual care

3

specific self-help versus general self-help

4

counselling versus self-help

5

counselling versus usual care

6

counselling + FU versus coun-selling

7

NRT + counselling versus coun-selling

Eliminating cost difference

Costs can be divided into those related to recruitment of participants, intervention costs, savings due to better health and costs resulting from people living longer.^{2 3} The standardisation procedure we used was restricted to the recruitment costs and the treatment (or intervention) costs, for two reasons. First there is evidence that savings due to better health are balanced out by future costs due to living longer.²⁵

Second, the studies analysed in this review provided insufficient data about future costs to allow the standardisation procedure to be applied: only three of the original studies reported savings due to better health and only one study reported costs incurred during the expanded lifetime.^{11 13 19}

An adequate cost determination requires three steps to be taken. First, it is important to draw up an overview of all costs involved, so step one involves identifying costs. With regard to intervention costs and recruitment costs, it is important to include only those costs that will have to be incurred if the intervention is performed again. This means that development costs and costs incurred for research purposes should not be included. After the relevant cost components have been defined the volume is attached to each component in step 2. Finally, step three involves valuing the costs.

First, the recruitment costs reported by the individual studies were recalculated. Cost components of recruitment and their volume components were derived from the original studies where possible. In many studies, recruitment consisted of 5 minutes of additional physician time for each smoker visiting a physician. Assuming a 25% acceptance rate, recruitment thus required 20 minutes of physician time per person actually participating in the study.^{14 19 22} If we assume a 50% acceptance rate, recruitment required 10 minutes of physician time per participant.^{11 15 16 20} In the study by Bertera et al., recruitment consisted of four 1-hour lectures for all smokers in a company.¹² The counsellor devoted 3.5 minutes per participant to recruitment. Recruitment costs in the studies by Mudde et al. and Altman et al. consisted of start-up costs and the costs of the telephone helpline.^{17 24} Their articles did not provide enough data to recalculate these costs. We used data provided by Mudde et al. to estimate the recruitment costs per participant and applied this value to both studies. Stapleton et al. were unclear about recruitment, so theirs is a missing value.²¹ Finally, some studies compared counselling with self-help, which means that recruitment costs were the same for the intervention and the comparative intervention, and

thus not relevant to an incremental comparison.^{12 17 24} There were also some studies in which all smokers were counselled or given a self-help manual, which meant that no recruitment costs were incurred at all.^{3 15 16 23}

Valuation of these recruitment costs was performed in a standardised way, using Dutch price levels for the year 2002. Although we used Dutch price levels, the costs are presented in US Dollars. Table 2 shows the values attached to each individual service, together with the source of the prices used. Because Dutch values are used, the results are applicable to the Dutch situation and they cannot be used for other countries without concerns. We will return to this point in the Discussion section.

After having recalculated recruitment costs, we then recalculated the intervention costs, using the subgroups defined in table 1. Because many studies performed incomplete cost-analysis, intervention costs were first re-identified from the societal perspective. Relevant intervention components for each subgroup were defined. Table 1 shows the cost components that were relevant to the incremental comparison between the two interventions reported. Because there were minor differences between interventions belonging to the same subgroup, not all costs defined were relevant for all studies within a subgroup. For instance, travel costs made by the counsellor were included if counselling was part of a community intervention, but not if counselling took place in a hospital where the counsellor was an employee. Travel time or travel costs for patients were not calculated if the study subjects were hospital inpatients, and room rent was not incorporated in the cost analysis if the study had been performed at a hospital. After having thus defined cost components, we attached the volume components, using information from the individual studies if possible. If no specific information was available, assumptions had to be made, based on information from other articles using the same intervention or (in some cases) from other literature. The following assumptions were made:

- The costs of a nicotine nasal spray are the same as those of nicotine gum;
- When group size was unclear in interventions involving group counselling, it was assumed that the group had consisted of 10 persons;
- The distance travelled was assumed to be the mean distance from a person's home to the nearest hospital²⁶;
- The time spent travelling to a hospital was assumed to be 10 minutes²⁶
- Travel costs were estimated at \$0.10 per kilometer²⁶.
- Follow-up visits were assumed to take 15 minutes;

- Distribution of the self-help material was estimated to require
- Five minutes of counsellor time when the self-help material was handed over personally;
- Five minutes of secretary time and a \$1 stamp when the self-help material was posted.

The final step in the recalculation of the intervention costs was the valuation of costs, which was again performed using Dutch prices for the year 2002 (table 2). We expressed the costs in US Dollars, because most studies reported this currency.

Table 2: The valuation of the material and personnel input

Cost component	price in the year 2002 (\$)	source
time input by GP	21,60****	Dutch guidelines ²⁷
time input by non-physician counsellor	56,80**	financial records Heartbeat Limburg
time input by secretary	20**	financial records Heartbeat Limburg
time input by patient	9,20**	Dutch guidelines ²⁷
travel costs	0,11***	Dutch guidelines ²⁷
gum 2 mg	0,23*	internet pharmacy 2002
gum 4mg	0,27*	internet pharmacy 2002
patch 5 mg	2,60*	internet pharmacy 2002
patch 10 mg	2,60*	internet pharmacy 2002
patch 15 mg	2,60*	internet pharmacy 2002
self-help manual	5*	mean of studies
relaxation tape	2,5*	study by Bertera et al. ¹³
stamps for distributing manual	1*	financial records Heartbeat Limburg
room rent	21**	financial records Heartbeat Limburg

* per piece, ** per hour, *** per kilometre, **** per consult

Eliminating differences in effect sizes in terms of quitters

The earlier systematic review that is presented as chapter 2 from this thesis revealed that studies differed considerably in the way they calculated effect sizes in terms of quitters.²⁷ The present analysis calculated the so-called lifetime incremental quit rates in order to standardise aspects that cause undesirable differences in effect sizes in terms of quitters between studies – such as differences in values used for short term and long term relapse, annual unaided cessation and comparative quit rates. We calculated the long-term effect-size resulting from a particular anti-smoking intervention, taking into

account the short-term incremental quit rate (resulting from the specific intervention), short-term relapse (within 1 year), long-term relapse (after 1 year) and annual unaided cessation.

Uniform values for short-term relapse, long-term relapse and annual unaided cessation were used to eliminate differences between studies. If the study duration had been less than 1 year, our analysis controlled for short-term relapse. Based on the studies by Prathiba et al. (1998), a 50% short-term relapse was assumed for studies with a follow-up period of 2 months or less, which implies that after 1 year the success rate would be reduced from 50% to 25%.²⁰ When studies had a follow-up period of 3 months, 33% of the quitters were assumed to relapse within the first year of cessation, while a 12.5% relapse rate was assumed when the follow-up period was 6 months.²⁰ We assumed a long-term relapse rate of 35% after 1 year of follow-up¹⁴. Annual unaided cessation was assumed to be 1.5%.²¹ Following Oster et al. (1988), we assumed annual unaided cessation to occur until the age of 72.¹⁸

Quit rates of comparative interventions were standardised when possible, meaning that uniform quit rates were used for comparative interventions that were the same. The quit rate resulting from self-help was assumed to be 4%. Some exceptions had to be made.

First, in most cases, there were differences between alternative interventions used in studies belonging to the same subgroup. An example is the use of counselling as a comparative intervention. In some studies, the comparative intervention consisted of one 5-minute counselling session, while others used more or longer sessions. The quit rate resulting from short advice was assumed to be 4.5%,^{18 21 22} while longer counselling was assumed to result in a higher quit rate. The quit rate resulting from longer counselling was estimated, on the basis of only one study, to be 10%.¹¹ Another example is the use of 'usual care' as a comparator intervention. Sometimes usual care means no intervention, while in other studies usual care is a brief advisory session by the physician. The quit rate resulting from brief physician counselling was assumed to be 4.5%.^{18 21 22} When usual care meant no intervention, the annual unaided cessation rate of 1.5% was used to estimate the alternative quit rate.

The second exception is related to the study population. Most studies included all smokers, but some included only hospitalised patients or even only patients having a smoking-related disease. Therefore, standardised comparative quit rates were only applied to studies whose population consisted of a sample of smokers from the general population. If the study had been performed among a

highly specific population (e.g. hospitalised persons or persons recovering from myocardial infarction), the comparative quit rate was taken from the original study. Finally, our analysis also involved comparisons that were not made in the original study. These analyses were often also made on the basis of quit rates used in the original studies.

Eliminating differences in extrapolating the incremental cessation rate to yols

Effect data can be made more useful for medical decision-making by extrapolating the effect size in terms of quitters to an effect size in terms of yols. Some of the studies included in our systematic review failed to apply this extrapolation, leading to the calculation of CE ratios in terms of costs per quitter.^{12 17 23 24} In the other studies, this extrapolation made it possible to express the results in terms of costs per yols.^{11 13 14 15 16 18 19 20 21} The studies that did extrapolate effect sizes in terms of quitters to yols used different methods, leading to different numbers of yols per quitter. The number of yols per quitter ranges from 0.5 in the study by Akehurst et al. (1994) to 2 in that by Prathiba et al. (1998). All of the techniques used are subject to one or more objections. Because it cannot be judged at this moment which method of extrapolation results in the most realistic data about years of life saved, we standardised this by using the data provided by Oster et al. (1988). Arguments in favour of using their data are that they seem to have developed an adequate model (face validity), produced age- and sex-specific data, produced figures that were in the centre of the range referred to above (0.5 to 2 years per quitter), and last but not least, that their data were the most frequently used by other studies in the systematic review. By taking the work of Oster et al. as a standard, we simultaneously standardised the discount rate (5%). If the characteristics of the study population were known, yols were calculated using age- and sex-specific characteristics of the specific population. In cases where the study population was not clear, data for a 45-year old male were used for the present analysis.

Results

Changes in cost-effectiveness ratio resulting from our recalculations may have different causes, including changes in costs, changes in effect size, and/or differences in the way the effect size in terms of quitters is extrapolated to the effect size in terms of yols.

Changes in costs

There were very large differences between the studies in the changes in costs resulting from standardisation. Costs might increase by up to 1000%, but there were even studies for which costs slightly decreased. In most cases, however, the standardised costs were considerably higher than those reported in the original articles, the mean increase being over 200%. Costs reported in the original articles and standardised costs are compared in table 3.

Table 3: Costs of the original article and the standardised costs

study	sub-group	original costs (\$)	standard-ised re-cruitment costs (\$)	standard-ised per-formance costs (\$)	standard-ised total costs (\$)	standard-ised total costs excl. year of study (\$)	change in costs (%)	change in costs (%) excl. year of study
Bertera	1	26	3	100	103	?	293	?
Mudde	1	141	48	61	109	76	-23	-46
Altman	2	5	40	11	51	27	1009	487
Bertera	2	17	9	23	32	?	93	?
Mudde	2	6	68	11	79	55	1154	773
Windsor	2	5	0	13	13	7	157	39
Windsor	2	5	0	13	13	7	157	39
Windsor	3	0	0	0	0	0	0	0
Altman	4	78	0	146	146	72	88	-7
Bertera	4	16	0	112	112	?	618	?
Mudde	4	53	0	177	177	123	236	133
Altman	5	82	40	157	197	103	139	25
Bertera	5	32	6	135	141	?	338	?
Cummings	5	12	0	15	15	10	25	-17
Krumholz	5	100	14	176	190	140	90	40
Meenan	5	159	14	62	76	60	-52	-62
Mudde	5	59	170	188	358	248	507	320
Prathiba	5	107	14	224	238	182	123	70
Cummings	6	30	0	28,5	28,5	19	48	-37
Akehurst	7	154	15	234	249	184	62	19
Fiscella	7	69	29	117	146	118	113	72
Oster	7	16	29	48	77	45	370	174
Plans-Rubio	7	201	29	192	221	184	10	-8
Plans-Rubio	7	320	29	240	269	224	-16	-30
Stapleton	7	51	?	78	78	69	52	35
Wasley	7	42	29	117	146	118	248	181

Besides the original costs, the standardised recruitment costs, the standardised performance costs the standardised total costs and the percentual changes after complete standardisation, table 3 also shows the standardised total costs and the changes in costs when year of performance (the year of publication was used as a proxy) was not controlled for. Both analyses are presented because they serve different goals. The analysis without a correction for the year of performance provides information about the magnitude of the error in the CE-ratio's due to not following guidelines for economic evaluation. Analysing the results with a correction for the year of performance provides up to date CE-ratio's. These results are thus useful for decision making in the present time.

Changes in effect size in terms of quitters

Just like costs, quit rates changed considerably after standardisation. The effect sizes reported by most studies decreased after the standardisation procedure, by percentages ranging from 7% to 94% (table 4). Table 4 shows the original effect size in terms of quitters (%), the effect size in terms of quitters (%) when short term relapse was controlled for, the effect size in terms of quitters when short term as well as long term relapse were controlled for and the percentual changes between the standardised effect size and the effect size mentioned in the original article.

Twenty-eight cost-effectiveness ratios were calculated (table 5). In twelve non-standardised cases, no adjustment had been made for short-term relapse.^{13 17 23}

²⁴ Lifetime relapse had not been controlled for in eighteen cases.^{12 15 16 17 18 20 23}

²⁴ Sixteen studies did not correct for annual unaided quit rates when the effect size in terms of quitters.^{12 13 15 16 17 18 20 23 24} In six cases, no comparative quit rate had been used.^{12 17 24}

Changes in extrapolation from effect size in terms of quitters to effect size in terms of years of life saved

In four of the studies, the standardised extrapolation rates had the same value as the original extrapolation rates reported.^{13 14 18 22} For two studies, our standardisation procedure led to a higher extrapolation factor,^{11 14} i.e. the yols due to a given number of quitters is higher in the current analysis. The increase in the extrapolation factor is 42% and 10% respectively. The transformation factor decreased in five cases,^{15 19 20 28} by percentages ranging from 21% to 45%.

Table 4: Effect-sizes of the original article and standardised effect-sizes

study	subgroup	original quit rate (%)	one-year standardised quit rate(%)	life time standardised quit rate (%)*	change in quit rate* (%)
Bertera	1	17,14	15,6	6,15	-64
Mudde	1	15,5	13,8	5,5	-65
Altman	2	21	17,5	4	-81
Bertera	2	11	9,5	3,8	-65
Mudde	2	13	9,9	4	-69
Windsor	2	4	0,7	0,24	-94
Windsor	2	12	7,8	2,69	-78
Windsor	3	8	7,1	2,45	-69
Altman	4	14	7	2,9	-79
Bertera	4	10	10,5	3,9	-61
Mudde	4	9	8,7	3,6	-60
Altman	5	35	16	6,9	-80
Bertera	5	21	19,5	7,7	-63
Cummings	5	2,43	3	1,3	-47
Krumholz	5	26	26	12,5	-52
Meenan	5	4,3	4,3	1,8	-58
Mudde	5	22	18,6	7,6	-65
Prathiba	5	13,5	13,5	5,8	-57
Cummings	6	1 to 12	range 1 -12	0,43-5,2	-57
Akehurst	7	16	16	6,2	-61
Fiscella	7	1,3	3,4	1,5	15
Oster	7	0,3	1,2	0,7	133
Plans-Rubio	7	0,7	2	0,9	29
Plans-Rubio	7	1,1	3,6	1,6	45
Stapleton	7	0,6	1,3	0,56	-7
Wasley	7	0,9	8,4	3,7	311

* effect size in terms of quitter

Standardised cost-effectiveness ratios

The non-standardised cost-effectiveness ratios of the studies that presented the costs per yols, ranged from \$220 to \$5050 per yols. After complete standardisation, these values ranged from \$490 to \$15.280 per yols. When standardisation excluded adjustment for the year of performance, the CE-ratios ranged from \$332 to \$12750.

Non-standardised cost-effectiveness ratios reported by studies expressing cost-effectiveness in terms of costs per quitter ranged from \$22 to \$940 per quitter. After extrapolation of the effect size in terms of quitters to years of life saved as

proposed by Oster et al. (1999), the cost-effectiveness ratios for these studies ranged from \$895 to \$10031 per years of life saved, if costs were adjusted for the year of performance. If the CE-ratio was only adjusted for guideline aspects, the cost-effectiveness ratios of these studies range from \$481 to \$5400.

Table 5: Original and standardised cost-effectiveness ratios

study	sub-group	original effect parameter	Original CE-ratio	standardised CE-ratio adjusted for year of study			standardised CE-ratio not adjusted for year of study		
				costs per quitter	costs per yols	change (%)*	costs per quitter	costs per yols	change (%)*
Bertera*	1	quitter	153	1675	2233	1000	?	?	?
Mudde	1	quitter	940	1982	2447	110	1382	1557	50
Altman	2	quitter	22	1275	1614	5700	675	855	2510
Bertera	2	quitter	150	842	1040	460	?	?	?
Mudde	2	quitter	48	1975	2324	4020	1375	1618	2770
Windsor	2	quitter	119	5417	10031	4450	2917	5402	2350
Windsor	2	quitter	51	483	895	850	260	481	410
Windsor	3	na	na	0	0	0	0	0	0
Altman	4	na	na	5034	6538	na	2483	3228	na
Bertera	4	na	na	?	3989	na	?	?	na
Mudde	4	na	na	4917	6385	na	3417	4544	na
Altman	5	quitter	235	2855	3708	1120	1493	1941	540
Bertera	5	quitter	154	1831	2543	1090	?	?	?
Cummings	5	yols	748	1154	1049	40	769	700	-6
Krumholz	5	yols	220	1530	1520	590	1120	1120	400
Meenan	5	yols	3680	4222	5556	50		4333	20
Mudde	5	quitter	328	4710	6118	340	3263	5503	900
Prathiba	5	yols	652	4103	3730	470	3137	2856	340
Cummings	6	yols	241-5051	548-6628	498-6025	110	365-4419	332-4017	60
Akehrst	7	yols	2188	4016	5657	160	2968	4155	90
Fiscella	7	qaly	4671	9733	8849	na	7867	7159	na
Oster	7	qaly	4113	11000	10000	240	6429	5850	1330
Plans-Rubio	7	qaly	2877	?	9391	?	?	?	?
Plans-Rubio	7	qaly	3297	16812	15282	360	14000	12740	290
Stapleton	7	qaly	660	?	?	?	?	?	?
Wasley	7	qaly	1796	3946	3591	100	3189	2902	60

Note: CE = cost-effectiveness; yols = years of life saved; qaly = quality adjusted life years; na = not applicable.

* percentage of change responds to the change in the standardized CE ratio compared to the CE ratio of the original study

Thus, the standardised cost-effectiveness ratios were systematically and considerably higher than those presented in the original articles. Increases in cost-effectiveness ratios after standardisation ranged from 0 to as much as 5800%. All original and standardised cost-effectiveness ratios are presented in table 5.

The table reveals a pattern in the magnitude of the cost-effectiveness ratios, with incremental cost-effectiveness ratios generally being lower when the intervention was less resource consuming. Figure 1 summarises these results by presenting the mean standardised incremental cost-effectiveness ratios per subgroup.

Figure 1 shows that the most cost-effective intervention included in our analysis consisted of a self-help manual written for a specific subgroup of smokers, namely smoking pregnant women.²³ This intervention led to an incremental cost effectiveness of \$0. The cost of the specific self-help manual was equal to that of a general self-help manual, but the number of quitters increased when the information in the manual was more specific about the risks of smoking while pregnant. The second most cost-effective intervention consisted of both counselling and self-help, provided to a general sample of smokers (\$2340). The smokers chose the interventions based on their own preferences. Self-help and counselling provided in separate intervention programmes were slightly less cost-effective than when participants could choose either of them, but the cost-effectiveness ratio was still very favourable (\$3179 and \$3213 respectively). The incremental cost-effectiveness of counselling versus self-help was \$5637. When NRT was added to a counselling programme, the incremental cost-effectiveness increased to \$8794. One study investigated the value of providing a follow-up visit in addition to counselling. Because there were no other studies that addressed the issue of follow-up in addition to counselling in the same way, a broad sensitivity analysis was performed. Using a broad sensitivity range, the incremental cost-effectiveness of counselling plus follow-up compared with a counselling session alone ranged from about \$500 to about \$6000.

Figure 1: The incremental cost-effectiveness of various smoking cessation therapies

NRT = Nicotine replacement therapy

Discussion and conclusions

To increase the value of economic evaluations in the field of tobacco dependence treatment, we recalculated and standardised cost-effectiveness ratios of studies on this topic using the guidelines proposed by Drummond et al. (1997). The standardisation procedure is performed to the effect size, the input of material and personnel resources and to the monetary value of the resources. We would have preferred to provide results that were applicable to all countries in all situations. This goal could not completely be achieved: although the effect size is expected to be context independent and although both the material and personnel input are not likely to vary much between countries, in each country different costs apply to specific material resources and personnel. As a result of this, it is impossible to present CE-ratios that are fully applicable to all countries and situations. In spite of this 'problem', we provided information relevant for all countries by presenting a detailed overview of input that is necessary for different smoking cessation therapies. This information can be applied to all countries. Then, we applied the model to the Dutch situation. For decision makers in other countries, only a small step has to be taken to make the data applicable to their own situation, namely replacing the values used in the current study by county-specific cost values.

Following these steps, we did not only make CE-ratios in the field of smoking cessation comparable and more useful, we also developed a new method for reviewing CE-studies. This can be applied to other fields of medicine.

Changes in costs

There were a number of reasons for the increase in costs resulting from standardisation.

