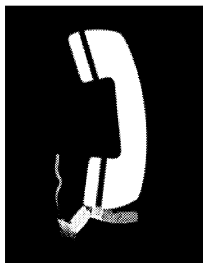


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Telephone support for smoking cessation
The Swedish example

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ABSTRACT

Background: Tobacco is a major public health problem that needs to be addressed. The Swedish quitline is a telephone-based free-of-charge tobacco cessation service.

Objective: To study the effectiveness and the cost-effectiveness of the Swedish quitline.

Methods: The study population comprised clients calling the quitline and returning a registration questionnaire mailed home to the caller directly after first call from April 1999 to November 2002. Each individual was followed up 12 months after first contact (follow-up questionnaire). All those returning the registration questionnaire were included in the study base. The questionnaires assessed point prevalence abstinence as well as several factors potentially related to abstinence. Study I comprised 496 and 629 smokers receiving a reactive and a proactive treatment respectively. Studies II, III and IV comprised all 1131 smokers who had signed up for smoking cessation treatment from February 2000 to November 2001. Of those, 741 individuals (66%) reporting to have been abstinent for at least 24 hours were examined in study II. In study III, a sample of 84 out of 475 non-responders were included in a drop-out analysis. Study IV, was based on 354 abstinent smokers. Outcome measures were cost per quitter and cost per life year saved (LYS).

Main findings: Factors significantly related to abstinence (I) included no nicotine use at baseline, the adjusted OR and 95% CI, being 6.4 (2.1-19.4), additional support from health care professionals 3.5 (1.0-12.3), additional social support 3.1 (1.6-6.1), absence of stress or depressive mood 2.7 (1.6-4.7), nicotine replacement therapy (NRT) for five weeks or more 2.1 (1.1-4.1), and no exposure to second-hand smoke 1.9 (1.1-3.3). High intensity of craving, irritability, apprehension/anxiety, difficulties concentrating, restlessness, depressed mood, and insomnia were related to unsuccessful quitting attempts (II). With the exception of insomnia all these symptoms comprised a factor labelled 'psychological' which was related to unsuccessful quitting attempts. Using NRT for five weeks or longer was correlated with lower intensity of the 'psychological' symptoms. Of the non-responders in study III, 39% claimed to have been smoke-free at the time they received the 12-month follow-up questionnaire compared with 31% of the responders in the original study population (III). The cost per quitter in the investigated cohort (IV) was 1062 USD and cost per life year saved was estimated to be 311 USD.

Conclusions: The Swedish quitline proved to be a cost-effective intervention that significantly increased 12 month abstinence. Treatment efficacy may be further enhanced by focusing on factors identified in the different studies as being related to 12 month abstinence. Non-responders to the 12 month follow-up questionnaire were not more likely to be unsuccessful quitters.

Keywords: Quitline, smoking cessation, cost-effectiveness, withdrawal, symptoms, Sweden

PUBLICATIONS

- I. Helgason AR, Tomson T, Lund KE, Galanti R, Ahnve S, Gilljam H. Factors related to abstinence in a telephone helpline for smoking cessation. Eur J Public Health, 2004;14:306-310
- II. Tomson T, Toftgård M, Gilljam H, Helgason AR. Symptoms in smokers trying to quit (submitted)
- III. Tomson T, Björnström C, Gilljam H, Helgason AR. Are non-responders in a quitline evaluation more likely to be smokers? BMC Public Health 2005;5:52
- IV. Tomson T, Helgason AR, Gilljam H. Quitline in smoking cessation: A cost-effectiveness analysis. Int J Health Technol Assess Health Care 2004;20(4):469-474

The papers will be referred to by their Roman numerals I-IV.

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List of abbreviations

CI	Confidence Interval
CEA	Cost Effectiveness Analysis
CPI	Consumer Price Index
FCTC	Framework Convention on Tobacco Control
EU	European Union
GDP	Growth Domestic Product
GP	General practitioner
LYS	Life Years Saved
NRT	Nicotine Replacement Therapy
OR	Odds Ratio
SEK	Swedish kronor
SBU	The Swedish Council on Technology Assessment in Health Care
SRL	Sluta Röka Linjen-Swedish Quitline
SR	Sustained Release
TTM	Transtheoretical Model
USD	U.S. Dollars
WHO	World Health Organisation

1 INTRODUCTION

1.1 THE GLOBAL TOBACCO EPIDEMIC

Tobacco is the major preventable cause of death globally (WHO 2004). The World Health Organisation (WHO) projects that by 2025, today's five million tobacco-related deaths will have almost doubled (WHO 2004). Altogether there are almost 1.3 billion smokers worldwide. In high income countries, tobacco is the leading risk factor, accounting for 12% of the disease burden (Ezzati et al., 2002). Over 13 million Europeans suffer from a serious chronic disease as a result of their smoking, and over half a million die every year. Those that die in middle age as a result of their smoking lose on average 22 years of life. In 2004 the most common cause of death in Europe was cancer accounting for 20% of all deaths. The overwhelming majority of lung cancer cases are caused by tobacco smoking (Boyle & Ferlay 2005) and while there has been a substantial decrease in incidence in males, the situation for females is worrying.

In Sweden, the smoking prevalence among men has declined during the 1980s and 1990s whereas smoking among females is considerably higher compared to many other European countries (FHR 2005). In 2004, 14 % of men and 19% of women smoked on a daily basis. The heaviest smokers were in the 45-65 age group and the least were found among the youngest and oldest groups. Smoking is related to approximately 6 400 premature deaths annually and a further 500 die from exposure to second-hand smoke (Statistics Sweden 2004). Social inequalities in smoking persist among men with prevalence being higher among those in low income groups. In recent years, there has been a tendency towards a similar pattern among women. (FHR 2005).

Sweden has a national public health strategy "Public health objectives 2002/03:35" which provides the basis for creating conditions for better public health for the entire population on equal terms. One of its eleven target areas focuses on reduced use of tobacco. The Swedish Council on Technology Assessment in Health Care carried out a systematic review on smoking cessation guidelines (SBU 1998) and recommended that resources for professional counselling and dissemination of smoking cessation be made available in every region. However, no national tobacco guidelines have been issued.

The effects of tobacco place a heavy burden on health care systems. The cost of treating tobacco-related illness is very high not only for governments, but also for individuals and their families. Given this, effective tobacco control has the "potential to be one of the most rational, evidence-based policies in medicine" (WHO 2004).

1.2 ADDICTION AND DEPENDENCE

Addiction and dependence are terms whose definition has a social as well as a scientific dimension. In principle, they may be distinguished from each other, but in practice such a distinction serves little purpose and thus the terms are used interchangeably. They are socially and scientifically defined in that their meaning can be, and has been, changed to reflect changing perceptions. Under the current definition, the terms refer to a state in which a drug or stimulus has unreasonably come to control behaviour (American

Psychiatric Association 1995). This definition is very different from that used in the past and to which the general public usually subscribes (Bull WHO 1964). The earlier and popular view is that addiction refers to a state in which an individual needs to continue to take a drug in order to stave off unpleasant or dangerous withdrawal effects. The main shortcoming of this approach to defining addiction is that it addresses just one aspect of a wider problem. Certainly, many drug addicts experience withdrawal discomfort when they abstain, and this provides an important motive for continuing to use the drug. However, it has also long been recognized that this motive plays a relatively modest role in the apparently unreasonable continued use of a drug, despite protestations of users that they want to stop, and despite the harm their drug use is doing both to them and to those around them.

Many characteristics of tobacco use are strikingly similar to those of heroin, alcohol, and cocaine (Surgeon General 1988). None of these drugs are essential to normal physiologic functioning. Tobacco and other drug addictions differ from such behaviour as overeating or compulsive jogging in that the drug addictions are determined primarily by the drug's action on the brain. Cigarette smoking and tobacco use meet the criteria for drug dependence that are presented in the US Surgeon General's report, *The Health Consequences of Smoking* (Surgeon General 1988). Nicotine is clearly the dependence-producing component of tobacco use, and the concept of dependence has been addressed by the American Psychiatric Association (APA 1994).

Addiction to nicotine has been established as the psychopharmacologic mechanism that maintains cigarette smoking behaviour (Surgeon General 1988). Nicotine activates the brain's mesolimbic dopaminergic reward system (Pontieri et al., 1996) and produces dependence resulting in physical and neurobiological withdrawal symptoms on abrupt cessation (Epping-Jordan et al., 1998). Nicotine has a distributional half life of 15-20 minutes and a terminal half-life in the blood of two hours. Smokers therefore experience a pattern of repetitive and transient high blood nicotine concentrations from each cigarette, so that regular hourly cigarettes are often needed to maintain raised concentrations further, overnight blood levels drop to those of non-smokers (Jarvis 2004). Failure to maintain these concentrations results in symptoms of nicotine withdrawal (APA 1994). Hence, describing nicotine addiction as a disease of the brain seems justified.