Firstly, standardised costs were generally more complete than those reported in the original article, because our analysis was based on guidelines for cost determination, whereas the cost analyses in the original articles often failed to include factors like patient time, travel time, travel costs, room rent and recruitment costs. The effect of incomplete cost calculations can be very large, as was the case, for example, in the studies by Altman et al. and Mudde et al., comparing self-help with usual care.^{17 24} In both cases, recruitment costs were not included. The costs that have to be made to recruit one participant, however, often represent a considerable part of the total costs. Recruitment in the studies by Altman et al. (1997) and Mudde et al. (1996) included TV and radio commercials, posters and telephone quit lines, while the actual intervention was a low-cost self-help manual. Standardised recruitment costs per participant in the studies by Altman et al. and Mudde et al. were \$40 and \$68 respectively, while the original articles mentioned intervention costs of only \$11 per participant (table 5).

Secondly, some of the studies were performed many years ago. If, for example, the costs of a study performed 20 years ago are corrected for an annual inflation rate of 3%, they increase by almost 100%. Because the impact of the year of performance on the costs can be considerable, table 3 also presents the standardised costs corrected for the year the study was conducted. This allows for increases in costs due to differences in methodology to be distinguished from increases in costs due to a study characteristic like the year it was conducted.

Recalculation caused a decrease in costs in three studies.^{16 17 19} The article by Plans-Rubio et al. (1998) used a very high valuation of the nicotine patch¹⁹, which seems to be the main cause of the high costs. The other two studies included development costs in the cost assessment, which explains a large proportion of the decrease in costs after our recalculation.^{16 17} Furthermore, both studies used a very detailed cost analysis, monitoring prospectively all costs incurred during the study period. Our own standardised analysis was

somewhat less detailed, and might therefore have slightly underestimated real costs.

Changes in effects

The impact of the standardisation procedure on the effect size can be illustrated by the study by Altman et al. (1981),²⁴ which compared counselling with usual care. Altman et al. used the 6-8 week quit rate of 35% as their final quit rate. Within the first year after the intervention, however, 50% of these quitters can be expected to relapse, based on the data by Prathiba et al..²⁰ Adjustment thus reduces the 1-year quit rate to 17.5%. Furthermore, their study used no comparative quit rate. (In essence, they did not correctly apply an incremental analysis). Counselling was compared with usual care (which meant hardly any intervention). Based on the data by Prathiba et al. (1998) it can be assumed that 1.5% of this group of smokers would have quit without any intervention.²⁰ Adjusting for the annual unaided quit rate further reduced the rate reported by Altman et al. to 16%. To calculate the standardized effect size (=lifetime incremental quit rate), our analysis adjusted this percentage for a 35% lifetime relapse and annually for a 1.5% spontaneous quit rate. This resulted in a standardised effect size in terms of quitters of 6.9%. So, applying the entire standardisation procedure to the study by Altman et al. reduced the quit rate from 35% to 6.9%.

As was mentioned above, there were some studies whose effect size increased after standardisation. This was only the case in those studies in which the original cost-effectiveness ratios were calculated on an intention-to-treat basis,^{14 18 19 22} since the present analysis calculated cost-effectiveness ratios for persons actually making use of the intervention. Although the number of quitters obviously remains the same, the percentage of quitters will be higher when it is based only on those persons accepting the intervention, than when it is based on all persons to whom the intervention has been offered. These four studies had assessed the cost-effectiveness of nicotine replacement therapy (NRT) in addition to counselling. Since the acceptance rate of NRT is estimated to be 25%, the study population is four times larger in the original articles than in our analysis. Accepting a given number of quitters due to the intervention thus means that the percentage of quitters after one year in our analysis is 4 times higher than that in the original articles, resulting in a higher standardised effect size. This, however, does not affect the CE-ratio. The reason for this is that the recruitment costs are four times higher when calculating CE based on persons

actually making use of the intervention instead of calculating the CE based on intention to treat. The decrease in effect after standardisation is thus balanced out by the increase in costs.

In the present analysis, effect sizes in terms of quitters were adjusted for study duration (if this was less than 1 year), lifetime relapse and unaided annual quit rate. If studies had calculated average cost-effectiveness instead of incremental cost-effectiveness ratios, this was also corrected for. The original articles had often failed to apply these corrections to the observed quit rate.

CE-ratio

The present study revealed that the standardised cost-effectiveness ratios of smoking cessation interventions were systematically higher than the non-standardised ratios. Despite this, interventions aimed at reducing the prevalence of smokers were still found to be cost-effective. It was also concluded that, in general, less intensive interventions were more cost-effective than more intensive interventions. Although this general trend is apparent among all studies, it cannot completely account for individual variations and will thus not be applicable to every single smoker. For example, persons who are less motivated are likely to benefit more from the more expensive interventions than from less intensive ones. The fact that less resource consuming interventions are in general more CE than more resource consuming interventions does not mean, however, that more intensive interventions should not be performed, as their cost-effectiveness ratio is still lower than that of many accepted curative interventions. Furthermore, more intensive interventions may have their own value by inducing specific groups of smokers (e.g., heavy smokers) to quit smoking, where less intensive interventions have failed.

Although the CE ratios of all interventions remained acceptable after standardisation, the differences between studies in the percentage increase in cost-effectiveness ratio after standardisation are striking. This not only confirms the observation made in our previous review, that there has been no uniform method to calculate cost-effectiveness in the studies performed until now, but also shows that the use of non-standardised methodologies in cost and effect calculation has a considerable influence on the outcome in terms of cost-effectiveness: even when standardisation only includes standardisation to the guidelines (that means that the CE-ratio is not adjusted to the year 2002), the CE-ratio increases up to 2800 percent.

The method of analysis used in the present study has several advantages. It makes cost-effectiveness ratios more informative: costs are complete and up to date and information about intermediate effects (in this case costs per quitter) are transformed into information about costs per years of life saved. This increases our knowledge. Most CE-studies performed in the past can be used for current decision making and even studies reporting only intermediate effects, without an additional economic analysis, can be made useful for medical decision-making at the macro level by applying the method used in the present article. Because evidence exists that the quality of economic evaluations in other fields of medicine is also a subject of concern, this method might be applied to other fields of medicine as well.

Although it would be useful to apply the analysis used in this article to other fields of medicine, there are some disadvantages to the present methodology. Our primary aim was to make CE-ratios from different studies comparable. In doing so, we used information from the reviewed CE-studies. We did not aim at providing the best CE-data as possible. This led to two caveats. The most troublesome is that models need to be used to extrapolate intermediate effects (effect size in terms of quitters) to the effect size in terms of yols. The decision for which model to use in this study was based on the frequency with which the models were used in the original studies. We used the model that was most frequently applied in the original studies. This was also the model with the extrapolation rate most close to average. So, in the present study, no efforts were made to gain insight into these models. In other words, they were treated as black boxes. CE-estimates are expected to be even more reliable when insight is gained into the models. Future research should focus on this aspect. Second, we did not aim to search all the literature for the best figures about effects available, but we used information from the reviewed studies themselves. An additional search on effectiveness rates for smoking cessation might result in more precise estimations of the CE-ratios.

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4

Cost-effectiveness of prevention in the low socio-economic classes: what lessons can be learned?

Based on: Ronckers ET, Evers SMAA, Ament AJHA. Cost-effectiveness of prevention in the low socio-economic classes: what lessons can be learned? (submitted for publication)

Abstract

The prevalence of cardiovascular diseases (CVD) as well as the prevalence and clustering of (biological) risk factors for CVD is higher among persons with a low socio-economic status (LSES) than among persons with a high socio-economic status (HSES). Because biological risk factors for CVD exert a negative exponential effect on CVD, the potential health gain from preventive interventions is expected to be larger among LSES groups than among groups with a HSES. From a medical point of view, it seems thus more efficient to focus on LSES groups than on HSES or the general population. In the current article, we used information from previous research in order to critically debate health promotion to LSES groups from an economic point of view. The results of this study suggest that focussing on LSES groups does not result in an additional health benefit among these groups. Furthermore, an intervention program among LSES groups would induce much more costs than is the case among HSES groups.

We conclude that there is no evidence for community programs focussing on LSES groups to be more cost-effective than community programs designed to reach the society as a whole. Implications of this conclusion for policy and research are discussed.

Introduction

Health among persons with a higher socioeconomic status (HSES) has consistently been shown to be better than that among persons with a lower socioeconomic status (LSES).^{1 2 3} Because of the high prevalence of cardiovascular diseases (CVD) in the Netherlands and the rest of Western Europe,⁴ this article focuses on CVD. The risk of CVD has been reported to be 3 to 4 times higher in LSES persons than in HSES persons, and the prevalence of risk factors for CVD is also much higher among LSES groups.^{2 5 6} Since health improvements resulting from lifestyle interventions are often thought to be greatest in groups at highest risk (in this case LSES groups), interventions to reduce CVD are often implemented in LSES groups. In addition to the assumption of being more effective, health-promoting interventions among LSES groups provide at first glance a semblance of cost-effectiveness.

This article investigates the assumption that preventive interventions are more cost-effective in LSES groups than in HSES groups.

Potential benefits in LSES: a ‘medical’ perspective

Current beliefs about the effectiveness of lifestyle interventions among LSES groups seem to be greatly influenced by medical knowledge about CVD, and its classical risk factors.^{6 7} It is well-known that high blood pressure, an unfavourable cholesterol profile and the negative biological effects of smoking increase the risk of CVD.^{8 9} These biological risk factors have even been proved to exert exponential negative effects on cardiovascular health.^{10 11 12} The lifestyle factors smoking, exercise and diet influence cardiovascular risk mainly through the above biological risk factors.¹³ This is the basic knowledge medical practitioners use in CVD management.

Since CVD as well as traditional biological and behavioural risk factors are more prevalent among LSES groups they can be seen as a group at high risk.^{2 3 10 14 15 16 17} As targeting high risk groups generally yields greater effects than targeting groups at low risk,^{17 18} the cost-effectiveness ratio of CVD prevention programmes is also expected to be more favourable when they are implemented among LSES groups than among HSES groups or, for that matter, in the total population.

Actual benefits of health promotion in LSES

The contribution of traditional risk factors for CVD to the risk on CVD in LSES groups was the focus of research within a number of longitudinal observational studies.^{2 3 5 6 14 15 19 20} These studies involved large adult populations followed for 7 to 10 years. The studies recorded the prevalence of CVD (and CVD mortality) during the follow-up period. From all participants, risk factors for CVD (biological and / or lifestyle) and SES were available. The observational data were used to calculate CVD risks and compare the risk for the lowest SES group with that for the highest SES group, resulting in observed (relative risk) RR ratios for LSES groups compared to HSES groups. The results are summarized in table 1.

Furthermore, the RR ratio for CVD in LSES groups compared to HSES groups was calculated correcting for traditional (behavioural and / or lifestyle) risk factors. Statistical adjustment for the traditional risk factors for LSES groups shows how much of the RR of LSES persons can be explained by traditional risk factors, compared to HSES persons. The findings are presented in table 1.

Among studies in which only lifestyle differences between LSES and HSES groups were made equal, risk reductions for CVD mortality and all-cause mortality among LSES groups were calculated to be about 30% and 12% respectively.^{5 6} See table 1.

Adjustment of traditional biological factors has been found to yield reductions of the RR of CVD (and CVD mortality) from LSES groups compared to HSES groups ranging from 14 to about 40 percent.^{5 14 15 19 20} See table 1. However, the risk of CVD mortality remained higher in the LSES groups (RR 1.2 and 3.8) even when biological risk factors of LSES groups were made equal to HSES levels.

Even when biological and behavioural risk factors among LSES persons are equated to those of HSES persons, the CVD risk among the LSES groups was reduced by only 15% to 35%. The RR for LSES persons compared to HSES persons is thus still 1.6 to 2.6.^{2 3 15} Improving unhealthy lifestyles therefore does not lead to a proportional decrease in the relative CVD risk, and the medical exponential model of traditional medical risk factors for CVD cannot be fully applied to LSES groups. As was made clear in the previous section, this model is often used when estimating the potential effectiveness of CVD prevention programmes. The observation that the medical exponential model of traditional medical risk factors for CVD cannot be fully applied to LSES groups means that

the benefits of life-style improving interventions among LSES groups may thus not be as effective as they are often believed to be.

Factors described in the literature, such as living conditions, social environment, working environment, material and financial conditions, psychosocial stress and coping mechanisms, also play a role in explaining the risk for CVD among LSES groups.²¹

Table 1: The effects of biological and lifestyle risk factors for cardiovascular diseases on cardiovascular risk among low socio-economic status groups

study	SES indicator	Classes ¹	observed RR LSES ²	Adjusted RR LSES ³	Reduction RR LSES (%)
Biological risk factors					
Davey-smith, 1990	employment grade/ car owner	4	2.0 (CVD mortality)	1.6	20
Davey-smith, 1990	employment grade/ no car	4	6.5 (CVD)	3.8	42
Lynch, 1996	Income	5	4.3 (fatal AMI)	2.8	35
Marmot, 1984	employment grade	4	2.7 (CVD mortality)	2.1	22
Pocock, 1987	employment grade	2	1.4 (IHD events)	1.2	14
Salonen, 1982	education	2	?	2.1	?
Salonen, 1982	income	2	?	1.7	?
Lifestyle risk factors					
Lynch, 1996	Income	5	2.7 (CVD mortality)	1.8	30
Lantz, 1998	income	3	3.2	2.8	14
Biological and lifestyle risk factors					
Rose, 1981	employment grade	4	4.0 (CVD mortality)	2.6	35
Rosengren, 1988	employment grade	5	2.1 (coronary death)	1.6	24
Rosengren, 1988	employment grade	5	2.3 (nonfatal MI)	1.9	17
Rosengren, 1988	employment grade	5	2.2 (total CAD)	1.9	14

¹ Number of classes used to classify SES

² The relative risk ratio from LSES compared to HSES as is observed within the longitudinal follow-up study

³ The relative risk ratio from LSES compared to HSES after statistical correction of the classical biological and / or lifestyle risk factors.

The costs of preventive interventions among LSES groups

In addition to the problem of the effectiveness of interventions among LSES groups, there is the additional problem of their costs.

The literature provides several factors influencing the success of interventions among LSES persons. The summary of these factors presented below is mainly based on Jansen and ten Dam (2002) and on Lindenberg, et al. (2001).^{21 22}

Effective preventive measures require a community partnership to be built, which means getting to know the needs of the target population. This should lead to long-term participation by various community-based institutions (health institutions, welfare service, local policymakers, etc.). There should also be enough capacity (in terms of funding and partnerships) to allow the project to continue for a long time. The best way to contact LSES groups is by including members of the target groups in the team, because they can identify with the clients. Personal contact is essential to recruit persons from LSES groups for preventive activities. In addition, it is very important that the intervention is tailored to the social context and the knowledge available among the target population. Furthermore, a multiple intervention strategy is needed when targeting LSES groups.

It will be clear that such interventions require much greater resources than traditional community programmes. The high level of staffing and material resources required also results in costs that are much higher than for programmes targeting HSES persons. This puts a negative strain on the cost-effectiveness ratio of preventive interventions in LSES groups.

Discussion

The hypothesis that prevention among LSES groups would result in a more efficient use of resources than prevention among HSES groups could not be confirmed based on the current overview of literature on this field. This has two reasons.

First, the effects of CVD prevention among LSES groups are less than could be expected from the medical exponential model: even if all traditional biological and lifestyle risk factors of LSES groups were to be equated to the HSES groups, the risk of CVD among LSES groups would not decrease to the level

found in the HSES groups. Therefore, the traditional medical model should be adapted for LSES groups²³. Although other factors than the traditional risk factors are found to play a role in the LSES, we have as yet found no information how the adaptation of the model should be performed. The only conclusion that can be drawn with certainty from the information available is that the risk of CVD among LSES groups cannot be completely eliminated by changing traditional biological and lifestyle factors. It is important, however, to assess the quantitative impact of all variables influencing the risk of CVD (individually and in combination) among LSES groups, in order to select the most efficient combination of interventions to reduce health inequalities.

The second reason why prevention among LSES groups may not result in a more efficient use of resources than among HSES groups is that the costs are higher than those of preventions aimed at HSES groups or at the whole population.

The conclusion that targeting lifestyle interventions to LSES groups does not necessarily lead to a more efficient resource use than targeting HSES groups does not mean that LSES groups should be neglected. There are several political reasons to continue the prevention of CVD and poor health in general among LSES groups.

First, health differences between LSES and HSES groups in Western Europe are large and in some countries, such as the Netherlands, they have not decreased over time.²⁴ For reasons of solidarity, equity has become a major policy goal, for which lifestyle changes among LSES groups might be more important than among HSES groups.

Second, lifestyle-promoting interventions not only affect physical health. Such programmes also lead to advantages in terms of welfare and social well-being.

Third, making lifestyle interventions part of a broader intervention strategy to reduce socio-economic health differences will increase health effects. Next to lifestyle interventions, attention should also be paid to aspects like education and reduction of income differences between LSES and HSES.²⁴

Finally, it should be mentioned that the problem of health inequalities is a complex issue and successes will probably be gained in small steps, so long-term investment in the various strategies to reduce this inequality will be necessary.

The present study was restricted to CVD and only a selection of the relevant literature was used. In spite of this we think that our conclusion that lifestyle interventions among LSES groups are not necessarily more efficient than

lifestyle interventions among HSES, groups is not restricted to the field of CVD, because the underlying mechanism is the same.

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5

Primary and secondary prevention of cardiovascular diseases: the influence of behavioural counselling on quality of life within the 'Hartslag Limburg' programme

Based on: Ronckers ET, Groot, W, Hübben M, Ament A. Prevention of cardiovascular diseases in primary and secondary care: the influence of behavioural counselling on quality of life within the 'Hartslag Limburg' programme. (submitted for publication)

Abstract

Little is known about the effects of behavioural counselling to prevent cardiovascular diseases on quality of life. The aim of the present study is to gain more insight into this relationship for both persons at risk for cardiovascular diseases (secondary prevention) and persons with established cardiovascular diseases (tertiary prevention). Within the secondary prevention study, a cluster randomised controlled design was used to assess the effectiveness. Within the tertiary prevention study a randomised controlled trial was used. Quality of Life was assessed with the RAND-36. To assess any effects of the intervention, multilevel analyses were performed after four and 18 months within the secondary prevention study, while multiple linear regression analyses were used within the tertiary prevention study. In the secondary prevention trial, significant differences were observed on physical functioning in the intervention group compared with the control group after 18 months of follow-up ($p=0.006$). No effects of behavioural counselling on quality of life were found within the tertiary prevention trial. It can be concluded that, in spite of the difference in physical functioning between the intervention and control population within the secondary prevention trial, the present study could not firmly prove the effectiveness of behavioural counselling on quality of life.

Introduction

Cardiovascular diseases (CVD) are the main causes of death in today's western society.¹ It is widely known that exercise, nutrition and smoking are major behavioural risk factors for CVD. In order to reduce the prevalence of CVD, a number of behavioural risk factor interventions have been developed. An example of such an intervention is behavioural counselling, in which people receive personal advice about behavioural risk factors and assistance in adopting healthy behaviour. A number of studies evaluated the effects of these interventions.

Most studies performed so far have evaluated changes in behavioural or biological risk factors due to behavioural counselling. Evidence exists that behavioural counselling can be effective in both persons at risk for CVD and persons with established CVD in short-term² and long-term.^{3 4 5 6 7} However, some studies did not report long term effects on these parameters^{8 9} while one study was not able to show any effects of the intervention at all.¹⁰

For economic evaluation research, however, it is not the change in behavioural or biological risk factors, but the quality-adjusted life years gained which is the most favourable outcome measure. This outcome-measure not only takes into account changes in mortality, but also changes in quality of life (QoL). With this uniform outcome-measure, effects of different interventions within the whole field of medical care can be compared.

As far as we are aware, only one study on behavioural counselling measured effects in terms of QoL.¹¹ Although no changes in biological risk factors could be observed, there were changes reported on QoL at 12 months after counselling. It concerned effects on the SF-36 scales general health, role physical, vitality and bodily pain. This means that health education can improve QoL, even when effects on biological parameters cannot be shown.

The aim of the present study is to gain more insight into the effects of individual behavioural counselling on quality of life of both persons with established CVD and persons at risk for CVD.

Methods

Study population

Two independent study populations were enrolled, namely a GP-population, and a cardiology population.

Within the GP-population, the effects of secondary preventive counselling on QoL were investigated. The aim within the cardiology population was to gain more insight into the effects of tertiary prevention on QoL.

The GP population consisted of persons with a risk of at least 20% of incurring a cardiovascular event within 10 years. The absolute risk was determined using the 'American Association, risk tables from Framingham'. The participants were recruited from 19 GP-practices (including 56 GP's), settled in the southern part of the South of Limburg.

GP-patients were included if they met one of the following criteria:

- One of the following diseases: angina pectoris, myocardial infarct, cerebrovascular accident, transient ischaemic attack, PAV, concentric left ventricle hypertrophy, or heart failure
- Diabetes mellitus
- Very high blood pressure (>105 diastolic) measured at any time in the past
- Very high cholesterol (>8.0 mmol/l) measured at any time in the past
- All men younger than 60 years of age with 2 or more of the following risk factors: in current treatment for hypertension or hypercholesterolaemia, smoking, cardiovascular disease in a first degree family member younger than 60 years of age
- And finally all men older than 60 years of age with one or more of the following risk factors: in current treatment for hypertension or hypercholesterolaemia, smoking, cardiovascular disease in a first degree family member younger than 60 years of age

The cardiology population consisted of persons with established CVD. These participants were recruited from the outpatient cardiology ward of the Academic Hospital in Maastricht.

Persons visiting the department of cardiology were included if they suffered from one of the following diseases: angina pectoris, myocardial infarct, cerebrovascular accident, transient ischaemic attack, PAV, concentric left ventricle hypertrophy, or heart failure.