1.3 TOBACCO PREVENTION

There are two main approaches to smoking prevention. The first is to prevent tobacco use initiation, that is, prevent young people from starting. The second is to treat tobacco dependence in established users and to prevent them from relapsing when they have stopped. Relapse appears to lead back into regular smoking unless an effort is made to alter the smoking behaviour (Ossip-Klein et al., 1986). This thesis focuses on the second approach.

Tobacco control may be achieved by decreasing demand for tobacco products through taxation, consumer education, research, bans on advertising and promotion, warning labels, control on smuggling, restrictions on public smoking, and education of children and adolescents.

Cessation methods traditionally include pharmacological treatment, behavioural support through face-to-face counselling, and more recently through quitlines and internet programmes. There is evidence that many of these methods are effective in helping smokers to quit (Stead et al., 2003; Silagy et al., 2004; Zhu et al., 2002). Pharmacological agents include nicotine replacement therapy (NRT) and bupropion. On balance, NRT (Silagy et al., 2005) and bupropion (Hughes et al., 2004) approximately double the effectiveness of other cessation efforts.

Studies have consistently shown that methods of assistance for smoking cessation such as behavioural counselling can significantly increase success rates in quitting (Fiore et al., 2000). Of smokers who receive intensive cessation-focused interventions, about 70% resume smoking within a year of treatment (Fiore et al., 2000). However, among unaided quitters, the relapse rate is closer to 97% (CDC 1999).

Behavioural cessation interventions include group sessions, social support networks, or individual counselling and can be clinic, school, community, or population-based. Formats range from informal contacts with peers or professional counsellors to regularly scheduled intensive counselling programmes. More recent initiatives include the use of internet-based interactions and telephone counselling (quitlines). When offered the choice between a telephone helpline and personal face-to-face consultation at a clinic, most smokers (75-85%) prefer telephone counselling (Mc Afee et al., 1998).

1.3.1 Quitlines

Quitlines are telephone-based tobacco cessation services and since the late 1980's, they have been established in many countries such as Australia, Brazil, Canada, New Zealand, in many U.S. states, South Africa, Iran, some Asian and most European countries (World Bank 2004). They vary greatly in degree of sophistication. Many have been set up recently and are in the early stages of development. The contexts in which they operate vary considerably, both in terms of socio-economic factors, literacy, telephone density, and use of information technology. (World Bank 2004). Estimates from several countries show that quitlines may have reached approximately 2-3% of the smoking population in the course of a year (Stead et al., 2003). However, they are considered to have an impact beyond that which can be measured in terms of quit rates amongst callers and fulfil a symbolic role, communicating to smokers that smoking cessation is important (Wakefield & Borland 2000).

Most quitlines are accessed through a toll-free telephone number and provide individual telephone counselling that may be combined with a variety of services such as free educational materials, free-of-charge NRT, and referral to local programs. Counsellors answer callers' questions about the cessation process and help them develop an effective plan for quitting (World Bank 2004). Telephone counselling can be reactive or proactive (Lichtenstein 1996). *Reactive* quitlines only respond to incoming calls. *Proactive* quitlines handle incoming calls and then follow up the initial contact with additional outbound calls, to help initiate a quit attempt and/or to assist in preventing relapse. It is important to have an understanding of the characteristics of a quitline when discussing performance and results. Proactive telephone counselling has been shown to have a marked effect on callers' probability of success in quitting and in maintaining long-term abstinence from tobacco use, comparable to the effects of pharmacotherapies (World Bank 2004). Although reactive helplines have been widely implemented, controlled evaluation has been limited. Evaluations involving these

services have been more likely to compare variants in service than to use a no intervention control. Two studies support use of a reactive quitline in the context of a comprehensive tobacco control programme (Zhu et al., 1996; Ossip Klein et al., 1991).