For both the cardiology and the GP-participants, the following exclusion criteria were defined:

- Age > 75
- Participation in another cardiovascular intervention study
- Existence of serious cardiac co morbidity
- Existence of other lethal, non-cardiovascular diseases
- Cognitive inability to participate in the study
- Not being able to visit hospital regularly
- Living outside the intervention area

Intervention

The intended intervention was twofold, namely individual health counselling in combination with an optimisation of the individual cardiovascular drug treatment.

Nurses or dieticians, who received special education for counselling, provided the health counselling. The counselling focussed on quitting smoking, improving the dietary pattern and increasing the exercise rate. The patients and the counsellor decided in consultation which lifestyle factors would be counselled. Within the secondary prevention trial, the mean number of counselling sessions was 2.31, with a mean total duration of counselling 83 minutes. Within the tertiary trial, persons received on average 2.76 counselling sessions, with a mean total duration of the counselling of 91 minutes.

Besides the health counselling, an optimisation of individual drug treatment was intended to be an important aspect of the intervention. Based on a computerized absolute cardiovascular risk factor profile, individual treatment should be improved by adjusting the medication to recent guidelines. This should have been achieved via communication with the GP. During the intervention period, it was the health counselling that received most attention.

For a more detailed description of the intervention, see Harting et al. 2004.^{12 13}

Design and procedure

The GP intervention was performed within a cluster randomised controlled trial. Within the GP practices, potential participants were pre-selected, based on information from their medical status. They were either personally asked to join in into the program during a routine consultation or they received an invitation letter.

The cardiology intervention was carried out within a randomised controlled trial. The participants of the cardiology intervention were recruited when they visited the outpatients' cardiology clinic with one of the above-mentioned diseases. Recruitment took place from April 1999 until October 2001. After having signed informed consent, the participants filled out the first questionnaire. At 4 months and 12 months post-test, they received a similar questionnaire by post.

At baseline, and after 4 and 18 months, quality of life was assessed with the RAND-36 questionnaire and the visual analogue scale of the Euroqol.¹⁴

The current study was added to an already existing study addressing the effects of health counselling on health behaviour and biomedical risk factors for cardiovascular disease. This study had already started at the time that we sent out the quality of life questionnaires. As a result of this, not all the participants were sent a questionnaire at baseline and T4. Because our study started more than one year later, there were even some participants from which no questionnaire at all was available. This is true for the intervention groups as well as the control groups.

Questionnaire

Quality of life was assessed with the RAND-36 questionnaire and the visual analogue scale of the Euroqol.¹⁴ The RAND-36 covers the following scales: physical functioning, social functioning, role physical, role emotional, mental health, vitality, bodily pain, general health, changes in health.

Statistical analysis

T-tests were used to detect any selection bias at baseline. Because not all the participants were sent the questionnaires at baseline and T4, the research groups do not consist of the same individuals at the different moments of measurement. This means that the analysis should either be restricted to those individuals having received all the questionnaires, implicating loss of data, or the analysis should be performed on a group level. It was decided to perform a group analysis to prevent loss of data.

T-tests were used to detect any differences between the demographical variables of the intervention and control groups at baseline, T4 and T18.

To assess any effects of the intervention, multilevel analyses, using TSP 4.5 software, were performed in the GP population (due to the cluster randomised design). Within the cardiology population, multiple linear regression analyses were done using SPSS 11.5.

When investigating the relationship between the condition (intervention versus control) and the dependent variables the following variable were controlled for: age, gender, educational level, smoking, body mass index, the baseline value of the dependent variable and – for the GP population – GP-practice.

Results

Participant flow and follow-up

GP-population

Within the GP-research 1355 patients were included. 698 Persons were included into the intervention group, while the control group consisted of 657 persons (figure 1). 292 (173+119) persons did not receive a baseline questionnaire; to 177 (118+59) persons no questionnaire was sent to and at T4 and 82 (54+28) persons did not receive any of the questionnaires (figure 1).

Figure 1: Patient flow in the secondary prevention trial

Furthermore, figure 1 shows that within the first 4 months, 143 (94+49) persons (10 percent) of the initially included persons had dropped out. Between 4 and 18 months of follow-up another 158 (80+78) persons (12 percent) were lost to follow-up. This means that 78 percent of the participants completed the study successfully.

Cardiology population

The total number of included participants within the cardiology study was 1388. Of these, 700 persons were randomised into the intervention group, and 688 in the control group (figure 2). No questionnaire was sent to 647 (337+310) persons at baseline, whereas 417 (216+201) and 194 (89+105) persons did not receive a questionnaire at T4 and T18 respectively (figure 2).

At T4, 100 persons were lost to follow-up. This represents 7 percent of the research population. From the follow-up measurement at 4 months until the 18th month of follow-up, another 156 persons of the original research population (11 percent) did not return the questionnaire. This means that the total dropout rate is 18 percent. This is also shown in figure 2.

Figure 2: patient flow in the tertiary prevention trial

Baseline analysis

As was mentioned before, only a subgroup of the participants received a questionnaire at baseline. The question rises whether the persons who started the study later due to organisational problems are comparable to the persons who received all the questionnaires.

Table 1 shows that these groups do not differ much on baseline characteristics. Only the mean age of the non-participants at baseline within the GP control group was significantly lower (1.2 years) than the age of the participants within this group. Within the cardiology intervention group, the non-participants at baseline were significantly younger (1.8 years) than the participants at baseline. Although these differences do not appear to be clinically relevant, a 'per protocol' analysis was performed in addition to the group analysis, so as to obtain more reliable results.

Table 1: Demographic characteristics of persons that received a baseline questionnaire and persons that did not receive a baseline questionnaire

	Intervention			Control group		
	T0 received	T0 not received	p-value	T0 received	T0 not received	p-value
GP						
age (mean)	62,4	61,2	0,174	62,9	59,9	0,002
male (%)	63,40%	61,00%	0,596	70,80%	64,60%	0,223
education						
low	52,20%	54,70%	0,57	47,70%	52,30%	0,706
average	34,80%	33,60%		37,90%	29,90%	
high	13,90%	11,70%		14,70%	18,20%	
Cardiology						
age	60	61,8	0,016	61,7	60,8	0,213
sex	71,50%	71,10%	0,922	67,60%	65,30%	0,533
education						
low	54,30%	51,10%	0,945	52,40%	57,50%	0,188
average	29,50%	39,40%		31,80%	29,50%	
high	16,20%	11,70%		15,80%	13%	

Furthermore, analysis showed that more males were included in the GP-intervention group than in the GP-control group. The percentage of males in the intervention group, however, was the same at T0, T4 and T18. Finally, the analysis showed that more males were in the control group, compared with the intervention group at T18.

Baseline characteristics of the RAND-36 scales are shown in table 2. In the GP-study the control group did not differ from the intervention group on any of the

variables. Within the cardiology study, the control group had a higher score on the scale 'role physical' than the intervention group.

Table 2: Mean values of the quality of life indicators at baseline and after 4 and 18 months of follow-up

	T0		T4		T18	
	Intervention mean (SD)	Controle mean (SD)	Intervention mean (SD)	Controle mean (SD)	Intervention mean (SD)	Controle mean (SD)
GP						
physical functioning	72.7 (23.4)	73.7 (24.7)	74.5 (23.1)	73.5 (24.1)	74.3 (23.8)	71.7 (25.0)
social functioning	81.8 (22.4)	80.9 (23.9)	82.5 (22.8)	80.7 (24.7)	81.3 (22.9)	80.6 (24.3)
role physical	68.8 (39.9)	72.9 (38.6)	74.0 (37.9)	72.7 (40.0)	71.7 (39.0)	70.3 (41.0)
role emotional	79.4 (35.7)	78.6 (37.2)	77.4 (37.3)	78.4 (37.0)	76.5 (38.1)	78.0 (37.6)
mental health	72.6 (19.4)	70.3 (19.6)	72.8 (19.2)	70.6 (20.3)	73.1 (18.4)	71.8 (20.3)
vitality	61.7 (20.5)	59.9 (20.0)	63.0 (19.7)	62.6 (20.1)	63.4 (19.1)	61.9 (20.7)
bodily pain	77.3 (24.4)	75.9 (24.9)	77.6 (24.6)	77.1 (24.3)	76.9 (25.5)	77.2 (24.8)
general health	56.1 (18.0)	56.1 (18.7)	56.7 (18.0)	56.8 (19.6)	56.9 (18.2)	56.2 (19.6)
thermometer	71.8 (16.4)	72.9 (15.4)	70.8 (16.5)	73.3 (15.0)	74.1 (45.9)	71.6 (15.8)
Cardiology						
physical functioning	68.5 (23.9)	68.1 (25.2)	68.7 (25.4)	67.0 (25.8)	69.9 (24.8)	66.9 (25.8)
social functioning	72.7 (25.1)	71.9 (26.0)	75.9 (25.0)	76.4 (25.6)	79.0 (23.6)	78.7 (24.4)
role physical	47.4 (43.2)	54.4 (43.5)*	58.4 (42.4)	59.8 (42.9)	66.7 (41.0)	65.3 (41.3)
role emotional	63.4 (43.8)	65.5 (42.8)	70.9 (41.0)	69.1 (42.3)	76.7 (37.6)	74.2 (39.3)
mental health	66.6 (20.5)	66.6 (20.5)	68.3 (20.5)	69.3 (20.9)	70.9 (19.5)	70.7 (19.5)
vitality	54.9 (21.9)	54.7 (21.1)	57.1 (22.4)	57.5 (21.3)	59.1 (20.9)	59.2 (20.7)
bodily pain	69.3 (25.7)	72.3 (24.6)	75.0 (26.1)	75.8 (23.9)	76.7 (25.4)	77.1 (24.3)
general health	52.6 (18.9)	52.2 (18.5)	54.4 (20.7)	51.8 (19.1)	53.5 (20.2)	53.1 (20.3)
thermometer	66.9 (17.4)	67.5 (16.5)	68.1 (16.4)	67.4 (16.7)	69.3 (16.2)	68.9 (16.3)

* P<0.05

Effects of the intervention

GP population

No effects of the intervention could be shown after 4 months of the intervention (table 3): the QoL scores of the RAND questionnaire at T4 were almost equal to the QoL scores at T0 in both the intervention population and the control population. This is shown in table 2. For most QoL scales, this was also true at 18 months of follow-up (see tables 2 and 3). One significant difference between the intervention and the control population emerged however: the score on the QoL scale physical functioning was significantly higher in the intervention group

compared with the control group after 18 months of follow-up ($p=0.006$). As table 2 shows, this seems to be the result from a slight deterioration of physical functioning in the control population.

Cardiology population

Within the cardiology population the QoL of persons having experienced a coronary event increased over time (see table 2). This phenomenon was observed for almost all scales of the RAND-36. However, both at 4 months and 18 months follow-up there were no differences observed in the change of QoL between persons from the intervention group and persons from the control population. This means that the intervention was not effective in improving the QoL for persons having recently experienced cardiovascular problems.

Table 3: The effects of the individual counselling sessions after 4 months and 18 months of follow-up

	T4		T18	
	unstandardised coefficient (SE)	p-value	unstandardised coefficient (SE)	p-value
GP				
physical functioning	1.301 (1.116)	0.244	2.587 (0.949)	0.006
social functioning	0.469 (1.328)	0.724	0.202 (1.733)	0.907
role physical	2.893 (2.709)	0.286	1.547 (3.163)	0.625
role emotional	0.421 (1.896)	0.824	0.873 (1.062)	0.251
mental health	0.734 (0.019)	0.286	0.873 (1.062)	0.934
bodily pain	-0.651 (1.126)	0.563	-2.845 (1.386)	0.894
general health	0.576 (0.975)	0.555	0.634 (0.238)	0.897
thermometer	0.432 (0.968)	0.772	1.502 (1.053)	0.238
Cardiology				
physical functioning	0.652 (0.863)	0.450	1.619 (0.674)	0.106
social functioning	-0.681 (0.959)	0.478	-0.093 (1.002)	0.929
role physical	0.449 (1.586)	0.777	1.519 (1.049)	0.389
role emotional	1.257 (1.583)	0.427	1.571 (1.639)	0.338
mental health	0.601 (0.713)	0.400	0.020 (0.806)	0.980
vitality	-0.412 (0.757)	0.587	-0.297 (0.849)	0.727
bodily pain	0.136 (0.939)	0.885	-0.093 (1.061)	0.930
general health	1.338 (0.705)	0.058	-0.110 (0.846)	0.990
thermometer	0.516 (0.597)	0.388	0.244 (1.031)	0.717

Conclusion and discussion

The present study tried to gain more insight into the effects of individual behavioural counselling on QoL within two different populations, namely persons at risk for cardiovascular diseases (secondary prevention) and persons with established cardiovascular disease (tertiary prevention).

Within the secondary prevention study, individual counselling did not show any effects on QoL four months after the intervention stopped. However, after 18

months of follow-up, significant differences on the RAND-36 scale physical health were observed between the intervention and control group. Persons having received individual counselling had higher scores on this subscale than persons who had not received counselling. This might indicate an effect of individual health counselling, but the effects should be interpreted with care for several reasons.

First, no changes were observed within the intervention population. Instead, the control population reported a lowered physical functioning than at baseline and at four months after the intervention started. Although it was expected that the physical health increased in the intervention population this finding might imply that the effects of individual counselling are postponed, in that counselling will lead to a better lifestyle which in its turn will lead to maintained physical functioning in spite of growing older. However, these results are not in line with earlier research on health behaviour and physiological changes within the same study population. These studies observed slightly improved self-reported behaviour styles at 4 months (mainly a decrease in fat consumption) accompanied by slight improvements in body mass index, which vanished after 18 months of follow-up¹² (and P.van Limpt et al., in progress).

Another reason why the results should be interpreted with care is that the absolute changes on the QoL scale physical functioning are small: it concerns a decrease of 2 points on a 100-point scale. The difference with the intervention group concerns only 3 points on this 100-point scale. Although statistically significant, the clinical relevance of this change in QoL in terms of physical functioning is questionable.

Within the tertiary prevention study, neither at four nor at 18 months of follow-up, any effects of counselling on QoL could be shown. This means that the intervention in its present form was not effective in improving QoL. This is in line with earlier research performed on the same study group, which found no effects of counselling on lifestyle or physiological parameters.¹³ (and P.van Limpt et al., in progress).

Within both the intervention group and the control group, however, self-reported QoL increased substantially on almost all subscales of the RAND-36. This indicates that there is a natural recovery of QoL after having experienced a cardiovascular event. This recovery process was not increased or accelerated by the counselling sessions.

Contrary to our findings, an earlier research of Elley et al (2003) did report improvements on QoL scales after behavioural counselling.¹¹ The studies

differed on some points, which might at least partly explain the different outcomes of the studies.

First, the present study included all persons for counselling, regardless of their behavioural styles. Patients' involvement in the process of determining the behavioural risk factor to which most attention was paid during the counselling sessions was high. In contrast to this, the study of Elley et al. (2003) only included persons with low exercise rates and the counselling was specifically designed to improve this exercise pattern.¹¹ This might indicate that it is more effective to focus on one aspect of lifestyle that needs improvement, than to apply a general multiple life style approach.

Furthermore, the interventions of both studies differed slightly. In addition to counselling, persons in the present study were encouraged to improve their lifestyle by providing them with general information about lifestyle courses in their neighbourhood. Elley et al (2003) used the counselling sessions to set concrete goals for increasing exercise, which were evaluated during telephone follow-up calls.¹¹ The formulation of concrete goals might be more effective than providing general advice. Extending counselling with elements that facilitate changing the life-style, like classes on skills for adopting and maintaining healthy behaviour and exercise programs, was found to be favourable in other studies too.^{15 16 17}

In addition to these aspects the intervention in the current study might have been more effective if several other aspects had been taken into account.

First of all, the quality of the counselling was not optimal.¹⁸ Although the quality did improve over time, it used to be sub-optimal in many cases. A better counselling might have led to more improvements in lifestyle, possibly resulting in an improved biomedical cardiovascular risk profile and improved QoL.

Second, the optimisation of the medication was not carried out as was planned at forehand. Computerized risk profiles could not always be implemented because many GP practices were not equipped with computerized patient registers. When computerized systems were available, GP's simply often did not adjust the medical therapy to the guidelines. A recent review revealed that counselling is more effective (at least in behavioural and biological terms) when provided in addition to drug treatment.⁷

Finally, the effects might have been larger if the duration of the study period had been longer. Evidence exists that more extensive counselling during a long period of time reaches more effect than less extensive counselling during a short period of time.¹⁶

Besides these aspects related to the counselling intervention itself, there are some other points worth mentioning.

Due to the fact that the QoL questionnaires were added to an already existing research, a number of participants did not receive a questionnaire at baseline. Some did even not receive the questionnaire of the first follow-up measurement at four months. In spite of this flaw, we believe that the results of the study are still reliable for several reasons. First, the groups that received a questionnaire at baseline were comparable to the group that did not receive a baseline questionnaire at baseline regarding demographic characteristics. Furthermore, a per-protocol analysis was performed in addition to the group analysis to assess the robustness of the results. The results of both analyses were comparable, which implies that the results of the study are reliable.

In addition, there are some important remarks concerning the implementation of counselling sessions within secondary and tertiary practice. It turned out to be very difficult to recruit GP's and cardiologists to participate in the study. This means that the results can only be generalizable to a selection of physicians. Furthermore, in the current study all patients who fulfilled the inclusion criteria and who were motivated to participate were included into the study. Physicians stated that they believe that some patients will benefit from counselling more than others. In a real life situation, it is thus expected that physicians will offer individual counselling only to a subgroup of patients instead of to all patients. Cardiovascular risk, life style and motivation of the patient to engage in counselling sessions might become important factors for inclusion in a real life situation. This will probably lead to changes in effectiveness. Further research is needed to investigate the effects of changes in referrals on the effectiveness of counselling within secondary and tertiary prevention.

In short it can be concluded that the present study could not prove the effectiveness of individual counselling on QoL. Improvements (e.g. increasing the quality of counselling) to and expansions (e.g. inclusion of medication optimisation or life style programs, increasing duration of the intervention) of the intervention will possibly contribute to the effectiveness of individual counselling. It is still possible however that changes in QoL of a-symptomatic patients at risk for cardiovascular diseases, will only be visualised in far future.

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A public-private partnership for the prevention of cardiovascular diseases: a report on the Hartsлаг Limburg Programme

Based on: Ronckers ET, Groot W, Hübber M, Ament AJHA. A public-private partnership for the prevention of cardiovascular diseases: a report on the Hartsлаг Limburg Programme (submitted for publication)

Abstract

Results of community-based prevention strategies have generally been disappointing, possibly because they are performed in an environment that makes it difficult for people to change their behaviour. Public-private partnerships could be used to change this environment, which might make it easier to adopt healthy behaviour. We analysed the effects of health education and price incentives at a butcher's shop. The health education intervention at the butcher's shop consisted of (1) labelling low-fat meat products (2) posters and leaflets and (3) education about healthy food provided to clients by the shop's staff. The effects of price reductions (special offers) were analysed using information about these price reduction periods. The analysis was based on information about price elasticity and the additional amounts of products sold during periods of price reduction. The results showed that the health education intervention did not result in a shift in consumption from high-fat meat to low-fat meat. Price elasticity values of -4 to -28 were found. It can thus be concluded that the use of price incentives seems to be a particularly strong instrument to influence the sales of low-fat meat products. Price incentives haven proved to be successful in other food areas as well.

Introduction

Western Europe has a high prevalence of and mortality from cardiovascular diseases. In the Netherlands, almost 50,000 persons a year die from such diseases.¹ This represents 35% of the total mortality. Unhealthy behaviour like smoking, unhealthy nutrition and lack of exercise are known to contribute to the development of these diseases. In order to reduce the prevalence of cardiovascular diseases, efforts are made to increase healthy behaviour, using health education. Results of community-based prevention strategies have, however, generally been disappointing.^{2 3} A reason for this might be that it is difficult to change people's behaviour by education alone, in a society in which unhealthy behaviour is promoted at the same time by commercial parties and in which unhealthy behaviour is often less expensive than healthy behaviour.

An increase in healthy behaviour among the population is most likely to occur when it becomes easier to adopt such behaviour. This might be achieved using a public-private partnership, meaning that non-profit institutions and commercial parties work together for the promotion of healthy behaviour.

Commercial parties could contribute in two ways. One method is to shift the emphasis in advertising from unhealthy products to healthier products, while the second method involves the use of financial incentives. Both methods have been the subject of previous research. Previous researchers found that small, short-term effects could be gained, in terms of larger sales of low-fat food, by using health education in restaurants and cafeterias,^{4 5 6 7} but not in a grocery store.⁸ The effect of price reductions on the consumption of healthier food in restaurants and cafeterias was found to be more substantial.^{4 9 5 10} Most studies were performed in restaurants and cafeterias. Although it is useful to change behaviour in these settings, the results cannot simply be generalised to other settings.

We were interested in the effects of health education and price incentives on the everyday purchase of food items by households. We therefore evaluated the effects of health education and price incentives on meat consumption.

As far as we are aware, public-private partnerships aiming at increased consumption of low-fat meat products using health education and price incentives have never been evaluated.

Such a public-private partnership was established within the community part of a large-scale prevention programme for cardiovascular diseases, called Hartslag Limburg (Dutch for Hearbeat Limburg; named after the Dutch province of Limburg, where it took place). A butcher joined the prevention programme by providing education at his shop about fat and low-fat meat products. In addition to the health education, prices of meat products (low-fat as well as high-fat) were regularly reduced in price during special offers.