Meta-analytical reviews have established that proactive telephone counselling is an effective intervention for smoking cessation (Lichtenstein et al., 1996; Fiore et al., 2000; Stead et al., 2003). The most recent of these (Stead et al., 2003) examined 13 studies of proactive interventions and found that callers who received counselling were successful at least 50% more often than those who only received self-help materials OR 1.56 (95% CI 1.38-1.77). A large randomised, controlled trial served as the basis for the California Smokers' Helpline, the first publicly supported and state-wide quitline. This study found that the telephone counselling increased the percentage of smokers making a quit attempt and decreased the rate of relapse for those attempts. It also found a strong dose-response relationship between the level of intended treatment intensity (i.e., number of follow-up sessions) and the treatment effect (Zhu et al., 1996). Other research has demonstrated continued effectiveness in randomised controlled trials and "real world" settings (Borland et al., 2001; Zhu et al., 2002; World Bank 2004). In 2003, "The National Action Plan for Tobacco Cessation in United States" (Fiore et al. 2004) recommended the establishment of a federally funded National Tobacco Quitline that would provide a national portal to available state or regionally managed quitlines. Worldwide, there are several approaches for managing quitlines with some of them being non-governmental organisations, group health cooperative's, health maintenance organisations, private companies, charities but mostly as part of the public health care system.

1.4 SWEDISH HEALTH INDICATORS AND HEALTH CARE

By international standards, health in Sweden is relatively good. Public health has steadily improved in recent years, in terms of average life expectancy and premature mortality as is obvious from some health indicators, (Table 1).

Table 1. Health indicators for Sweden

Indicators	
Infant mortality rate (per 1,000 live births)	3.1
Life expectancy (years)	79.5
-Male	77.1
-Female	81.9
Cardiovascular mortality from diseases per 100 000 population	220
Cancer mortality per 100 000 population	150
Lung cancer mortality per 100 000 population (male)	30
Lung cancer mortality per 100 000 population (female)	20

Source: OECD Health Data, 2005.

Deaths in injuries, alcohol-related diseases and suicide have also been on the decline for many years. The proportion of the population with allergic conditions, however, doubled during the 1980s, with more than one third of people living in Sweden reporting that they suffer from some form of allergy or over-sensitivity. Another public health problem is the growing proportion of overweight individuals among children, young, and the middle-aged. Mental health and psychosomatic problems are on the rise among children and young people. The number of elderly has risen substantially-with the greatest growth in the age group 80 years and older. There are differences in health between different socio-economic groups, and these differences are growing (FHR 2005).

In 2003, the cost for health services in Sweden exceeded 225 billion Swedish kronor (31bn USD)¹. This represents a substantial share (9.2%) of Sweden's gross domestic product (GDP) and an intermediate position among 15 EU countries. Health services in Sweden are overwhelmingly tax-financed, through county and municipal taxes. Patient fees (i.e., out-of-pocket) charged by the county councils account for 2.7% of the revenues. Privately financed care is marginal, approximately 500 million SEK annually (SI 2003).

The health care system in Sweden is highly decentralised. Mainly the 20 county councils (Stockholm County Council being one) and 290 municipalities in Sweden finance and manage health services within their respective areas. Health policy is a national-level responsibility that rests with the Government and the Parliament. A fundamental principle is that the provision and financing of health services for the entire population is a responsibility of the public sector (SALAR 2005).

The county councils and municipalities are the main providers of health care, with only about 10% of all health services delivered by private providers. All counties contract to varying degrees with private providers, mainly in primary care where approximately 25% of the primary care centres are managed privately. There are nine regional hospitals, some 70 county and provincial hospitals and just over 1000 health centres. The number of physicians and nurses are 3 and 9 per 1000 inhabitants respectively which is similar to the EU average (OECD 2005). Health care providers such as physicians or nurses are natural partners for quitlines and referral to quitlines for comprehensive cessation counselling can have a profound impact on patient health (World Bank 2004). Therefore linkages with health care providers create important opportunities for quitlines.

1.5 QUITLINE IN SWEDEN - SRL

The Swedish quitline – Sluta Röka Linjen (SRL) has been in operation since May 1998 and has served over 70 000 people and over 50 000 of these calls have been tobacco cessation calls (SRL Database). It is a nationwide free-of-charge telephone service operated by Tobacco Prevention in Stockholm, part of the Stockholm Centre of Public Health. Historically, financial support was provided by the Swedish Cancer Society, the National Institute of Public Health, the Swedish Lung and Heart Association and Apoteket AB (Swedish Pharmacies) and since 2004, by the Ministry for Health and

¹ The Swedish Bank annual aggregate currency fixing rate for 2003: 1 USD=7,2 SEK

Social Affairs. The service is available during: Monday – Thursday, 9.00-20.00 and Friday 9.00-16.00, weekends closed. When the service is closed, or all lines are busy, an answering machine and a 24-hour interactive voice response serves as back-up. Smokers or concerned citizens may call toll-free for advice or smoking cessation counselling. The quitline is based on three interrelated elements: flow of patients, counselling, and preparatory measures for evaluation.