The first aim of the present study was to evaluate the effect of the health education provided at the butcher's shop on sales patterns. The second aim related to price incentives and was twofold. We wanted to investigate whether it is possible to use price incentives to achieve a shift in consumption from high-fat to low-fat meat. In addition, we wanted to investigate whether different characteristics of the price reduction periods and of the products would induce different outcomes in terms of sales patterns.

Methods

Research questions

The following research questions were formulated:

- 1 Health education
Does providing health education at a butcher's shop result in a shift in consumption from high-fat to low-fat meat?
- 2 Price incentives
 - 2a Can sales of meat be affected by price incentives?
 - 2b Are there other characteristics besides the level of price reduction that influence sales?

Research design

A pretest-posttest design was used, with data gathered retrospectively. During a period of 1 year the intervention took place. The year preceding the intervention year was used as a reference. This means that there is a two-year observation period, with year 1 representing the reference year, and year 2 representing the intervention year.

Intervention

Health education

At a butcher's shop in Maastricht, all products with less than 10% fat were labelled as 'tasty and healthy' for a period of one year. In addition, the shop staff provided information about low-fat meat during two periods of three months within the intervention year. During these periods, posters and leaflets about low-fat meat were also displayed in the shop.

Price incentives

During the two-year observation period, the butcher regularly introduced price reductions during special offers (referred to below as 'price reduction periods'). The characteristics of these price reductions periods were as follows. In the year preceding the intervention, meat with a low fat percentage was reduced in price 92 times, while meat with a higher fat percentage was reduced in price 91 times (not significant (ns)). In the intervention year, this happened 71 and 75 times for low-fat meat and high-fat meat, respectively (ns) (see table 1).

There were no differences between the durations of the price reduction periods for low-fat meat and high-fat meat, nor in the mean number of products simultaneously reduced in price (table 1).

In the year preceding the intervention, the mean percentage of price reduction was the same for low-fat and high-fat meat, namely about 20% (ns). In the intervention year, the price reduction for low-fat meat increased to 26.8% ($p=0.01$), while the price reduction for high-fat meat increased to 22.2% (ns). (See table 1.) This meant significantly larger price reductions for low-fat meat than for high-fat meat in the intervention year.

Data collection

The information collected from the butcher's shop consisted of the prices and amounts (in kg) of all products sold during the intervention year and the year preceding the intervention. Composing usable data files took a great deal of effort. The information about prices and amounts sold were provided on a four-weekly basis. Price reduction periods differed in length (three days, six days or longer) as did the percentages of price reduction in the various price reduction periods. After a product had been reduced in price for some days, the additional amounts sold as a result of the price reduction had to be estimated from the four-week records.

Table 1: Characteristics of the price reduction periods

	year one		p1	year two		p2	p3	p4
	low-fat meat	high-fat meat		low-fat meat	high-fat meat			
number of price reduction periods	92	91		71	75			
mean number of days that a product was reduced in price	4.0	4.4	0.158	5.2	5.0	0.503	0.000	0.005
price reduction* (%)	-22.3	-20.0	0.102	-21.7	-19.4	0.353	0.739	0.719
price reduction** (%)	-20.3	-19.0	0.432	-27.8	-23.6	0.040	0.000	0.020
mean number of products reduced in price simultaneously	18.8	18.8	0.949	13.1	13.9	0.269	0.000	0.000
mean frequency of price reduction per product	14.4	12.3	0.020	15.9	13.6	0.018	0.096	0.159

* three-day intervention periods, ** six-days intervention period

- p1 low-fat versus high-fat year one
p2 low-fat versus high fat year two
p3 low-fat meat year one versus year two
p4 high-fat meat year one versus year two

Analysis

Research question 1

To answer the question whether there was an effect of labelling and additional information, the share of low-fat meat in the total sales of the selected products (in kg) during the intervention year was compared with the share of non-fat meat in the year preceding the intervention. A t-test for independent samples was used.

Research question 2a

The question whether it is possible to influence meat consumption patterns by price incentives at all was investigated using the concept of price elasticity (PE) and the total amount of meat sold during price reduction periods. PE values indicate by how much the sales of a product change (in percentages) when the price is changed by 1%. Mean PE values and additional amounts sold were calculated separately for high-fat meat low-fat meat. Because PE is a time dependent measure, price reduction periods were only included when the price reduction lasted for three or six days. This was true for 91.7 percent of all price reduction periods. Other periods were longer.

Research question 2b

The question which characteristics of the sales period and which characteristics of the products themselves influenced the sales during a price reduction period, were investigated with a multivariate regression analysis.

Characteristics of the sales period that were expected to potentially influence the effect of price reductions – in terms of the additional amounts sold – were:

- The number of products reduced in price simultaneously;
- The percentage of price reduction;
- The frequency with which a product was reduced in price;
- The duration of the price reduction period.

Characteristics of the product that were expected to potentially influence the effect of price reductions were:

- The sales volumes when a product was not reduced in price;
- The price of a product;
- Healthy versus less healthy products.

Results

Sales volumes and prices

The overall sales at this butcher's shop amounted to 6100 kg in the first four weeks of the observation period and 4800 kg in the final four weeks of the observation period. Of the 162 products selected for the intervention, a total of 4700 kg were sold during the first four weeks of the observation period, while 3550 kg were sold during the last four weeks of the observation period. Although sales in kg of all products were thus about 20% lower in the last four weeks of the observation period than in the first four weeks of the observation period, the share of the selected products in the shops total sales was constant at a mean of 75%.

Of the 162 products selected for the intervention, 58 (40%) had a fat percentage of less than 10 and were thus labelled as 'tasty and healthy', while 74 products (15%) had a fat percentage of more than 10 and received no label. A further 30 products (15%) had a fat percentage of less than 10, but were incorrectly not labelled as 'tasty and healthy'. In the analysis, these products were treated as not labelled. Sales of the products labelled as 'tasty and healthy' accounted for almost 50% of the sales of the products selected for the intervention (figure 1).

Figure 1: The share of the products used for Hartslag Limburg in the total sales of the butcher.

The top 10 products in terms of sales volumes are shown in table 2. Seven of these products have a fat percentage of less than 10.

Table 2: Overview of the ten most frequently sold products

product	kg sold per month	percentage of total sales	cumulative percentage
minced meat	376	8.9	8.9
ham*	192	4.6	13.5
chicken breasts*	160	3.9	17.4
round steak*	159	3.9	21.3
ham (grilled)*	132	3.2	24.5
beef*	127	3.1	27.6
lean pork chops*	127	3.1	30.7
streaky pork chops	103	2.5	33.2
steak tartare	101	2.4	35.6
smoke-dried beef*	77	1.9	37.5

* low-fat meat product

Overall, sales of low-fat meat exceeded those of high-fat meat ($p < 0.01$). The mean share of low-fat meat in the sales over the entire two-year period was 61% (table 3). At the start of the observation period, about 3000 kg of low-fat meat were sold, against 700 kg of high-fat meat. At the end of the observation period 1700 kg of low-fat meat were sold, against 500 kg of high-fat meat (table 3). The mean amount of meat sold by the butcher per week decreased by about

the same percentage for both groups of products, namely 29 and 27 percent for low-fat and high-fat products, respectively (table 3). Price developments can only be reported in relative terms here, since we were not allowed to publish absolute prices. Prices of non-labelled products at the start of the observation period were taken as a reference. At that time, the prices of the products labelled as 'tasty and healthy' were on average 56% higher than those of high-fat products (table 3). At the end of the intervention period, the labelled products were 47% more expensive than the non-labelled products. Prices of the labelled products increased by 10%, while those of the non-labelled products increased by 16% (table 3).

Table 3: Prices and amounts of meat sold of the products used in the analysis of Hartslag Limburg

	share in sales (%)	relative price at start of study (%)	relative price at end of study (%)	increase in price (%)	kg sold at start of study*	kg sold at end of study*	decrease in sales (%)
products labelled 'tasty and healthy'	47	156	170	10	2243	1680	29
non-labelled pro- ducts (>10% fat)	39	100	116	16	1844	1414	27
non-labelled pro- ducts (<10% fat)	15	132	153	16	693	483	30

* the mean value of five periods was used to obtain a more reliable value

Research question 1

The share of low-fat meat sold in the intervention year did not differ from that in the year preceding the intervention: 60% of the sales of the selected products. As mentioned above, there was a decrease in overall sales (figure 1).

Research question 2a

Price incentives turned out to have a strong influence on sales: the mean PE varied from -4.3 (for six-day intervention periods, high-fat meat, year 2) to -27.7 (for three-day intervention periods, low-fat meat, year 1), as shown in table 4. This table also shows that PE values were generally higher when the products were sold at reduced price for only three days than when they were reduced in price for six days.

There were generally no significant differences between the mean PE values for low-fat meat and high-fat meat (table 4). The only significant difference between PE values for low-fat and high-fat meat were found in the intervention year, and only for six-day price reduction periods (p=0.006). Nor were there generally

large differences in PE values between the two years. The only significant decrease in PE was found for low-fat meat products reduced in price for three days ($p=0.001$).

Table 4: Price elasticity of low-fat and high-fat meat products and additional amount of meat products sold during the price reduction periods.

	year one		p1	year two		p2	p3	p4
	low-fat meat	high-fat meat		low-fat meat	high-fat meat			
price elasticity*	-27.7	-22.1	0.206	-12.3	-22.7	0.069	0.001	0.904
price elasticity**	-9.4	-5.8	0.109	-8.1	-4.3	0.006	0.475	0.390
p5	0.000	0.000		ns	0.000			
Kilograms*	38.8	31.7	0.190	30.3	21.5	0.139	0.148	0.070
Kilograms**	36.9	22.1	0.004	41.4	30.0	0.111	0.498	0.207
p5	ns	ns		ns	ns			

* three days intervention period, ** six days intervention period

- p1 p-value of low-fat meat versus high-fat meat in year 1
 p2 p-value of low-fat meat versus high-fat meat in year 2
 p3 p-value of low-fat meat in year 1 versus low-fat meat in year 2
 p4 p-value of high-fat meat in year 1 versus high-fat meat in year 2
 p5 p-value of 3-days versus 6-days intervention period

Calculation of PE on the basis of the increases in price and decreases in sales that occurred during the complete study period (see table 3) yields PE values for the labelled low-fat meat products and the non-labelled high-fat products of 2.9 and 1.7, respectively.

To a butcher, it is not so much the PE value that matters, but the additional amounts sold relative to the periods when the products are not reduced in price. Unlike PE values, the amounts sold did not differ significantly between three- or six-day price reduction periods ($p=0.714$; $p=0.094$; $p=0.070$; $p=0.195$). This was true for low-fat meat as well as high-fat meat, and for the intervention year as well as the year preceding the intervention.

Furthermore, the large decrease over time in the PE of healthy meat products reduced in price for three days ($p=0.001$) did not result in a significant decrease in the extra amounts sold during the price reduction periods ($p=0.148$), as is shown in table 4. This implies that it is not only the price reduction that makes people decide what meat products to buy. The observation confirms our hypothesis that certain characteristics of the sales periods or of the product are important elements in the prediction of the amounts sold.

Research question 2b

The results of the multivariate regression analysis (Table 5) show that the amount of a product sold in periods without price reduction had the greatest influence on the additional amount sold during price reduction periods ($\beta=0.535$; $p<0.01$). The percentage of price reduction was the second most important characteristic influencing the additional amount sold during price reduction periods ($\beta=-0.401$; $p<0.01$) as shown in table 5. The higher the percentage of price reduction, the larger the additional amount of a product sold. A third factor was that the additional amounts sold during price reduction periods were larger for low-fat products than for high-fat products ($\beta=1.39$; $p<0.01$). The final characteristic that influenced the additional amounts sold during price reduction periods was the frequency with which a product was reduced in price ($\beta=0.106$; $p<0.05$). The more often a product was reduced in price, the larger the additional amounts sold during price reduction periods.

Table 5: The influence of independent variables on the additional amount sold during price reduction periods

	standardised coefficient (beta)	level of significance
basic sales	-.115	.000
price reduction (%)	-.268	.000
healthy (=2) versus less healthy (=1)	-.519	.000
number of products reduced in price simultaneously	-.026	.641
period (year 1 versus year 2)	.663	.000
basic price	-.009	.871
frequency of price reduction	.309	.000

Discussion

The present study found no shift in consumption from high-fat meat to low-fat meat as a result of the intervention. This does not necessarily mean, however, that health education in a butcher's shop is not effective. Some external factors have probably influenced the results. The most important of these is the economic recession which started during the research period, which meant that people had less money to spend. In such a situation, they can be expected to consume less meat in general and/or to shift their consumption from more expensive (low-fat) to less expensive (high-fat) meat products. In the present study, the total sales of the butcher did indeed decrease, but the share of the more expensive low-fat meat products sold remained the same. If the trend in the Netherlands as a whole for this period, contrary to the butcher's shop we

investigated, had been a shift from the consumption of the more expensive low-fat meat to the less expensive high-fat meat, then the health education intervention might be said to have been successful in preventing this decrease at this particular butcher's shop. In fact, however, the consumption of pork, beef, and poultry in this period remained constant in the Netherlands: no shift in meat consumption categories was observed.¹¹ Furthermore, Dutch meat consumption figures for the year 2001 and 2002, calculated by the Statistics Netherlands (CBS), allow the conclusion that the overall meat consumption in the Netherlands did not decrease.¹¹

The observation that the 30% decrease in total sales at this butcher's shop did not reflect a general trend rises the question what could explain this decrease. The reason for this decrease is probably the increase of meat being bought at supermarkets instead of at butcher's shops in the Netherlands.¹² In 2002, 80 to 90 percent of all meat was bought at supermarkets. Furthermore, during the research period, a new supermarket was opened right across the street from the butcher's shop we studied. Because meat in supermarkets is generally less expensive, it seems likely that clients kept buying the same low-fat meat products, but bought them from less expensive shops (supermarkets). This might be true for the clientele of the butcher's shop under study as well as for the Dutch population in general.

It can be concluded, nevertheless, that we were not able to show the effectiveness of health education in a butcher's shop.

The study further confirmed the findings of earlier research, that price reductions can be used to guide sales.^{4 5 9 13} The observed mean PE values of –11 and –16.6 for high-fat and low fat-meat, respectively, are high, indicating that price reduction is an effective tool to influence sales patterns. Because high-fat meat was reduced in price just as often as low-fat meat, the desired health effects of price reductions for low-fat meat might have vanished. The calculated PE value is much higher than those reported in other studies, which have reported values of 0.3 to 0.6.^{14 15} This large difference probably results from a different starting point in calculating PE values. In the present study, PE values were calculated based on temporary price reductions, while other studies calculated PE values based on permanent price reductions or increases. Sales volumes during regular price reduction periods might show additional increases because of anticipatory buying behaviour. In other words, the meat sold during price reduction periods does not necessarily have to be consumed in the short term. It is likely that customers buy more meat and store most of it for

consumption at a later moment. Furthermore, it is possible that customers who usually patronise another butcher may have bought their meat at the butcher's shop participating in our study only during price reduction periods. Meat that is bought by persons visiting the butcher's shop only once causes an increase in the sales, but does not reflect an increase in low-fat meat consumption among regular customers. Purchase acceleration and store switching are indeed common phenomena when price incentives are used.¹³ In our study, the fact that the PE values for three-day price reduction periods were higher than those for six-day periods confirms that these mechanisms did indeed play a role. Further evidence of purchase acceleration is that the PE values in the present study were considerably lower when calculated on the basis of price increases and decreases in sales for the entire study period rather than for the short-term, recurrent price reductions.

In spite of these phenomena, the current study confirms the finding of previous research that price incentives have a greater influence on consumption behaviour than health education.^{4 5 9 10} This is in agreement with the study by Lannernas (1997), in which a representative sample of European citizens rated price and taste above health when asked what determined their food choices.¹⁶ Some evidence even exists that health messages might reduce the effect of price incentives when provided at the same time.⁵ The authors' conclusion from this observation was that healthy food is not always associated with being tasty, whereas the taste and the price of a product are generally more important than health aspects.¹⁶ As far as meat is concerned, however, it is our impression that low-fat meat products are generally preferred over high-fat meat products in terms of taste.

In addition to the effect of price reduction and health education, we tried to evaluate other characteristics that influenced the butcher's sales. The finding that the basic sales (sales in non-price reduction periods) and the type of product (low-fat versus high-fat) influenced the sales, while the basic price does not, suggests that the customers of this particular butcher's shop either based their product choices primarily on whether they liked the taste, or were already consciously making healthy choices. This is confirmed by the fact that seven of the ten most frequently sold products were the more expensive low-fat meat products.

Our results should be interpreted with care. The study used a rather weak design. First, no control group was available. Second, price reductions for high-fat meat were the same as those for low-fat meat in terms of numbers and

percentages. Further, a number of circumstances made it difficult to analyse the data properly. During the two years of observation, the price of most products increased, total sales decreased by 33 percent, the euro was introduced, there was an epidemic of foot and mouth disease and an economic recession started. In addition to this, the butcher's shop changed its sales policy on price reductions. When the observation period started, price reduction percentages were relatively small, and a rather large number of products were reduced in price simultaneously. At some time during the second year of observation, the shop decided to decrease the number of products that were reduced in price simultaneously, but to increase the percentage of price reduction. Finally, the butcher's shop that participated in our study was located in a high social class neighbourhood. Results might have been rather different if we had done the same study at a butcher's shop with a clientele from a lower social class. In the general discussion of this thesis, we will go into the improvements for the study design.

Further research is needed allow firmer conclusions. Before starting a study of public-private partnership, some precautions need to be taken. First, it is of great importance to pay attention to the design of the study. Furthermore, clear agreements should be made with the private partners, to prevent confounding due to decisions made by them during the intervention period. This could be done, for example, through contracts.

In our study, a butcher was chosen as our private partner from the food industry. However, since (1) more and more people buy their meat at supermarkets instead of at the butcher's and (2) there is a rising consumption of fast-food and microwave meals, working together with a traditional butcher's shop does not seem the most logical option when trying to influence community health. Greater effects could probably be achieved by asking supermarkets or firms producing microwave meals to collaborate.

Even with better agreements with the private partners and using partners like supermarkets, however, a major problem remains when trying to implement long-term public-private partnerships. This problem follows directly from the goals of the public and private partners. The public sector consists of non-profit organisations and aims to increase public health, whereas the main goal of the private sector is profit maximisation. It is probably very difficult to merge the goals of the two sectors.

It might be better to coordinate the use of price incentives at the political level, by introducing measures like special taxes on food with a high fat or a high

sugar percentage. Such a regulatory measure has already been successfully applied in the Netherlands for many years with regard to cigarette smoking. In 17 states of the United States of America, special taxes on snacks and soft drinks have already been implemented.¹⁷

Implementing special taxes in more countries around the world might stop the rise in the percentage of overweight people, which might substantially reduce the morbidity and mortality connected with cardiovascular diseases.

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Costs of the Hartslag Limburg Heart Health Intervention

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Abstract

Little is known about the costs of community programmes to prevent cardiovascular diseases. The present study calculated the economic costs of all interventions within a Dutch community programme called Hartslag Limburg, in such a way as to facilitate generalisation to other countries. Costs were calculated using the guidelines for economic evaluation in health care. An overview of the material and staffing input involved was drawn up for every single intervention, and volume components were attached to each intervention component. These data were gathered during to the implementation of the intervention. Finally, the input was valued, using Dutch price levels for 2004. The economic costs of the interventions that were implemented within the five-year community programme ($n=180,000$) were calculated to be about €900,000. €555,000 was spent on interventions to change people's exercise patterns, €250,000 on improving nutrition, €50,000 on smoking cessation, and €45,000 on lifestyle in general. The current cost-calculation allowed the costs to be easily adapted to other countries and regions. The study further showed that the difference between economic costs and the costs incurred by the coordinating agency can be very large. Cost sharing was facilitated by the unique approach used in the Hartslag Limburg programme.

Background

Many western countries have a very high prevalence of cardiovascular diseases (CVD).¹ In the Netherlands, more than a million persons suffer from CVD,² corresponding to 8% of the adult population. Because of their high prevalence, CVD lead to high costs. The 2003 medical costs for cardiovascular diseases in the Netherlands, were €5.2 billion,³ corresponding to almost 10% of the total Dutch health care costs.

Reducing risk factors for CVD might reduce the burden that they impose on public health and on the health care budget. There are many ways in which this can be achieved. A promising method to reduce the prevalence of CVD is the implementation of community programmes.

While there is a considerable body of evidence on the effectiveness of community programmes to prevent CVD,^{4 5 6} little is known about the costs of these complex interventions. There have been some attempts to calculate the costs of community interventions,^{7 8 9 10 11 12 13 14 15 16} but the studies performed so far have lacked two essential elements, namely (1) costs are not calculated according to guidelines for economic evaluation research and (2) costs are presented at an aggregated level.

It is important that the costs are calculated according to guidelines because previous research, which is amongst others presented in chapter three of this thesis, has shown that considerable bias may occur in the costs when guidelines are ignored.^{17 18 19} Only if the costs are calculated according to economic guidelines and in a uniform way can they be combined with data on the effectiveness of a programme and used for policy making.^{20 21}

The value of presenting costs of community programmes in a detailed overview instead of presenting the costs at an aggregated level is twofold. First, providing insight into the costs of all individual interventions in a community programme facilitates budgeting for anyone who might want to implement such a programme. The combinations of interventions to change lifestyle that are used in community programmes are different for each programme and it is thus important to know which specific interventions are used, how they are implemented and what their individual costs are. The second advantage of presenting detailed costs instead of only final costs is that the latter may give rise to problems when generalising the costs to other regions and countries,

because local factors are likely to affect the costs of a programme. Presenting detailed costs avoids these disadvantages of aggregated presentation. The present article reports on the costs of the community programme included in the Hartslag Limburg campaign, which aimed at preventing cardiovascular diseases.