The typical caller is a woman of 47 years of age with 12 years of education. The calls are geographically evenly distributed with slightly more calls from urban clients. The counselling is provided by health professionals (with few exceptions) like nurses, health educators, dentists, dental hygienists, psychologists, and doctors. All counsellors receive at least six months of training followed by supervision for another six. Continuing education, mentoring and de-briefing are provided for the counsellors. At present, Autumn 2005, the service employs 18 counsellors.

Clients calling the Swedish quitline receive tailored information by mail according to the Stages of Change (see 1.5.2). They are offered four follow-up phone calls in accordance with findings indicating that there is a relationship between the intensity of treatment and outcome measured as rate of smoking abstinence (Fiore et al., 2000). The average length of time for the first call is 22 minutes and for the following calls approximately 12 minutes. All callers are encouraged to call back as often as they need. A computerised client record is kept to enable the smoking cessation counsellors to effectively identify a caller and to allow for easy continuation of the treatment. The quitline is promoted as a referral service for the primary health care.

Research into routines for Nordic general practitioners' (GPs) work with tobacco prevention revealed that eight out of ten reported shortage of smoking cessation experts to refer to as a main problem. (Helgason & Lund 2002). Many physicians conceive even short advice to be too time-consuming and feel that the results (outcome) may not be adequate to justify the time spent (Cabana et al., 1999). A review analysing why physicians do not follow clinical guidelines showed that, depending on the nature of the medical problem, different barriers emerge stressing the need to assess each aspect separately (McAvoy et al., 1999). Hence, physicians in primary care or elsewhere are invited to refer smokers to quitlines where advice, assistance, and follow-up can be arranged. The importance of the individual physician has been highlighted, (Fiore et al., 2000; Cummings et al., 1989) but relatively few physicians actively engage in smoking cessation support (Helgason & Lund 2002).

According to a primary health care survey carried out by the Swedish National Institute of Public Health in 2003, less than half the country's health care centres used smoking cessation counsellors to help those wanting to stop smoking (NIPH 2004).

1.5.1 The treatment protocol

The treatment protocol is best described as a mix of motivational interviewing (Miller & Rollnik 2002), cognitive behaviour therapy, the Transtheoretical Model (TTM), and pharmacological consultation. Materials which are tailored to the characteristics of individual smokers are more likely to be effective (Lancaster & Stead 2005). The tailored treatment material sent to people calling the quitline makes use of the Stages of Change, and this printed material is offered free of charge. The four existing folders

were developed with each corresponding to one of the four stages. 1) What you gain if you quit, 2) Prepare to quit smoking, 3) NRT and withdrawal symptoms, and 4) Hold on!

1.5.2 Theoretical framework

One of the most widely used models of individual health behaviour of change is the Transtheoretical Model (TTM). It focuses on the intention to change and on the decision making of the individual. The model was developed by James Prochaska and Carlo DiClemente in the early 80's, based on the experiences of people attempting smoking cessation with and without professional help. Inspired by others before them, the two researchers attempted to make explicit various aspects of the intentional behaviour change process in a unifying model (Prochaska & DiClemente 1983).

One of the advantages of the TTM is that it postulates that the process of change takes time and involves progress through a series of stages that characterise different degrees of readiness to change (Prochaska & DiClemente 1983; Velicer et al., 2000) and that people in different stages of change need different interventions to progress in their behaviour change (Prochaska et al., 1992). Health promoters² have been developing tailored interventions by matching messages to the individuals' readiness to change (Prochaska et al., 1992; Rakowski 1999). Over the past two decades, there has been a substantial increase in the use and evaluation of stage-matched interventions with regard to a variety of health behaviours (Rakowski 1999).

In Sweden smoking is becoming less acceptable, and many smokers express a desire to quit. Individual differences in factors related to smoking cessation including differences in readiness to change, may be important when designing effective interventions (Prochaska & DiClemente 1983). The Swedish quitline makes use of the principles outlined in the Stages of Change of TTM. Stages are used as outcome variables to assess success in study I. The central organising construct of this model is an approach to assess readiness to change health behaviour (Prochaska & DiClemente 1983; Prochaska et al., 1992). The TTM presumes that behavioural change, for most people, occurs gradually through five different stages, ranging from being unaware or unwilling to make a change (precontemplation) to attempting to maintain a behaviour change. Relapse is considered to be a part of the process of establishing a life-long change (Prochaska et al., 1992). The stages are both stable and dynamic, that is, they may be constant over a longer period but are still open to change.