The aim of the study was to provide detailed information about costs of interventions within a community programme, calculated in accordance with guidelines for economic evaluation and in such a way as to facilitate generalisation to other countries.

Methods

Target population

The intervention region consisted of the town of Maastricht (120,000 inhabitants) and four adjacent municipalities (60,000 inhabitants). The majority of the people thus lived in urban areas. 62% of the inhabitants of the intervention region had paid jobs, while 17% of the inhabitants were older than 65 years.

In the intervention region, cardiovascular diseases accounted for 32% of all deaths. The prevalence of the acute heart infarction in the intervention region was 3.7%, which is almost 2% higher than the average prevalence in the Netherlands.

As regards lifestyle, 32% of the inhabitants smoked and almost 50% of the inhabitants in the intervention region did not meet national recommendations for exercise (30 minutes a day for at least 5 days a week).

Development of the community programme

The community programme in the Hartslag Limburg campaign aims at health promotion among all inhabitants of the intervention region, that is, the town of Maastricht and four adjacent municipalities (n=180,000). Special attention was paid to inhabitants of four low socio-economic status (LSES) neighbourhoods (n=20,000), in which 50% of the interventions took place.

The programme is based on a unique design. Before interventions were implemented, a network was formed consisting of large number of participating organisations. Amongst these organisations were the campaigns coordinating agency, which is the Regional Public Health Institute of Maastricht, as well as

other health promotion agencies, the local hospital, general practitioners, welfare services and local authorities. This network can be described as the cornerstone of the campaign. Each of the agencies implemented a number of CVD prevention interventions, and also contributed financially. In this way, the network served as the starting point for the implementation of interventions. The network made it possible to implement a multiple intervention strategy and to reach inhabitants of the region in a variety of ways. Both would have been very difficult to achieve if a network had not been created first.

The community-based health promotion within the campaign was implemented through nine local health committees: one in each of the five municipalities and one in each of the four LSES areas. Each committee consisted of employees of the Regional Public Health Institute and of welfare services, civil servants and individuals from the target population themselves. The committees approached individuals and groups within the target populations by means of health promotion projects and activities.

The participation of community members in the local health committees was essential to facilitate the recruitment and participation of inhabitants. This was especially true for the LSES regions, because their residents are difficult to reach with general health promotion activities.

The participation of civil servants was important as they could effect policy changes, and because health promotion activities are partially financed by city councils.

The choices about which interventions to implement came about in a variety of ways. The most occurring were the following: (1) The coordinating agency or one of the other partners proposed an intervention, which was preferably evidence based. Together with one of the local health committees its value was discussed and the best way to implement the intervention was determined. When necessary partners or 'external' institutions were approached to collaborate in the implementation (2) The health committees explored the needs and wishes of the target-population. Based on this information, existing interventions were implemented or new ones were developed. When cooperation of institutions or organisations was needed, these were approached (3) Agencies outside the network contacted the coordinating agency of Hartslag Limburg with a suggested intervention. Together with the coordinating agency or a local health committee, the suggested intervention was evaluated on its merit for Hartslag Limburg and its attainability. In case of a positive attitude towards the intervention, implementation followed.

The similarity between these ways is that they were based on the observed needs within the community and on the expertise of the various implementers about the methods to reach the inhabitants in the region.

Cost calculation

An adequate cost calculation requires three steps to be taken, namely identification, quantification and valuation.²¹

In the identification phase, decisions were made about the aspects of the complex Hartslag Limburg programme that were to be included in the cost analysis and those that were to be excluded.

Starting from this framework, the quantification step addressed the methods used to obtain an overview of the material and personnel resources necessary for the campaign interventions to be successfully implemented.

Finally, the valuation phase applied the pricing methods.

Identification

Since the present study focused on the costs of the actual interventions, costs related to creating and maintaining the network were excluded from the analysis. The reason for doing so was that the latter costs were dependent on local organisational aspects, which means that no context-independent estimate was possible. Furthermore, the network was not solely used for the CVD prevention programme, but might serve many purposes. Hence, we were unable to estimate which part of the network costs had to be attributed to the community program of Hartslag Limburg.

We focused on calculating the costs of the interventions. Because of the large diversity of interventions, the aim was to calculate the costs of every single intervention separately. Within Hartslag Limburg, about 1000 interventions were implemented. About 800 of these were large-scale or frequently recurring interventions. In addition, there were about 200 small-scale, nonrecurring events. For practical reasons, only a random sample of the small-scale interventions was used to calculate costs according to the guidelines, and the resulting costs were then extrapolated to all other small-scale and non-recurring interventions. We think this is justified, because of the relatively small contribution of these smaller interventions to the total costs of the programme.

Not all the costs related to the interventions were relevant to the present cost calculation. Costs incurred for the *development* of new interventions were irrelevant because they do not have to be incurred again when the intervention is applied elsewhere, nor would future implementers have to pay indirectly for

the development costs. Hence, they were excluded from the analysis. Because future programmes might involve developing new interventions, we provide an indication of the development costs within Hartslag Limburg, which are reported separately.

Finally, a cost calculation according to the guidelines implies that all inputs should be included to obtain a reliable overview of the actual costs of a programme. This also means that all input should be given a monetary value. For the present cost calculation this meant that (1) monetary input or input in kind that was received from other institutions (subsidies, sponsors) was included in the cost analysis, and (2) input from volunteers was also included. Although the guidelines recommend to include input from participants in the cost analysis as well, the current analysis did not include time input by participants, due to lack of data.

Quantification

In the quantification phase, an overview of all the material and staffing input involved (both in kind and in quantity) was drawn up for every single intervention. The overview was based on documentation, like budget statements, registrations of hours worked by staff, plans of action, evaluation reports and accounts. After an intervention had been implemented, we verified whether the actual input was in agreement with the anticipated input. This was done in regular meetings (once every two months) with health education specialists involved in implementing the interventions. This information was used for an accurate estimation of the resources that were necessary for the intervention to be successfully implemented.

Valuation

In the third and final step, the staff and material inputs were valued, using Dutch price levels for 2004. Interventions were mainly valued using prices.

Staff input

In order to obtain reliable estimates of the costs of staff input, and in accordance with guidelines for cost research,^{20 21 22} staff input was valued using salaries based on national mean wage levels for each task level, instead of taking staffing costs in terms of hourly wages directly from the programme's records. This made the cost estimation less dependent on the local context and made it more likely that the estimated costs will correspond to the actual costs of future programmes implemented elsewhere.

In valuing staff input, we assumed an efficient use of input. This meant that adjustments had to be made for inefficient use of staff input by the programme

due to start-up problems. When identifying staff input, we used the task level necessary to implement an intervention successfully to define the type of staff input and thus the price attached to it.

Material input

The prices of the material input were derived from the Hartslag Limburg records.

Results

From 1999 until 2003, a total of 790 interventions were implemented. These included 21 different types of large-scale or frequently repeated interventions, accounting for 590 interventions over the five-year intervention period. Table 1 presents an overview of these interventions. Of the 590 major interventions, 193 were aimed at dietary change, 361 were related to physical activity and 9 aimed to make people give up smoking (table 1). There were an additional 27 interventions that aimed at a healthier lifestyle in general. In addition to these interventions, 200 small-scale and non-recurring interventions were implemented. Almost 50% of the interventions took place in disadvantaged areas.

The costs of the individual major interventions and the resulting total costs of the Hartslag Limburg community programme are shown in table 2. Tables 3 and 4 present the monetary value of the material and staff input.

As table 2 shows, the total expenditures over the five-year period were estimated to be about €900,000. Of this amount, about €86,000 took the form of so-called start-up costs. These are expenditures that are incurred only once to allow an intervention to be implemented. Examples of such costs in the Hartslag Limburg programme are the training costs of various professionals and of the staff of the butcher's shop involved in one of the interventions. Furthermore, €80,000 of these start-up costs was spent on a single intervention, namely the intervention called 'Tasty and Healthy'. There were large differences in the investments made to influence the various behavioural risk factors. The greatest investments were made to improve exercise habits (about €555,000). The smallest amount was spent on interventions to make people give up smoking (€50,000). On improving the dietary pattern €250,000 was spent. Another €45,000 was spent on improving lifestyle in general.

Table 1: Description of the interventions performed within the Hartslag Limburg community program

Intervention	Description
Nutrition	
Nutrition party	Discussion meeting about healthy food.
Orientation in supermarket	Education about healthy food in a supermarket.
Lifestyle seminar	Seminar about healthy living, focusing on nutrition.
Personal dietary advice	Based on a questionnaire about dietary habits, people receive written personal advice about dietary changes.
Cookery course	A course about healthy cooking.
Debt assistance	Persons with debts are taught to cook a healthy meal on a small budget.
Tasty and Healthy	Health education programme carried out at a butcher's chain, consisting of several components: 1) Labelling meat with less than 10% fat 2) Posters and postcards with healthy recipes 3) Education about healthy meat provided by the butcher's staff.
Exercise	
Walking guide	Guide showing 10 walking routes. Distribution via health centres, media etc.
Walking schedule	Guide showing 70 dates of guided walks.
Walking guide + schedule	Guide showing 10 walking routes and 70 guided walks.
Cycling guide	Guide showing cycling routes.
Exercise TV	Daily TV-guided aerobics programme, including information about the health advantages of exercising.
Walks/cycle tours	Organised walks and cycle tours.
Sports clubs	Weekly group sports activities.
Focus on Heart and Sports	Exercise education at schools, combined with introduction course at a sports club.
Smoking	
'Congratulations' campaign	Campaign consisting of five components: 1) 80 commercials, each lasting 34 seconds, on a local radio station; 2) 80 billboards ; 3) Posters and postcards in health centres. 500 posters and 7500 leaflets were placed in 250 health centres; 4) Information packages about quitting smoking containing 8 leaflets and an application form for free nicotine patches (300 requests). 5) Free nicotine patches (50 requests).
Theatre show on smoking	Intervention consisting of 2 components: 1) A lesson at school about quitting smoking ; 2) A theatre show.
Stop smoking around kids	1) An information package containing 9 leaflets and a poster was sent to all nursery schools and all health centres in the region; 2) Personal consultation by welfare worker with parents of small children; 3) Four seminars; 4) Distribution of 10 billboards; 5) Distribution of 100 t-shirts with the text: 'no smoking around kids'.
Quit smoking campaign	Anti-smoking campaign using billboards, posters and leaflets.
Lifestyle in general	
Lifestyle course	Six 3-hour sessions in which health aspects were discussed with teenagers.
Promotion stand	A display stand with health promotion materials.
Newspaper advertisement	Regular one-page advertisement in local newspaper with information about nutrition, smoking or exercise.

There were also large differences between the costs of individual interventions. Some interventions were very cheap (e.g. lifestyle seminars, the 'nutrition party' and cycle tours), whereas others involved very high costs, such as the interventions called 'Exercise TV', 'Tasty and Healthy' and 'Focus on Heart and Sports'. These three interventions accounted for 45% of the total costs.

Of the total of €900,000 that was spent on the interventions, the coordinating agency, the Regional Public Health Institute, supplied only about 10 percent, illustrating that only a fraction of the costs of the interventions have to be borne directly by the organising agency.

Table 2: Costs of the community program Hartsлаг Limburg

Intervention	Costs per intervention (€)	Number of interventions	Total costs (€)	Start-up costs (€)	Development costs
Nutrition					
Nutrition party	399	59	23.541		
Orientation in supermarket	224	63	14.143		
Lifestyle seminar	234	43	10.083		
Personal dietary advice	8.906	1	8.906	4.000	
Cookery course	1.937	16	30.992		
Debt assistance	534	8	4.272	500	4.500
Tasty and Healthy	50.000	1	50.000	80.000	2.700
Small non-recurring events	200	116	23.200		
Total costs/subsidy relating to nutrition			165.138	84.500	7.200
Exercise					
Walking guide	3.212	2	6.425		
Walking schedule	7.510	2	15.020		
Walking guide + schedule	15.910	1	15.910		
Cycling guide	7.910	1	7.910		
Exercise TV	2.000	120	240.000		
Walks/cycle tours	255	191	48.705		
Sports clubs	4.179	41	171.339		
Focus on Heart and Sports	39.909	1	39.909		
Small non-recurring events	200	51	10.200		
Total costs relating to exercise			555.148		
Smoking					
'Congratulations' campaign	11.162	2	22.325	1.500	5.000
Theatre show about smoking	575	3	1.725		
'Stop smoking around kids'	6.955	1	6.955		
Quit smoking campaign	8.727	1	8.727		
Small non-recurring events	200	23	4.600		
Total costs relating to smoking			44.332	1.500	5.000
Lifestyle in general					
Lifestyle course	1.557	16	24.912		
Promotion stand	300	10	3.000		
Newspaper advertisement	2.160	7	15.120		
Small non-recurring events	200	10	2.000		
Total costs relating to lifestyle			45.032		
Total costs of programme			809.650	86.000	13.200

Table 3: Overview of the monetary value of the material input

Resource	value (€/unit)	source
room rent	25*	Unit price within Hartslag
travelling expenses	0.15**	Dutch manual of cost research
printing costs		Unit price within Hartslag
- posters	0,6	
- leaflet/postcard	0,1	
- covering letter	0,1	
- billboard	4	
- nutritional advice questionnaire	0.25	
- book with recipes (dept assistance)	7	
- walking/cycling guide	0.8	
- walking guide+schedule	1.5	
- walking schedule	1.5	
- book with introductory courses by sports clubs	3	
envelope (A4)	0.15	Unit price within Hartslag
envelope (A5)	0.15	Unit price within Hartslag
stamped envelope (A5)	0.55	Unit price within Hartslag
postage (walking schedule, walking/cycling guide)	1.5	National rate
postage	0.4	National rate
distribution of billboard	20	Unit price within Hartslag
distribution of nicotine patches	1.5*****	Unit price within Hartslag
designing newspaper ad	500***	quotation by printer's
publication of newspaper ad	1300***	quotation by printer's
tv production and broadcast	160****	quotation by TV station
radio broadcast	1****	quotation by radio station
nicotine patches	20*****	Unit price within Hartslag
food for cookery course	100	Unit price within Hartslag
t-shirt	10	Unit price within Hartslag
billboard	100	Unit price within Hartslag

* € / hour, ** € / km, *** € / unit, **** € / minute tv or radio, ***** € / box

Table 4: Overview of the monetary value of the staff input

resource	value (€/hour)	source
dietician	40	national salary scale*
expert on walks	20	national salary scale*
health expert	45	national salary scale*
secretary	20	national salary scale*
welfare worker	70	national salary scale*
sports teacher	40	national salary scale*

* based on average salary

Discussion

As far as we are aware, this is the first study to present detailed costs of a large-scale community intervention programme, using the necessary material and staff input for every single intervention as a starting point and applying guidelines for economic evaluation.

The costs of the total programme were about €900,000. The 800 large-scale and recurring interventions accounted for 95% of the costs, while the 200 small-scale and non-recurrent interventions accounted for the remaining 5%.

The three most expensive interventions - 'Exercise TV', 'Tasty and Healthy' and 'Focus on Heart and Sports' - accounted for 45% of the costs. Because of the high costs incurred, it would be of great interest to assess the effectiveness of these interventions. However, the large number of interventions performed simultaneously within the Hartslag Limburg campaign makes it impossible to measure the effects of individual interventions.

The present methodology has some major advantages over those used in previous studies in this field, in terms of validity, reliability, generalisability and health promotion practice.

Validity: The costs were calculated according the societal perspective presented in chapter three of this thesis when possible. The accuracy with which the costs were calculated by using a bottom-up procedure based on necessary resources, instead of the specific resources used in Hartslag Limburg, improved the validity compared to previous studies. Previous attempts to calculate costs of community programmes were based on retrospectively analysing a programme's financial records. This can lead to considerable bias, because community programmes are often endowed with large contributions (monetary or in kind) by other agencies or organisations, which are often not incorporated in the coordinating agency's financial records and as a result are easily overlooked. Input from volunteers, which was included in the present study, is usually not shown in financial records either.

Reliability: The bottom-up procedure we used ensured that all relevant costs were included in the analysis, making the cost-calculation more reliable than previous studies. Unlike previous studies, which used a retrospective design, the present cost calculation was made during the implementation of the Hartslag Limburg interventions, decreasing the degree of bias. Another aspect that contributed to the reproducibility of our results is that efforts were made to detach the costs from the local context, for example by using average salaries

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for particular task levels instead of using the actual salaries paid within the campaign we studied.

Generalisability: Using average price levels instead of the actual price levels used within the Hartslag Limburg campaign makes the costs applicable to all parts of the Netherlands, and even to other countries with a price level comparable to that in the Netherlands.

Generalisation to other countries is facilitated by the fact that we have provided a detailed overview of the necessary material and staff input. Generalisation is thus a matter of linking local prices to the necessary material and personnel resources (which are not expected to differ much between regions or even between developed countries).

Added value for health promotion practice: The insights our study has provided into the resources necessary to perform lifestyle interventions facilitate budgeting, allowing costs to be anticipated.

The main shortcoming of our study is that the bottom-up procedure was not consistently used for the 200 small-scale and non-recurring interventions, but that their costs were estimated from the average costs of similar interventions. However, since these 200 small-scale interventions accounted for only 5% of the total costs, the bias resulting from this adjusted cost calculation method is not large.

A practical disadvantage of the present study was that applying a bottom-up methodology to such a complex programme is very time-consuming.

In spite of the fact that the present study paid more attention to the external validity than previous studies, it must be realized that the costs of community programs will never be completely independent of time and place.

As was shown in the Results section, it is possible to share the costs of such interventions among various parties. If such a cost-sharing approach is to be used in future programmes, it is important to form a network of participating organisations. These partners should be well informed about the goals of the project and the advantages for their own organisation, in order to improve cooperation. Effective collaboration can be promoted by the use of written agreements, especially when private organisations are included. The involvement of the partners can be enhanced by informing them about the progress of the programme. Furthermore, the programme should be brought to the attention of the public, to increase the likelihood of attracting external funding. This public attention can for example be achieved by using the media. Within Hartslag Limburg, it was the task of the project leader to create, maintain

and expand the network of partners. It is highly recommendable for future programmes to also appoint a person who can execute this task on a full-time basis. To give an indication of the staffing involved: the Hartslag Limburg coordinating agency invested an annual staff input of at least 1.5 full time equivalents (including a project coordinator, a health educator and a public relations coordinator).

The main question that remains is whether spending money on programmes like Hartslag Limburg is useful. This question can only be answered by relating the costs of the programme to its effects. Schuit et al. (in press) have already analysed the overall effects of the Hartslag Limburg campaign, and their findings are promising: the community part of the campaign seems to have succeeded in reducing the age- and time-related increase in body weight and blood pressure among the community.²³

Whether the effects of a community intervention like Hartslag Limburg will outweigh its costs will be addressed in the following chapter of the thesis.

Conclusions

The costs of the interventions of the community programme of the Hartslag Limburg campaign were calculated to be €900,000. Because the costs of all interventions were calculated separately, using a bottom-up procedure, our results should provide valuable information to health promotion specialists and policy makers. Furthermore, the methodology used improves the validity and reliability compared to previous studies in this field and it makes it easy to generalise the costs to other settings and countries.

This study further shows that the costs do not have to be borne by one agency. Cost sharing can be achieved by means of funding, subsidies and sponsoring. These can be regarded as valuable potential sources of funding. A network is required, however, to successfully implement a large-scale set of interventions like Hartslag Limburg.

Finally, contrary to previous studies, the present study calculated the costs according to guidelines for economic evaluation. This means that costs can easily be related to the effects of the intervention to calculate a cost-effectiveness ratio, which can be used for decision-making at macro-level.

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8

Cost-effectiveness of the 'Hartslag Limburg' community heart health program

Based on: Ronckers ET, Groot W, Hoogenveen RT, Schuit AJ, Wendel-Vos GCW, Steenbakkens M, Ament A. Cost-effectiveness of the 'Hartslag Limburg' community heart health program (submitted for publication)

Abstract

Up to now little is known about the cost-effectiveness of community programs to prevent cardiovascular diseases. The objective of the present study is to calculate the cost-effectiveness ratio of the 'Hartslag Limburg' Community Heart Health Program. The costs were calculated following economic guidelines. The intermediate effects (cholesterol level, blood pressure and the prevalence of smoking) were assessed at baseline and after five years of the intervention in a cohort of persons living in the intervention area and in a cohort of persons living in a comparable non-intervention area. To extrapolate the intermediate results into the number of years of life saved over a period of 5 years, a Markov-type multi-state transition model was used. Both costs and effects were discounted at a 4% rate in the baseline analysis. A sensitivity analysis was performed to assess the robustness of the results. In the base case analysis, Hartslag Limburg led to 108 yols. The costs of the intervention were estimated to be €1.350.000. The saved health care costs within the 5 years following the intervention are estimated to be €950.000. A conservative base-case scenario was chosen, resulting in a cost-effectiveness ratio (excluding saved health care costs) of €12,500, ranging from €950 to about €16,500 in the sensitivity analysis. Based on these results, it can be concluded that a program such as 'Hartslag Limburg' seems to be a cost-effective tool to decrease the prevalence of cardiovascular diseases, even under conservative assumptions.

Background

Many countries, who have adapted the Western life style, have a very high prevalence of cardiovascular diseases (CVD)s.¹ In the Netherlands, more than a million persons suffer from CVD,² corresponding to 8% of the adult population. Like in most other West-European countries - CVDs are the most important cause of death in the Netherlands: 35% of all deaths can be attributed to CVD each year.^{1 3} Therefore reducing the prevalence of CVD would imply a great improvement to public health.

Because of this high prevalence, CVDs lead to high costs. In the Netherlands, the 2003 medical expenses for CVD were €5.3 billion,⁴ corresponding to almost 10% of the total Dutch health care costs.

Improving risk factors for cardiovascular diseases may reduce the burden that CVDs impose on public health and on the health care budget. There is evidence that community programs to prevent CVDs may improve cardiovascular health.⁵

^{6 7} The limited health care budget, however, means that choices have to be made about the interventions to be implemented. Such choices can be facilitated by cost-effectiveness analyses.

Although cost-effectiveness information is available about curative interventions in the field of cardiovascular diseases, little is known about the cost-effectiveness of community-wide health education programs to prevent CVDs. Several reasons for this lack of knowledge can be identified.

First, only a limited number of studies have been performed in this area.^{8 9 10 11 12}

^{13 14 15 16} The reason for this may well be that it is rather difficult to perform economic evaluations of community programs to improve healthy behavior: (1) material and staffing input have to be monitored carefully during the whole study period, (2) effects are difficult to assess because no experimental design can be applied and because the process of change may require a long time, and (3) intermediate effects have to be extrapolated to years of life saved (yols) – which requires detailed knowledge about relative risks and modeling.

Second, the studies of the cost-effectiveness of interventions to prevent CVDs that have been performed so far did not calculate the cost-effectiveness according to economic guidelines, which limits the interpretability of the results. In chapter two of this thesis we highlighted the imperfections encountered in the cost-calculation of, for instance, community programs for the prevention of

CVDs.^{17 18} The most important shortcomings were that (1) cost calculations were performed from the viewpoint of the coordinating agency, rather than from a societal point of view;^{8 9 10 11 12 15} (2) the inclusion of irrelevant cost categories or the exclusion of relevant ones (e.g. the input of volunteers);^{9 11 12 15} and (3) the use of non-transparent methodologies.^{8 12 14 16}

Furthermore, most of the studies failed to include a control population when measuring effects. In some cases, effects were presented in intermediate end points instead of in terms of years of life saved (yols) or quality adjusted life years (qaly).^{9 13 14 15}

The current study calculated the cost-effectiveness ratio for the 'Hartslag Limburg' Community Heart Health Program, in accordance with guidelines for economic evaluation wherever possible.

A previous study, presented in chapter seven of this thesis, already presented the economic costs of the community programme of Hartslag Limburg.¹⁹ Although insight into the costs of a community programme is important for budgeting purposes, it does not provide information on whether the costs of a community programme like Hartslag Limburg outweigh its effects.

The current study constitutes an advance over the previous study, because it provides insight into the efficiency of a community programme like Hartslag Limburg and can thus be used for decision-making at macro level.

Methods

Intervention

The Hartslag Limburg community program aims at health promotion among all inhabitants of the intervention region, consisting of the city of Maastricht and 4 adjacent municipalities (n=180,000). Special attention was paid to inhabitants of 4 low socio-economic status (LSES) neighborhoods (n=20,000) situated in the town of Maastricht. For the implementation of the program a unique design was used, through a network of organizations. The Regional Public Health Institute (GGD) of Maastricht coordinated the program. It was joined by a large number of other agencies, including health promotion agencies, the local hospital, general practitioners, welfare services, and local authorities. The large number of participating organizations made it possible to implement a multiple intervention strategy and to reach inhabitants of the region in a variety of ways.

About 800 interventions were implemented over a 5-year period. (e.g. a TV-program providing aerobic lessons; guides containing walking routes; regular sports activities; small scale guides through supermarkets to teach persons about healthy food; healthy cooking lessons; discussion evenings about healthy food; radio commercials; food labeling in a butchers shop etc).

For a more detailed description of the Hartslag Limburg program, see Ruland et al. (1999) and Ronckers et al. (2006).^{19 20}

Estimation of the costs

The costs were calculated by following the guidelines for economic evaluation as closely as possible. Contrary to the guidelines of Gold et al. (1996) and Drummond et al. (1997) who advise a 3% discount-rate,^{21 22} we used a discount rate of 4% according to Dutch guidelines.²³ The analysis included the costs of the program itself and the costs of building and maintaining a network. In the sensitivity analysis also the health care costs saved by improved health were included.

Costs of the program

The cost calculation of the program has been described in the previous chapter, but we present a brief description of the procedure here.

The aim was to calculate the costs according to guidelines for economic evaluation, in such a way that the costs could easily be generalized to other regions. The costs of the program were estimated using a bottom-up procedure, taking necessary input to perform the individual interventions as a starting point instead of the actual expenditures incurred by the coordinating agency. From an economic point of view, the time input by participants should also be included. However, because we lacked the necessary data to do this, the current analysis does not include this.

First, for every single intervention, a list was drawn up of all the material and staffing input necessary to perform the intervention. Input that was not directly paid for (e.g. the input by volunteers) was also included. We then attached volume components to each intervention component. To ensure generalizability, an efficient use of material and staffing input was assumed, instead of using the exact input within the Hartslag Limburg program. In the third and final step, intervention costs were valued, based on Dutch costs for the year 2003.²³

Not all of the costs incurred for the programme were relevant to the current cost calculation. For example, a number of interventions were developed during the programme, leading to so-called development costs. Development costs

incurred within the programme will not have to be paid again when the intervention is applied elsewhere, nor will future implementers have to pay indirectly for the development costs. These costs were therefore excluded from the analysis. In a previous article, an indication of the development costs was provided.¹⁹

Costs of building and maintaining the network

One of the characteristics of Hartsлаг Limburg is the use of a large network of contributing parties. Since the costs of creating, maintaining and expanding the network depend very much on the existing regional cooperation between agencies, they are expected to differ between regions. For the current cost-analysis, the investments by the coordinating agency were used in the baseline analysis as an estimate of the network costs.

Health care costs saved

The chronic disease model (explained below) is able to predict the number and types of cardiovascular cases that will be prevented. The diseases incorporated in the model for the present calculation were acute myocardial infarction, coronary heart disease, heart failure, cerebrovascular accident and diabetes mellitus. The health care costs saved were estimated using the available information about the number of cases of these diseases that were prevented, in combination with the costs related to these diseases. The disease costs were derived from a Dutch 'costs of diseases' study.⁴

Calculation of the benefits of the campaign

Reliable estimates of the effects of the campaign were obtained by measuring biomedical parameters (body mass index, cholesterol, and blood pressure), at baseline and after 5 years of intervention, in a cohort of inhabitants of both the intervention region (N = 3000) and a control region (N = 1000). The control region was carefully selected so as to be comparable to the intervention region in terms of the prevalence of CVDs, the degree of urbanization and the age structure of the population.

Both groups were selected from an existing cohort of people participating in a monitoring project for CVDs.

The long-term benefits in terms of yols were calculated using the chronic disease model (CDM). With this model, the public health gain over a period of 5 years (resulting from the intervention) was calculated.

The CDM is a dynamic multistate lifetable model and it describes the life course of parallel Dutch population cohorts. The model is described in detail by Hoogenveen et al.. (1998).²⁴

The CDM consists of a demographic module that is linked to several disease specific modules. The population is distributed over a number of risk factor classes and diseases states, specified for gender and age. Risk factor classes used in our study are blood pressure and cholesterol level (low - normal - high - very high), and BMI (low - normal - high).

The demographic module describes the annual changes of total population numbers due to birth, mortality, migration and aging and changes of risk factor class prevalence numbers in the form of transitions between the classes. The disease specific modules are epidemiological models that describe the annual changes of disease prevalence numbers due to disease incidence and mortality of several chronic diseases. Risk factor class specifies disease incidence risks. The disease modules thus describe the morbidity and mortality numbers over time for specific disease categories. Disease states used in our study are acute myocardial infarction, coronary heart failure, cerebrovascular accident, other coronary heart disease and diabetes mellitus (all: with - without disease).

All transition rates between risk factor classes and disease incidence and mortality rates are based on epidemiological data, which are described in (Hoogenveen et al. 2000).²⁵

When estimating mortality, the model takes account of competing death risks by distinguishing cause-specific mortality risks.

The model has the Markov-property, which means that the risk factor classes and health states one year ahead are only dependent on the current distribution of persons over risk factor classes and states: the model does not take into account past risk factor classes or health states. This implies for example that persons grouped into the same risk factor level (e.g. high blood pressure) have the same probability on a CVD, independent of their past risk factor profile.

Furthermore, the model is based on the assumption of conditional independence. That means, that conditional on age, sex and risk factors disease incidence rates are assumed conditionally independent. E.g., COPD and lung cancer rates are assumed independent for given smoking status. In case of so-called intermediate diseases such as diabetes the conditional independence structure is built hierarchically. Intermediate diseases are both dependent on risk factors such as obesity, and independent risk factors for other diseases such as CHD.

In the current calculation concerning the long-term effects of Hartslag Limburg in terms of yols, empirical findings about the risk factor prevalence in the intervention region and the control region were used as input into the model. The input into the risk factor classes of the CDM was thus adjusted to the real-life situation at the end of the Hartslag Limburg program. Two scenarios were simulated, one representing the situation with Hartslag Limburg, the other representing the situation without a program like Hartslag Limburg. Concretely this means that within the intervention scenario, fewer persons were grouped into the classes 'high' or 'very high' blood pressure, cholesterol and BMI than was the case within the control scenario. Transition probabilities between all risk factor classes were assumed to be the same for persons from the intervention region and persons from the control region.

Using this information, the CDM calculated the incidence and prevalence of CVDs and provided disease specific mortality figures during a period of 5 years within the two scenarios. Based on these data, the numbers of yols gained and the saved health care costs were calculated. Obviously, the difference in outcome between these scenarios represents an estimation of the long-term effects of Hartslag Limburg.

An important assumption made within the calculation of the CE-ratios, is that only the changes in yols and saved health care costs within the 5-year follow-up period were taken into account. This means that a death prevented can lead to maximum 5 yols, and the health care costs saved only reflect those costs that are prevented within these 5 years. The absence of a life-time horizon implies that the calculated CE-ratios are very conservative estimates.

In the base case scenario, the yols were discounted by 4% from the year the savings took place, in accordance with Dutch guidelines for economic evaluation.²³

Obviously, the difference in outcome between these scenarios represents an estimation of the long-term effects of Hartslag Limburg.

Sensitivity analysis

The base case scenario included the intervention costs and network costs. Both costs and effects were discounted with four percent. Contrary to most previous studies and with the aim to present very conservative CE estimates, the base case scenario excluded saved cardiovascular health care costs. For the same reason of conservativeness, only the effects that occurred during the five-year period following the intervention were included into the analysis.

Keeping all other variables constant, the input variables were manipulated one by one.

First, we examined the effects of different discount rates: in addition to the 4% baseline discount rate, we applied a 0% and a 6% discount rate.

Next, the effects on the cost-effectiveness ratio of a 10% decrease in the effectiveness of the intervention were calculated.

Since the costs of creating and maintaining a network are likely to differ in other regions, we examined the effects of doubling these costs on the cost-effectiveness ratio.

Another manipulation undertaken in the sensitivity analysis involved calculating the cost-effectiveness after including the health care costs saved.

The base case scenario assumed that the effects of the campaign would last for a period of 5 years. Because little is known about the duration of the effects of a community program like Hartsлаг Limburg, we also calculated the CE-ratio under the condition of 10 and 20 years duration of the effect. Because it might be unrealistic to assume the effects to be constant over a period of 10 to 20 years without additional input during this time period, we also calculated the CE under the assumption that the intervention would have to be continued during the respectively 10 and 20 years in order to maintain its effects.

Results

Costs

The baseline cost-effectiveness ratio will be based on the costs of executing the program and the costs of building and maintaining the network. For completeness, the health care costs that might be saved in the future due to the decreased prevalence of CVD are also presented in this section.

Costs of the program

The total economic costs of the interventions performed within the 5-year lasting community program on CVD 'Hartsлаг Limburg' were estimated to be €0.9 million. A detailed description of the costs has been presented elsewhere.¹⁹

Costs of building and maintaining the network

The coordinating agency invested an annual staffing input of 1.5 FTEs (including a project coordinator, a health educator and a public relations coordinator). This meant that a total amount of at least €90,000 each year

(€450,000 over 5 years) was spent by the coordinating agency to maintain the program's network.

Health care costs saved

The health care costs saved as a result of a decrease in the incidence of acute myocardial infarction, coronary heart disease, coronary heart failure, cerebrovascular accident and diabetes mellitus – discounted at 4% – were about €636.000 for men and €316.000 for women within the 5 years following the intervention. Thus, the total health care savings, discounted at 4%, were about €950.000 during the 5-year time period following Hartsлаг Limburg.

Benefits of the campaign

The intermediate effects in terms of reductions in cholesterol level, blood pressure, body mass index, and smoking were assessed by means of a regression analysis. The major effects are described in detail elsewhere.²⁶

In general, hartsлаг Limburg succeeded in reducing and in some cases even preventing the age and time related increases in body mass index, waist circumference, and blood pressure. The change in risk factors in the control group was according to our anticipation, except the increase in blood pressure, which was much higher than measured in earlier cohort groups (from which data happened to be available). Therefore we believe that the reference group may not be fully representative with respect to this parameter.

Furthermore, for the purpose of extrapolating the intermediate results into yols, large research groups and representative results are of crucial importance. The originally selected control population was too small for reliable estimations regarding yols. Since we had information about change in risk factors over 5 years in previous cohort groups (1997-2002 and 1996-2001) we decided to enlarge the reference group with subjects from these previous cohort years, making the results more representative.

Using three cohort-years as a control group led to the following results: The difference between the intervention and control group in body mass index, blood pressure and cholesterol levels was -0,32 kg/m², -0,03 mmHg and -0,10 mmol/l in favour of the intervention group.

This led to 108 years of life saved during 5 years following the intervention, discounted at a 4% rate.

Cost-effectiveness

The baseline cost-effectiveness ratio (5-year horizon, 4% discount rate, and the costs of 5-year campaign) was €12,500 per yols.

Again we stress the conservativeness of the estimation, following from the fact that only the yols within the 5 years following Hartslag Limburg were taken into account and the saved health care costs were excluded.

Keeping all other variables constant, we varied the input in several ways. Table 1 provides an overview of the scenarios, together with the corresponding CE ratios. Due to our conservative point of view, the saved health care costs in future due to decreased CVD is only included into the cost-effectiveness ratio that represents best case scenario. In all other cases, these costs are excluded. Without discounting, the CE ratio was estimated to be €10,800 per yols, while a 6% discount rate resulted in a CE ratio of €13,366 per yols.

If the effects of the intervention had been 10% smaller than was observed in the present study, the CE-ratio would be €13,917.

Table 1: Cost-effectiveness ratios in relation to different assumptions about costs, effects and discount-rates.

scenario	discount rate costs (%)	discount rate effects (%)	interven- tion costs (€)	costs for network (€)	saved health care costs (€)	yols	CE-ratio (€ per yols)
baseline	4	4	900.000	450.000	0	108	12.500
no discounting	0	0	900.000	450.000	0	125	10.800
discounting 6%	6	6	900.000	450.000	0	101	13.366
effects 10% smaller	4	4	900.000	450.000	0	97	13.917
inclusion saved costs	4	4	900.000	450.000	952.475	108	3.681
double network costs	4	4	900.000	900.000	0	108	16.666
horizon 10 years	4	4	900.000	450.000	0	418	3.230
horizon 10 years, plus 10 year extension of costs	4	4	2.418.360	1.209.180	0	418	8.678
horizon 20 years	4	4	900.000	450.000	0	1421	950
horizon 20 years, plus 20 years extension of costs	4	4	3.444.109	1.722.055	0	1421	3.635

If the costs of creating and maintaining the network were twice as high as in the baseline estimation, the cost-effectiveness ratio would be €16,666 per yols.

The Hartslag Limburg community intervention became highly cost-effective if the health care costs saved were included, namely €3,681 per yols.

Using the more positive assumptions that the intervention would be effective for 10 or 20 years, the CE-ratios decreased to €3,320 and €950 respectively. Even if the program would have to be continued to the same extent (and thus against

the same costs) for the 10- or 20-year follow-up period to maintain its effects, the cost-effectiveness would be more favorable than the base case scenario, namely €8,678 for a 10 year extension of the program and €3,635 for a 20-year extension of the program.

Discussion

The cost-effectiveness of a large-scale, multifactor community program for CVDs was estimated. The evaluated program differed from earlier community programs in that a network of participating organizations, thus approaching the inhabitants of the intervention region in different ways, implemented it. Furthermore, a great deal of effort was put into stimulating healthy behavior among persons with a low socio-economic status.

When estimating the CE-ratio of Hartslag Limburg, conservative starting points were chosen. First, it was assumed that the effects of Hartslag Limburg would be completely absent after 5 years of follow-up. Furthermore, only those costs and effects that occurred during the follow-up period were taken into account. This means for example that the prevention of a cardiovascular event in a 40-year-old male in the fourth year of follow-up only leads to one yols in the base case scenario. This is certainly an underestimation of the actual effect. In a real life situation the prevention of a death of a 40-year old male in the fourth year of follow-up would lead more yols. Assuming males have a life expectancy of 75 years, the total number of yols could be as high as 35. Finally, saved health care costs are excluded from the analysis. Their effects on the CE-ratio is only examined in one scenario. Including saved health care costs drastically decreases the CE-ratio, making a program like Hartslag Limburg far more favorable to implement.

Even under the conservative assumptions used, the cost-effectiveness ratio of the program was €12,500, ranging from €3,230 to €16,666 in the sensitivity analysis. This is below the acceptable CE ratio of €18,000 that is often used in the Netherlands. The CE-ratios of all but one scenario are also below the tentative international ceiling for CE ratios (€15,000 – €75,000).^{27 28} A community program for CVDs like Hartslag Limburg thus seems to be cost-effective, even under very conservative assumptions.

A more detailed look at the results reveals that continued investment to prevent relapse for a long period of time (e.g. 10 or 20 years) after a community

program like Hartslag Limburg had stopped might be more favorable to do, than to provide a program once for a fixed period of time and then stop all investments. This can be concluded from the CE-ratios calculated within the different scenarios, which show that the CE-ratio when providing Hartslag Limburg once, assuming the effects to maintain for 5 years, is far less favorable than the CE-ratio when it is assumed that investments would be made to prevent relapse for an additional 10 years or 20 years. The CE-ratio drops from €12,500 in the base case scenario to €8,678 or even €3,635 under the assumption that the same yearly costs have continued to be made for relapse prevention during the 10 or 20 years following Hartslag Limburg to maintain its effects. This can be explained by the preventative nature of Hartslag Limburg. The deaths prevented are not evenly distributed among the years following the intervention: only few deaths will be prevented in the first years after the intervention, while a relatively large number of diseases and thus deaths can be prevented if behavioral change is still present in far future. The same yearly financial investments will thus lead to an increasing number of yols per year when time passes. Investments to prevent relapse may thus be highly favorable due to this phenomenon. This is of course especially true when early relapse would occur. In the current analysis, we assumed that relapse prevention would be as expensive as performing a community program. This also seems to be a conservative premise. It is thus not unrealistic to expect even more favourable CE-ratios under the assumptions of longer follow-up periods combined with continued financial investments.

An additional advantage of investing in relapse prevention is that the effects might not be limited to the original cohort (the target population at the start of the intervention period), but that other persons entering the region or target population also benefit from the intervention, increasing the campaign's impact. However, even when a program like Hartslag Limburg would be completely discontinued, its effects would be gone after 5 years, only those yols that can actually be observed during the 5-year follow-up period are included, and saved health care costs are excluded, Hartslag Limburg turned out to be cost-effective.

The present study had a number of advantages over previous studies. First, contrary to most previous studies, the cost-effectiveness was calculated from the societal perspective where possible, producing CE-ratios that are applicable to macro-level decision making. In addition, the resulting cost

estimation can be generalized to other settings and countries. Finally, there was a control group available, allowing the effects of the program to be estimated.

Despite these advantages, the study had some limitations too. One of the imperfections was that the effects of the intervention were assessed using groups composed of persons from an existing cohort. This means that we may have measured the effectiveness of the intervention in a specific group of persons instead of a random sample of the population. The persons included in the study were motivated to participate in scientific research and might be more concerned with their health than a random sample of the population. Consequently, the effects might not be generalizable in that sense.

Almost 50% of the Hartslag Limburg interventions were performed in the 4 LSES areas, which comprise 20,000 inhabitants. It is not known whether our study population included persons from these areas. If this was not the case, this might have caused an underestimation of the effects of Hartslag Limburg. Results of an earlier study on the effects of Hartslag Limburg indicate, however, that there were no differences in effects between persons with a low SES and persons with a high SES.²⁶ However, there is no information available whether the LSES persons included into the research groups were also living in the LSES neighborhoods prioritized by Hartslag Limburg.

Besides the above uncertainties regarding the research group, which might affect the final effects and thus the cost-effectiveness ratio, the assumptions used in the chronic disease model – which was used to extrapolate the intermediate effects to yols – may have influenced the calculated CE ratio. For example, we assumed a cumulative effect of CVD risk factors on cardiovascular health and death. It is well known, however, that CVD risk factors have an exponential effect on CVD health. This also means that the effects – and thus the cost-effectiveness – of Hartslag Limburg may have been underestimated. As was discussed earlier in this section, constricting the time horizon to the follow-up time, also leads to conservative estimates of CE-ratios.

Conclusions

From the present study it can be concluded that the community program of 'Hartslag Limburg' is cost-effective, even under conservative assumptions. Implementation of the program seems thus to be favorable, at least from an economic point of view.

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9

General discussion

Introduction

The subject of this thesis is the economic evaluation of preventive interventions for cardiovascular diseases (CVD)s. The thesis (1) provides insight into methodological issues related to cost-effectiveness analysis of preventive interventions, (2) reports on the costs, effects, and cost-effectiveness of the CVD prevention programmes of Hartslag Limburg, and (3) critically examines one of the assumptions often made, namely that targeting LSES groups is most efficient because of the high potential health gain among these groups.

This chapter summarizes the main findings of the individual studies and draws general conclusions. Then we take a critical look at the methods used for the calculation of the costs, the effects, and the cost-effectiveness because the methodology used influences the internal and external validity of the results. The role of reviews in the collection of evidence of cost-effectiveness is also discussed.

Besides the methodology, the characteristics of the intervention and the specific choices made in the carrying out of the Hartslag Limburg programmes are expected to have influenced the outcome of the economic evaluation. This is especially true for the Hartslag Limburg community programme because of its complex and innovative design. The fourth section of this chapter describes some important choices made during the Hartslag Limburg programme and considers the effects that these choices are expected to have on the resulting cost-effectiveness ratio.

We conclude the chapter by elaborating on the expected influence of the study outcomes on policy-making. This is a relevant question because economic evaluation research attempts to facilitate decision-making, but is not independent within the decision-making process.

Summary of the main findings

Although guidelines for economic evaluation research are important for drawing firm conclusions from economic evaluation studies, it can be concluded from the present thesis that those studying cost-effectiveness in the field of prevention (Chapter 2) often do not adhere to the guidelines. It was also concluded that neglecting these guidelines could result in a large bias in the cost-effectiveness

ratio (Chapter 3). The bias gives a systematic increase of the cost-effectiveness. In order to prevent bias resulting from not applying the methods correctly, the present study adhered to the guidelines for economic evaluation research whenever possible. In Chapter 7, the costs of the Hartslag Limburg community programme are calculated according to the guidelines for cost calculation. The recommended bottom-up procedure is used to calculate the costs of the interventions within the community programme, which are about €0.9 million. In Chapter 8, the cost-effectiveness ratio was calculated to be in the range of €950 to €12,500 per yols. Thus it was concluded that community programmes like Hartslag Limburg's are quite favourable, even in the light of conservative assumptions. The result is positive in spite of the fact that the Hartslag Limburg community programme focussed on neighbourhoods with low socio-economic status, which might not have been the most preferred option from an economic point of view, as Chapter 4 shows.

We tried to evaluate the effects of one of the most expensive interventions within the Hartslag Limburg community programme separately, namely the 'Tasty and Healthy' intervention, which took place in a butcher shop. The effectiveness of the intervention, which consisted of labelling low-fat meat products and providing health education in the shops, could not be proven (chapter 6).

The Hartslag Limburg high-risk programmes do not receive as much attention in this thesis as the community programme does because previous studies do not find effects on behavioural or biomedical parameters. Calculating the cost-effectiveness ratio of the high-risk programmes only seemed important if the programmes were effective in terms of improving the quality of life. We evaluated the effects of the high-risk programmes on the quality of life in chapter 5, but as they could not be proven definitely, we did not consider an economic evaluation informative.

Methodological considerations

A variety of research methods were used for this thesis. The strengths and weaknesses of these methods are discussed here. The main points of the discussion of the methods are their influences on the internal and external validity of the study outcomes. We consider the methods used to establish the effectiveness, the methods used to calculate the costs, the methodology of

extrapolating intermediate effectiveness to years of lives saved (yols), and the innovative approach for reviewing cost-effectiveness studies of interventions to decrease the prevalence of smoking.

Validity aspects of the methods used to establish effectiveness

The use of a randomized, controlled trial to establish effectiveness in the Hartslag Limburg's secondary prevention trial

We evaluated the effects within the secondary prevention trial with the randomised controlled trial (RCT), which is the 'gold standard' in medicine because of its high internal validity.^{1 2 3} Only one condition for the RCT was not met: blinding of patients was impossible because the intervention took place in the behavioural sphere and a good placebo intervention could not be provided. The awareness of patients about their own condition (intervention or control) threatens the internal validity in two ways. First, it might lead to greater compliance in the intervention group than in the control group. In the present study, however, dropout was equal in both study groups. Second, patient awareness in combination with an often-occurring preference for being assigned to the intervention group instead of the control group might have influenced the outcome measure (in our case: self-rated quality of life). It is not very likely that this occurred in the present study because no significant differences between the intervention group and the control group were observed.

For the aim of the current thesis, which is to facilitate decision-making for a large population, a high degree of generalizability of the results is required.^{1 2 3 4} The drawback of the unquestionable internal validity of RCT designs, however, is that their external validity is often doubtful. In order to obtain unquestionably valid internal results, RCT designs are very experimental and do not represent the real-world situation very well.^{1 5}

Within the Hartslag Limburg secondary prevention trial, the blinding of the cardiologists prevented them from encouraging the patients to change their behaviour, something which they would probably do in a real-world situation, and which would increase the effectiveness of the intervention.

As in most RCTs, a selected group of cardiologists performed the intervention, which took place within a patient population that did not fully represent the target population.^{1 5}

The small number of cardiologists who participated in the study was probably due to the degree of belief and interest in the study as well as time

constraints.¹⁻⁵ The low degree of representation of the patient population in RCTs is generally due to (1) the strict inclusion and exclusion criteria, (2) the fact that not all eligible patients give informed consent for participation, and (3) dropouts, selective or not.¹⁻⁵

Within Hartsлаг Limburg, the use of strict inclusion criteria is probably the most important reason for the doubtful external validity of the study results. The intervention was available to all the patients who had recently suffered a cardiovascular event, in spite of the fact that most physicians (who refer the patients to the intervention) were of the opinion that the intervention would benefit only a subgroup of these patients. In a real-world situation, only this subgroup is expected to receive the intervention, and the results of the present study can only be generalized with caution.

As in almost all studies, not all the eligible patients gave informed consent. The percentage of patients that did not enter the study is not known, but the physicians who asked people to join the study reported a high rate of inclusion. About 20 percent of the participants dropped out during the study, but this was not selective.

The external validity of the primary and secondary prevention trial designs is especially problematic because the intervention is not in the biomedical sphere, but the behavioural. Outcomes of behavioural interventions depend to a much greater extent than those of biomedical interventions on characteristics of the patients and caregivers, such as the attitude towards the intervention and capacities.¹⁻²⁶

Those who participate to studies that aim at changing behaviour are likely to be more receptive to the intervention than persons who do not because they are likely to have a more positive attitude towards the intervention. The same is true for caregivers: those with a more positive attitude will participate in the study and promote the intervention enthusiastically. Furthermore, the quality of behavioural interventions, and thus their effectiveness, depends on the capacity of the person who is giving the care.

The use of a cluster randomized controlled trial to establish effectiveness in the primary prevention trial.

The primary prevention trial was in most aspects identical to the secondary prevention trial, and the remarks also apply to the primary prevention trial. There were two differences between the designs. The effects of the primary prevention trial were assessed within a *cluster* RCT, and the physicians were not blinded in the primary prevention trial.

The cluster RCT was used in order to prevent contamination between patients with the same general practitioner (GP). Not blinding the GPs approximates the real-world situation better because GPs can provide additional support for healthy behaviour to patients who receive health counselling.

The use of a cohort study to establish effectiveness of the Hartslag Limburg community programme

The Hartslag Limburg community programme was evaluated in a nonexperimental, real-world setting and can thus be described as a pragmatic trial.⁷ Within this community programme, a cohort study with a comparison group was used to study the effectiveness of the programme. An RCT design was not used because this design cannot accommodate the flexibility and the large scale of community programmes.^{8 9} Randomization cannot be achieved because not everybody has the same chance of receiving the intervention. Cohort studies that use an adequate comparison group are the preferred option for evaluating the effectiveness of health promotion programmes because the groups are then comparable with respect to most baseline characteristics and the known confounding variables.^{1 2 6} Blinding cannot be achieved in the evaluation of large-scale community programmes either.

In spite of the use of an adequate control group, the design has its drawbacks. Problems with the internal validity are the most prominent in pragmatic trials. The nonexperimental design makes the study vulnerable to bias, which threatens the internal validity of the study. In spite of the fact that we used a comparison group that was comparable to the intervention group for prevalence of CVD and its risk factors, demographic variables, and the degree of urbanization, other unknown confounding factors might not be distributed evenly among the regions and may have negatively affected the internal validity. However, a recent study shows that the quality of well-designed observational studies is not necessarily worse than that of RCT-designed studies.¹⁰

Contrary to the internal validity, the external validity of pragmatic trials is generally unquestionable because the evaluation takes place in a real-world setting. A marginal comment about the external validity of the Hartslag Limburg community programme must be made. The cohort that was used might not be representative for the general population because the participants were recruited from a former monitoring study. Although this might have affected the external validity, the comparison group also consisted of participants of a similar monitoring project, which means that this did not affect the internal validity of the study.

A consequence of community programmes is that the results are not completely independent of time and place.⁶ This means that evidence of community programmes for preventing CVD will always be in motion.

The use of an observational design to establish the effects of the 'Tasty and Healthy' intervention

Observational designs provide weaker empirical evidence than experimental studies do because of the potential for large confounding biases. This is especially true if an adequate control group is lacking, which is the case in the evaluation of the 'Tasty and Healthy' intervention.

The evaluation of the 'Tasty and Healthy' study was subject to a number of factors that threatened the internal and external validity of the study. They include the emergence of foot and mouth disease, the opening of a supermarket in front of the butcher shop, the owner's change of the sales policy during the intervention, and the nonadherence of the owner to agreements about the carrying out of the intervention. Furthermore, phenomena like store switching and purchase acceleration might have biased the results. The results of this study must therefore be interpreted with great caution because the design was far from optimal.

There were reasons for the use of this observational design. The first is related to the method of working in the Hartsлаг Limburg project. Health promotion specialists implemented the programmes, and the scientific staff evaluated them. In spite of the fact that the health promotion specialists who implemented the programme interventions were encouraged to appeal to the expertise of the scientific staff, this did not always happen. In the case of the intervention 'Tasty and Healthy', the scientific staff only became involved in the evaluation of the intervention after it had already been implemented. Obviously, this prevented us from achieving a better study design. The preferred option would have been to focus on the consumption pattern of the clientele instead of on the sales of the butcher shop. The second reason is that, although a control population was available, there had been no investigation about preconditions for performing a sound evaluation of the effectiveness. It turned out to be practically infeasible for the control butchers to provide us with the necessary information for the evaluation, namely, the amounts of meat products sold during the last 2 years. Finally, firmer agreements with the owner of the butcher shop might have prevented a further decline in the quality of the study.

Validity aspects of the cost calculation of the community programme

Internal validity

Although we strove for a societal view, costs related to productivity losses and participant costs were not included into the costs calculation. This means that the internal validity is not optimal.

Including productivity losses is useful if the research consists of a working population. Because of the age of both those with established CVD and those at risk of CVDs (i.e. Chapter 5, mean age >60), excluding productivity costs does not seem to affect the internal validity of the study much.

Participant costs were not included because of lack of data. For many interventions, such as those for the national TV programme and radio commercials, it is extremely difficult to estimate the time input of the participants, and it is thus difficult to estimate its impact on the internal validity.

Furthermore, we decided to exclude costs for the development of new interventions because costs would not have to be made if the particular intervention were implemented elsewhere. Looking back at Hartslag Limburg, it might have been more accurate to include these costs, as the choices for the interventions to be done cannot be determined beforehand, but depend on the region-specific pre-conditions to a large extent. Specific circumstances would thus ask for specific interventions to be developed, and for this reason, including development costs would have been more accurate. The development costs within 5 years of Hartslag Limburg accounted for only €13,000, which is less than 1 percent of the total costs. This means that the bias caused by not incorporating the development costs is small.

In spite of these imperfections, the internal validity remains acceptable in our opinion.

External validity

It is important to have insight into the generalizability of the costs to other regions and countries. Because the cost calculation of the interventions was based on the resources necessary for successfully implementing a programme like that of Hartslag Limburg, the intervention costs that are calculated within Hartslag Limburg can be generalized to comparable regions with the same price level. Generalization of the intervention costs to other regions in the Netherlands is thus permissible.

When price levels differ from those in the Netherlands, generalization is slightly more complicated. Recent research shows that cost-effectiveness results vary from country to country.¹¹ This variation is due to different price levels; resource use is shown to be comparable in different countries.¹¹ The best way to guarantee the generalizability of the intervention costs is to give a detailed overview of the resource use.¹¹ Assuming that the necessary resources and the effects of the intervention do not vary between countries,¹¹ the costs can be generalized by linking local prices to the resource used. In this thesis, we applied this method to calculate the intervention costs.

This method could not be applied to the calculation of the network costs because these are very dependent on the existing degree of cooperation between institutions in a region. The specific input within Hartsлаг Limburg was used, and although this is internally valid, the external validity is doubtful. Sensitivity analysis shows that variation in the network costs does not greatly affect the cost-effectiveness ratio.

Healthcare costs saved because of better cardiovascular health were also calculated differently. For the cost savings that take place in the future, modelling techniques are used. These are sensitive to bias, because assumptions have to be made. The modelling technique used in this thesis is considered in the following section.

The healthcare savings are not included in the base case analysis because the non-CVD healthcare costs due to living longer have been shown to undo the CVD healthcare savings.

Modelling considerations

The cost-effectiveness calculation for preventative interventions requires the use of modelling techniques because long-term follow up is usually not feasible.^{5 12 13}

Recently, properties for good modelling were formulated in a consensus statement.¹⁴ The chronic disease model (CDM) that was used in the current thesis is fairly well in line with this statement.^{14 15 16} First, the CDM is transparent; Hoogenveen et al. outline it in detail.^{15 16} Second, the model meets the criteria of consistency: all parameter values are consistent within the logic of the model, and both the structures used in the model and the data used to build the model are consistent with recent information.^{15 16} Third, an independent competent analyst is expected to be able to reproduce the results, which means that the model leads to reproducible results. Fourth, the results are expressed in

terms of CVD cases prevented, which can thus be used for calculating the years of life saved (yols) and can be interpreted easily. Fifth, the causal relationships included in the model are explained and substantiated by recent evidence. Sixth, the model is kept as simple as possible. Seventh, parameter uncertainty is explored.

The CDM has some specific advantages, e.g. it combines several risk factors and diseases in one model.^{15 16} Complex calculations, such as the effects on CVDs of changes in several risk factors occurring simultaneously, are possible. Another advantage of the model is the explicit modelling of 'competing risks'.¹⁵ This means that the model takes into account that people can die of the same disease in a later stage or of other diseases, due to an extension of the life span.¹⁵ This prevents an overestimation of the effects.

Obviously, the use of the CDM also has its disadvantages. First, as is the case with almost all models, historical validation is impossible^{17 18} because time series of empirical data are not available. Therefore, 'true' validity cannot be achieved.^{17 18} Second, the CDM is as strong as its weakest link. Continuous input of high quality is thus required. To maintain and improve the quality of the results, the CDM is regularly updated with the latest information. Third, models are unable to fully represent the reality, which means that the external validity is not optimal.^{12 13 19} Fourth, the CDM has Markov properties, which means that the risk of CVD is determined by the current value of the risk factor and not by the value of the risk factor in the past. This leads to an overestimation of the effect.¹⁵ For example, a decrease in body mass index in the CDM leads to a direct decrease in the risk of CVD. Fifth, a probabilistic sensitivity analysis is not possible because of the complexity of the CDM, although this is highly valued in the field of medical technology assessment.¹⁴

In spite of these imperfections, the model simplifications are not expected to lead to a large bias.

Reviews

The present thesis contains two reviews: a traditional review and a more reflective review. The traditional review was aimed at gaining insight into the quality of cost-effectiveness studies. The conclusions are in line with previous results, namely, that guideline adherence was low.^{20 21 22} The disadvantage of a traditional review is that it does not provide insight into the magnitude of the bias caused by nonadherence to the guidelines. Therefore we cannot judge

whether guideline nonadherence is problematic. In that sense, the traditional review is not very informative.

The observation from the traditional review that guidelines are often not adhered to means that the reviewed studies are not internally valid. If the bias is large, then meta-analyses for gaining insight into the effectiveness of interventions for larger populations⁸ are not informative. Reviews that incorporate standardization of the results of the individual studies are then more useful to obtain insight into the cost-effectiveness studies of interventions for larger populations. This is especially true if the interventions are behavioural in nature. These interventions are often heterogeneous, which does not allow the results of the studies to be directly compared.

Chapter 3 this thesis presents an example of a review that standardizes cost-effectiveness ratios by recalculating the cost-effectiveness according to the guidelines. The outcome shows that guideline nonadherence can cause a large bias. We hope that showing the magnitude of the bias due to guideline nonadherence will contribute to improving guideline adherence for economic evaluation.

Because standardization adds value to traditional reviews, it is recommended to perform standardization within reviews whenever possible. However, some conditions must be fulfilled in order to successfully apply this method. First, such reviews can only apply standardization if the intervention is rather simple. A reconstruction of the resources used for complex interventions (for example, community programmes) is hardly possible because detailed information about the intervention is necessary.

Second, standardization can only be achieved if the intermediate effect parameter has clear end points and the course of the effects in the future is known. In our example, we used the quitting rate of smokers. Because detailed information is available about relapse, the long-term effects of the studies that have only followed up participants for a short period of time can be estimated accurately. This is not possible for changes in diet or exercise pattern, because too little is known about relapse.

Third, a simple model should be available to extrapolate the intermediate effects to the yols. This was available for the case of smoking. A condition for a simple model to be available seems to be the dichotomy of the intermediate outcome measure. Dietary changes and changes in exercise cannot be captured in a dichotomy, and a simple model cannot be applied.

Fourthly, standardization is only possible if there is a single intermediate effect parameter: a simple model requires the existence of only one intermediate effect measure. If the study contains more than one intermediate effect measure, as is the case for Hartslag Limburg, complex models are required to calculate the yols.

Performing a standardized review is thus certainly relevant and useful, but, before starting such an exercise, it is important to ascertain that the preconditions for successfully completing such a review are fulfilled.

The influence of characteristics of the community programme on the study outcome

Hartslag Limburg is a complex programme that contains both favourable and unfavourable elements for the study outcome. These are discussed in the next sections.

Characteristics that have a positive influence on the study's effects

A number of characteristics of the Hartslag Limburg community programme contributed to the success of the programme, and they therefore contributed to the effectiveness and to the favourable cost-effectiveness ratio. These characteristics included the formation of a network, the use of media to bring the programme to the attention of the public, the formation of local committees to implement the interventions, and the cooperation between health education specialists and scientific staff.

Network

As discussed in Chapter 1, one of the major innovative aspects behind the success of Hartslag Limburg is the creation and maintenance of a network of participating agencies: without such a network it would be impossible to implement such a variety of interventions for such a long period of time. This network certainly contributed to the favourable cost-effectiveness ratio.

Media attention

Another valuable aspect of the implementation that influences the cost-effectiveness ratio is that the programme's initiatives and successes were brought to the attention of the public via newspaper, radio, local TV, and a conference. This increased the likelihood that inhabitants of the region would

participate, and it facilitated the expansion of the Hartslag Limburg network by attracting sponsors and commercial partners to join.

Local committees

The formation of local committees through which the interventions were implemented certainly increased the reach of the interventions. The support given to these committees by social workers and civil servants has been critical for the success of these committees. This is especially true for the committees situated in the low socioeconomic status (LSES) areas where social workers were able to engage local inhabitants because people from the disadvantaged areas are more likely to participate in an intervention when someone in their own neighbourhood invites them to do so. Having local committees guaranteed that the neighbourhood had some say in the interventions that were implemented.

Cooperation between health education specialists and scientific staff

Cooperation within Hartslag Limburg between health education specialists and scientific staff was good, and meant that health education specialists could consult scientific staff whenever necessary and that the scientific staff scientific staff was given the information that was needed in practice. Furthermore, it could contribute with scientific data to illustrate what progress was being made; this data was used to give feed back to financers, politicians and media, in order to sustain support.

Characteristics that have a negative influence on the study outcome

The Hartslag Limburg community programme also had some imperfections. Most of the Hartslag Limburg characteristics mentioned that were necessary for the success the community programme have their drawbacks, but there are also other disadvantages of the community programme.

Network

The drawback of needing a network is that the coordinating agency of Hartslag Limburg is dependent on its participating agencies. This implies that the coordinating agency had to make concessions to the wishes of the participating agencies when implementing interventions. As a result, the wishes of the participating agencies often took precedence over the evidence base of the interventions. As a consequence, the cost-effectiveness might be negatively affected.

Media attention

The fact that Hartslag Limburg can only be operational if it succeeds in getting the long-term attention of the public means that its interventions should be implemented without interruption. For this reason, Hartslag Limburg often put more emphasis on the number and reach of the interventions than on the quality. The cost-effectiveness ratio might have been higher if more attention had been paid to the quality of the interventions.

Local committees

Local committees are essential for the implementation of interventions, especially within the LSES neighbourhoods. Within these committees concessions had to be made as to what people wanted and would regard as feasible. Again, this led to the execution of interventions for which the effectiveness was not properly established. Moreover, the principle to respect people's choices caused that many interventions to increase dietary pattern and exercise were carried out, paying only little attention to smoking cessation (for which there was no support although effective interventions were available).

Focus on low socio-economic status

Many of the interventions were implemented in the LSES neighbourhoods. As Chapter 4 shows, this might not be the preferred option from an economic point of view because effects are more difficult to achieve and the costs for reaching people with LSES are much higher. This also implies that the external validity is limited because the results can only be generalized to comparable regions.

Public private partnership

The intervention carried out within a public private partnership was expensive and chapter 6 of this thesis shows that its effectiveness could not be proven. Including this intervention into Hartslag Limburg put thus a negative strain on the cost-effectiveness ratio.

All of these aspects might influence the cost-effectiveness ratio. However, it should be realized that, while improvement of these points should be attempted, these characteristics are to some extent inherent to a community programme like that of Hartslag Limburg and the negative side effects cannot be completely eliminated.

The influence of the study outcomes on policy-making

Chapter 8 shows that the Hartslag Limburg community programme seems to be cost-effective even when conservative assumptions are made. Remarkably, the community programme was not continued after the 5-year evaluation period despite its favourable outcome, while the individual health-counselling intervention, which showed no effects on biomedical risk factors, was implemented at Maastricht University Hospital. This is incomprehensible from an economic point of view. In spite of this, the observation confirms the results of previous research, which shows that economic evaluation studies have a rather limited impact on public health policy-making at both the national and the local level.^{23 24 25 26 27} Fortunately, most policy-makers regard economic considerations as important.^{24 28} Lack of interest for economic evaluation studies does not seem to be the main reason for their small impact. The most plausible explanation for the limited use of economic evaluation research in policy-making is that policy-making is not a rational process and its outcome depends on many aspects, such as social, economic, cultural, practical, ethical, personal, and political ones.^{23 29 30} We now explore the specific reasons for the policy decisions concerning the Hartslag Limburg project.

Hartslag Limburg

Hartslag Limburg fulfilled some preconditions that increased the likelihood that its scientific results will be used in the decision-making process. First, the research topic corresponds with the beliefs and existing focus of the policy-maker:^{23 29 31} national and local politicians were already aware of the necessity of lifestyle changes. Second, a collaborative team of professionals carried out the research.²⁹

The Hartslag Limburg community programme

In spite of these preconditions, the economic evaluation study of the community programme was not influential in the decision-making process. Obviously, other considerations were more important.

One of the reasons why the economic evaluation study of the community programme was not influential is that generating the scientific results took more time than the policy-making.²⁴ As no judgements could be made about the cost-effectiveness of the community programme at the time that the contributing

agencies reconsidered their budgets, many decision-makers decided not to continue the contribution to the community programme.

Furthermore, there was a tightening of the contributing agencies' budgets available for health promotion activities as a result of the recession in the Netherlands. This was also unfavourable for the continuation of Hartslag Limburg, especially because decision-makers experience considerable difficulty in moving resources from one sector to another, as research has shown.^{24 26}

However, even if the results of the economic evaluation study had been available at the time the decisions were being made, the Hartslag Limburg community programme would probably still not have been implemented. There are some specific characteristics of community programmes that make it extremely difficult to realise a translation of scientific findings into policy.

First, the complex nature of Hartslag Limburg requires support from local decision-makers instead of from central decision-makers. Local policy-making is – more than central policy-making – marked by negotiation and uncertainty, which makes economic evaluation research less influential in local policy.²³

A second complicating factor is that a community programme like that of Hartslag Limburg only succeeds if many decision-makers support it. All these decision-makers are exposed to their specific myriad of competing pressures, including social, financial, electoral, strategic development, terms and conditions of employees, and colleagues' opinions.²³ For this reason, it is rather difficult to change policy in many agencies at the same time.

Third, decision-makers are often unconvinced of the study outcomes.^{23 24} Because of its complexity and preventive nature, the Hartslag Limburg community programme is especially vulnerable to this: its effects and costs cannot be estimated with standard designs and guidelines, and many assumptions are made in the calculation of the cost-effectiveness ratio.

Fourth – and this is also true for similar complex preventive interventions – economic evaluation studies do not always fulfil the expectations of the policy-makers. For example, policy-makers have a short time horizon and are interested in the allocation of resources. In contrast, health economists use a lifetime horizon and usually do not go into the allocation of resources.²⁶ Within the economic evaluation of Hartslag Limburg, the base case cost-effectiveness did not include costs saved in the future (Chapter 8). Furthermore, the study tried to meet the wishes of the policy-makers in the allocation of resources by listing the kinds and quantities of resources used for every intervention implemented within Hartslag Limburg (Chapter 7). However, this was on an

overall level, and we were not able to specify this allocation for the contributing organisations separately.

Many other factors besides efficiency considerations influence the decision-making, so that actively promoting the Hartslag Limburg community programme is crucial. The need to inform decision-makers personally is great because they are often unconvinced of the outcomes of economic evaluation research and their interests in the issues are not always described in economic evaluation reports. Unfortunately, within Hartslag Limburg, the coordinating agency withdrew at the time when many contributing agencies were about to make decisions, and active lobbying diminished.

The Hartslag Limburg high-risk programme

Secondary prevention trial

Contrary to the community programme, the secondary prevention counselling intervention was implemented at the Maastricht University Hospital. A number of aspects contributed to this.

To start with, cardiologists believed that the intervention would be more effective and cost-effective if only a subgroup of patients who had had recent CVD events were referred to the counselling sessions. Second, only one decision-maker was involved: the Chairman of the Board of Directors of the hospital. Furthermore, implementing the intervention had only a small but clear effect on the budget. The intervention is straightforward and implementation is easy: the only resources necessary are a counsellor and a room in which the specialist can carry out the counselling sessions. Ethical aspects, in the sense of feeling obliged to offer patients preventive care, might also have contributed to the decision to implement the counselling interventions in the hospital.

Primary prevention trial

Even though the behavioural counselling in the general practices was identical to the behavioural counselling in the hospital setting, the intervention was not implemented in the general practices. This was probably due to a combination of unfavourable factors.

First, although it was shown not to be decisive in the decision-making process, there was no scientific evidence that the intervention was effective. Second, many decision-makers were involved, so that making decisions was difficult. There were also some practical implementation problems, like the housing of the counsellor. Furthermore, in order to refer patients to the counsellor, GPs need to have an overview of high-risk patients. As we experienced within Hartslag Limburg, GPs are not willing to put any effort into selecting high-risk

patients. A time constraint on GPs is another factor why the intervention was not implemented. In contrast to the cardiologists in the secondary prevention trial, GPs are expected to spend additional time in a consultation on the CVD risk factors of the patient, which would not be the usual subject of the consultation.

The Hartslag Limburg experience thus confirms previous research that concludes that economic evaluation studies are not likely to have a direct impact on policy-making.

Economic evaluation research can be more influential if researchers change their attitude by broadening their view and by learning to understand the policy-making process better.²³ Furthermore, researchers need greater access to information about the priorities and needs of policy-makers.²³ To influence policy-making more, researchers should broaden their work to include these priorities and needs. Providing information about the cost-effectiveness in reports of results is not enough, especially if interventions are as complex as those of Hartslag Limburg. All other information that might influence the results should be reported, as well as the promises and pitfalls of the intervention and recommendations for future research. Policy-makers can contribute by communicating their needs more clearly to the researchers.²³ It is important that policy-makers learn more about economic evaluation research in order to be able to judge its value.³¹

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Summary

The focus of this thesis is the economic evaluation of the prevention of cardiovascular diseases (CVDs). In the Netherlands, more than a million people suffer from CVDs, and 35% of all deaths each year can be attributed to CVD. The high prevalence and the chronic condition of many CVDs induce high costs: about 10 percent of the total Dutch healthcare budget is spent on preventing and curing CVD.

The continuous rise of the healthcare costs during the last decades has led to an increasing interest in economic evaluation research. However, most economic evaluation studies have focussed on curative and medical interventions. Relatively few in the preventive and behavioural sphere have been economically evaluated. Obviously, this has led to an imbalance of evidence, the evidence favouring the latter. Very little knowledge is available about the cost-effectiveness of large-scale community programmes.

This thesis is particularly useful because of the growing need of economic evaluation research into preventive and behavioural interventions. We aim at providing insight into the methodology of economic evaluation research and present a cost-effectiveness analysis of a large-scale prevention project.

Chapter 1 provides background information about CVD and about economic evaluation research. It gives an overview about the different types of CVD and CVD risk factors. It describes the available methods for achieving behavioural change. Trends in prevalence, incidence, and mortality are also mentioned, and the difficulties that emerge in cost-effectiveness studies in the field of prevention are explained. Finally, a description of the Hartslag Limburg (the Limburg Heartbeat) project is given.

Chapter 2 aims at providing insight into the quality of cost-effectiveness studies related to the prevention of CVD. We used guidelines for economic evaluation research to review studies that reported on the cost-effectiveness of interventions to reduce tobacco dependence. It was concluded that the quality of the studies leaves much to be desired.

Chapter 3 was designed to gain more insight into the direction and degree of bias resulting from nonadherence to the guidelines for economic evaluation. The cost-effectiveness ratios from the studies reviewed in Chapter 2, were recalculated, using the guidelines for economic evaluation research in

healthcare. This standardization procedure caused increases of cost-effectiveness ratios in all cases. However, the degree of increase varies considerably: increases ranged from 120 percent to 5600 percent. This shows that nonadherence to the guidelines can lead to considerable bias in the cost-effectiveness ratio.

Chapter 4 reports a literature search to investigate one of the premises of Hartslag Limburg, namely, that focussing the community programme on people with low socio-economic status (LSES) is more efficient than focussing on the general population. This assumption is based on the observation that the prevalence of both CVD and its risk factors are greater among those with LSES than among those with a higher socio-economic status. The present study does not support the hypothesis that focussing on LSES groups is more efficient. This is partly due to the fact that people with LSES are also exposed to risk factors other than the classical risk factors for CVD, which causes the effected reduction of the classical risk factors of CVD to be smaller than expected. Further, the costs of reaching LSES groups with preventive measurements are much greater than the costs of reaching people with a higher socio-economic status. From an economical perspective, focussing on LSES groups is not advantageous.

Chapter 5 reports the effects in terms of quality of life, of individual counselling sessions carried for by people with an increased risk of CVD and by people with established CVD. We evaluated two studies with a randomized design; one was a cluster study. The RAND 36-Item Short Form Health Survey and the EuroQol visual analogue scale were used to assess the quality of life. Although the study showed a statistically significant difference for physical functioning between the intervention group at risk of CVD and the control group, the study does not clearly prove the effectiveness of behavioural counselling for quality of life.

Chapter 6 describes the evaluation of a health-promoting intervention that was established with a public-private partnership. In a butcher shop, low-fat meat products were labelled and the personnel of the shop provided information to the customers about low-fat meat. The effectiveness of the intervention could not be shown. In the same study, the effect of regular price reductions was evaluated. Although the price elasticity was high, no shift from the sales of high-fat meat to low-fat meat was observed. Because of potential confounding factors, some of which are related to the partnership with a private organisation, the results of this study must be interpreted with care.

Chapter 7 provides a detailed calculation of the economic costs of the Hartslag Limburg community programme. We calculated the costs in a bottom-up procedure and followed the steps for cost-calculation recommended by Drummond et al. (1997), namely, identification, quantification, and valuation. This study is the first to give an overview of all the resources necessary to implement a large-scale intervention like that Hartslag Limburg's. This facilitates budgeting. The bottom-up procedure contributes to the generalizability of the results.

Chapter 8 presents the cost-effectiveness analysis of the Hartslag Limburg community programme. We analysed the cost-effectiveness according to the guidelines for economic evaluation research wherever possible. The intermediate effects were determined by measuring the biomedical risk factors for CVD before and after the intervention in the intervention region as well as in a comparable control region. A Markov multistate transition model was used to extrapolate the intermediate effects to the years of lives saved. To test the robustness of the results, a sensitivity analysis was used. The base case cost-effectiveness was based on conservative estimates and was calculated to be €12,500, ranging from €950 to about €16,500. Thus, it was concluded that programmes like Hartslag Limburg are cost-effective, even with negative assumptions.

Chapter 9 starts with an overview of the conclusions that can be drawn from this thesis. Then it reviews the methodologies used within the thesis, focussing on the internal and external validity of the studies. The Hartslag Limburg community programme has a unique design, and its characteristics influence the outcome. Chapter 9 considers these aspects and the way in which they influence the cost-effectiveness ratio. We conclude the chapter by discussing the effects of the favourable outcome of the economic evaluation of the community programme on policy-making. Although the Hartslag Limburg community programme is cost-effective and methodologically well evaluated, it is not likely that it will be implemented because of factors that are explained in Chapter 9.

Samenvatting

Centraal in dit proefschrift staat de economische evaluatie van preventie van hart- en vaatziekten. Meer dan een miljoen Nederlanders leidt aan een hartvaatziekte en 35 procent van de totale sterfte is eraan te wijten. Door de hoge prevalentie en de chronische aard van veel hart- en vaatziekten brengen ze hoge kosten met zich mee: ongeveer 10 procent van de totale gezondheidszorgkosten wordt besteed aan het voorkomen, maar vooral aan het genezen van hart- en vaatziekten.

De aanhoudende stijging van de kosten binnen de gezondheidszorg heeft de afgelopen jaren geleid tot een toenemende belangstelling voor economisch evaluatie onderzoek. Tot nu toe waren de meeste economische evaluatie onderzoeken gericht op curatieve en medische interventies. Hierdoor is er een scheefgroei ontstaan in de bewijskracht in het voordeel van dit soort interventies ten opzichte van preventieve en gedragsmatige interventies. Vooral over de kosten-effectiviteit (KE) van complexe preventieve programma's die gericht zijn op een grote bevolkingsgroep is nog weinig bekend.

Het huidige proefschrift sluit aan bij de steeds groter wordende behoefte aan economisch evaluatieonderzoek van preventieve en gedragsmatige interventies. Het beoogt inzicht te verschaffen in zowel de methodologie van economisch evaluatieonderzoek binnen dit gebied als in de uiteindelijke uitkomsten in termen van KE ratio's.

Hoofdstuk 1 geeft achtergrondinformatie over hart- en vaatziekten en over economische evaluatie onderzoek. In dit hoofdstuk wordt een overzicht gegeven van de verschillende verschijningsvormen van hart- en vaatziekten, van de risicofactoren voor hart- en vaatziekten en van methoden om gedragsverandering te bewerkstelligen. Ook de trends in prevalentie, incidentie en sterfte van hart- en vaatziekten worden besproken. Vervolgens wordt er ingegaan op de specifieke problemen die zich voordoen bij het uitvoeren van economisch evaluatieonderzoek bij preventieve interventies. Het hoofdstuk sluit af met uitleg over het Hartslag Limburg project.

Hoofdstuk 2 had als doel inzicht te verkrijgen in de kwaliteit van KE studies binnen het gebied van preventie van hart- en vaatziekten. Als voorbeeld is de kwaliteit van KE studies van 'stoppen met roken' interventies geëvalueerd aan

de hand van richtlijnen voor economische evaluatie. De conclusie van de studie was dat de kwaliteit van de studies veel te wensen over laat.

Hoofdstuk 3 is opgezet om meer inzicht te krijgen in de richting en mate van bias die het niet naleven van de van richtlijnen met zich meebrengt. De KE ratio's van de studies die gebruikt zijn bij de review van hoofdstuk twee zijn - gebruikmakend van de richtlijnen voor economische evaluatie - opnieuw berekend. Deze standaardisatieprocedure zorgde bij alle studies voor een verhoging van de KE ratio. Echter de mate van toename verschillende zeer sterk: van 120 procent tot 5600 procent. Dit geeft aan dat het niet opvolgen van richtlijnen kan leiden tot enorme bias in de KE ratio.

Hoofdstuk 4 onderzoekt middels een literatuuronderzoek één van de aannamen die ten grondslag ligt aan Hartslag Limburg, namelijk dat het richten van een community programma op personen met een lage sociaal economische status (LSES) efficiënter is dan het richten van een community programma op de algehele bevolking. Deze veronderstelling is gebaseerd op de waarneming dat cardiovasculaire ziekten en ook de gedragsmatige en biomedische risicofactoren het meest voorkomen bij personen met een LSES. De huidige studie vindt geen bewijs dat het efficiënter is om te focussen op LSES groepen dan op de algehele bevolking. Dit komt omdat er bij LSES groepen meerdere risicofactoren een rol spelen, waardoor de effecten van een afname in risicofactoren onder LSES groepen lager is dan verwacht kan worden op basis van het medisch exponentieel model. Daarbij zijn de kosten die gemaakt moeten worden om LSES groepen te bereiken met preventieve maatregelen veel hoger dan de kosten om personen met een hoge sociaal economische status bereiken. Vanuit een economisch perspectief heeft het dus niet de voorkeur om te focussen op LSES groepen.

Hoofdstuk 5 beschrijft een voorbeeld van een samenwerkingsverband tussen de publieke en private sector. Een slager droeg via het labellen van vleesproducten met een laag vetpercentage en voorlichting door het personeel bij aan de preventieve activiteiten van Hartslag Limburg. Er is geen bewijs gevonden voor effecten van deze voorlichtingsinterventie. Verder was het effect van prijsreducties geëvalueerd. Er is geen verschuiving waargenomen in de verkoop van vlees met een hoog, naar vlees met een laag vetpercentage. De resultaten van deze moeten met voorzichtig geïnterpreteerd worden vanwege het feit dat er tijdens de studie gebeurtenissen plaatsvonden die de resultaten van de studie kunnen vertekenen. Een belangrijke boodschap van dit hoofdstuk

is dat de samenwerking met een private partner in de gezondheidsvoorlichting specifieke moeilijkheden met zich meebrengt, die onderkend moeten worden voordat een samenwerkingsverband aangegaan wordt.

Hoofdstuk 6 evalueert de effecten van individuele counseling bij personen met een verhoogd risico op hart- en vaatziekte en personen die recent een hartvaatziekte hebben meegemaakt in termen van kwaliteit van leven. De studies waren opgezet volgens een (geclusterd) gerandomiseerd design. Kwaliteit van leven is gemeten met behulp van de RAND-36 vragenlijst en de thermometer van de euroqol. Ondanks de bevinding dat interventiepersonen met een verhoogd risico op hart- en vaatziekten een hoger lichamelijk functioneren dan controle personen met een verhoogd risico, kon deze studie niet duidelijk de effectiviteit van individuele counseling op kwaliteit van leven aantonen.

Hoofdstuk 7 geeft een gedetailleerde beschrijving van zowel de methodologie van de kostenbepaling als de economische kosten van het community programma van Hartslag Limburg. De kosten zijn via een bottom-up procedure berekend en volgde de stappen van Drummond et al (1997), namelijk identificatie, volumebepaling en waardering van de kosten. De meerwaarde van deze studie is dat de opbouw van de kosten voor het eerst zichtbaar is gemaakt. Dit vergemakkelijkt budgettering. Daarbij is de bottom-up methode nauwkeurig en draagt ze bij aan generaliseerbaarheid van de gegevens.

Hoofdstuk 8 presenteert de kosten-effectiviteitsanalyse van het community programma van Hartslag Limburg. Zoals uitvoerig besproken in hoofdstuk 7 zijn de kosten berekend volgens richtlijnen voor economische evaluatie. De intermediaire effecten zijn bepaald door de biomedische risicofactoren voor hart- en vaatziekten (bloeddruk, cholesterol en BMI) zowel voor aanvang als na afloop van de interventie te meten en dit te vergelijken met cohort uit een vergelijkbare controle regio.

Een zogenaamd Markov-type multi state transitie model is gebruikt om de intermediaire resultaten te extrapoleren naar het aantal gewonnen levensjaren en een gevoeligheidsanalyse is uitgevoerd om de robuustheid van de resultaten te testen. De op conservatieve aannamen gebaseerde KE ratio kwam uit op €12,500, met een range van €950 tot ongeveer €16,500 in de gevoeligheidsanalyse. De conclusie is dat programma's zoals Hartslag Limburg zelfs onder negatieve aannamen KE lijken.

Hoofdstuk 9 blikt terug op het uitgevoerde onderzoek. Na een kort overzicht betreffende de conclusies van het proefschrift, worden de methoden die

gebruikt zijn in het proefschrift geëvalueerd. De invloed van de gebruikte methoden op de interne en externe validiteit staat hierbij centraal. Vervolgens wordt bediscussieerd welke gevolgen de keuzen die gemaakt zijn binnen Hartslag Limburg hebben gehad op de uitkomst van het economisch evaluatie onderzoek. Omdat economisch evaluatie onderzoek als doel heeft beleidsbeslissingen te vergemakkelijken, sluit het hoofdstuk met een beschouwing over de te verwachten invloed van Hartslag Limburg en soortgelijke programma's op beleid.

Ondanks dat Hartslag Limburg een kosten-effectief programma is gebleken dat methodologisch goed geëvalueerd is, is de kans dat het programma daadwerkelijk geïmplementeerd gaat worden niet groot. Een aantal factoren die in Hoofdstuk 9 besproken worden zijn hiervoor verantwoordelijk.

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Sandy

Curriculum Vitae

Sandy Ronckers was born on April 7th, 1976 in Roermond, the Netherlands. She attended secondary school (VWO) at the Bisschoppelijk College Schöndeln in Roermond. After graduation in 1994, she studied Health Sciences and Psychology, both at Maastricht University. She graduated with specializations in Mental Health Sciences and Biological Psychology in 1999.

In 1999 she enrolled as a PhD student at Maastricht University: Department of Health Organisation, Policy and Economics (HOPE / BEOZ). During her PhD training, she was involved in the research described in this thesis. During the first years of her PhD training, she also worked as a researcher at the Department of General Practice at the same university.

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