Precontemplation is a stage where individuals have no intention of stopping an unhealthy behaviour or starting a healthy one in the near future, usually within 6 months.

Contemplation is the stage in which people are considering a behavioural change within the next six months but have not yet made a commitment.

Preparation is the stage in which people have made decisions to change their behaviour within a given period (usually within 30 days). *Action* is the stage where people have changed their behaviour within the past 6 months.

² Those who work to promote health as defined in the Ottawa Charter, regardless of professional designation, including individuals, organisations, and groups from various sectors. www.ohpe.ca (403.2)

Maintenance is the final stage in the change process. People are defined as being in the maintenance stage after sustaining the behaviour change for at least 6 months (Prochaska et al. 1992).

Evidence in support of the TTM as applies to tobacco use is strong, but not conclusive (Spencer et al. 2002). The model has recently been brought into question (West 2005) which will be elaborated in the discussion section (5).

1.6 PERSPECTIVES

1.6.1 Public health

Public health is collaborative actions to improve sustained population-wide health and reduce health inequalities (Beaglehole & Dal Poz 2003). Hallmarks of public health practice include the focus on actions and interventions which require collective (or collaborative or organized) actions, sustainability, and the need to embed policies within supportive systems. The goals of public health are population-wide health improvement, which implies a concern to reduce health inequalities.

The importance of this definition is that it is broad enough to include an overview of the activities of the medical care system and recognizes the importance of responding to the underlying social, economic, and cultural determinants of health and disease. Public health research is a multidisciplinary activity. It involves the application of the entire range of biological, social, and behavioral sciences to the health problems of human populations (Beaglehole & Bonita 2004).

The WHO Framework Convention on Tobacco Control (WHO FCTC)³ - an international effort to protect the public's health from the "consequences of tobacco consumption and exposure to tobacco smoke" - recommends comprehensive tobacco control strategies to be implemented by participant members. Through the FCTC, efforts to reduce tobacco use, one of the most significant risk factors for premature death and disease, are strategically coordinated for an effective global response. While the FCTC provides the framework for action against tobacco, the actual work to combat tobacco use must necessarily occur at country level (WHO 2004). Evidence is needed when a new technology is introduced. This is the case with the Swedish quitline, an individualised quit smoking service which is provided to a large geographic area from a single centralized base. Since essential elements were documented -from the client to financial records- prerequisites for an evaluation existed.

1.6.2 Real world research

One of the challenges in carrying out investigations in the real world lies in seeking to say something sensible about a complex, relatively poorly controlled, and generally "messy" situation. Another way of saying this was developed by Robson who claimed that the laboratory approximates a "closed" system shut off from external influences, while studies outside the laboratory such as this thesis operate in "open" systems (Robson 2004). Much inquiry in the real world is essentially some form of evaluation. The intention is that the research and its findings will be used in some way to make a

³ Available at: <http://www.fctc.org/highlightsEN.pdf>

difference to the lives and situations of those involved in the study, and /or to others. This takes us into the field of evaluation research.

The purpose of an evaluation is to assess the effects and effectiveness of something, typically an innovation, intervention, policy, practice or service (Robson 2004). It is commonly referred to as program evaluation. In all aspects of carrying out an evaluation, great attention has to be paid to feasibility. The design must take note of constraints on time and resources; on how information is to be collected; on the permissions and co-operation necessary to put this into practice; on what records and other information are available. The Swedish quitline provided the above mentioned aspects regarding both feasibility and relevance.

Inherent in the concept of real world is the notion of relevance. The tobacco issue was listed by WHO as one of the three major threats (the others being HIV/AIDS and malaria) to global health (WHO 1999).

Establishing trustworthiness is fundamental in research. Two key issues about the inquiry itself are involved here, that of validity and generalisability. Validity refers to the accuracy of a result. Does it “really” correspond to, or adequately capture, the actual state of affairs? Are any relationships established in the findings “true”, or due to the effect of something else? Generalisability refers to the extent to which the findings of the enquiry are more generally applicable, for example, in other contexts, situations or times, or to persons other than those directly involved. Additional problems may come under the heading of reliability referring to the stability or consistency with which we measure something. All these issues will be discussed further in the methodological part of the discussion. Finally, it is not only the treatment and related effects of outcome that is the focus of this thesis, but also the ability to estimate the costs of the treatment.

1.6.3 Health economics

“Health economy can be defined as the application of the theories, tools and concepts of economics as a discipline to the topics of health and health care” (Kobelt 2002). Since economy as a science is concerned with the allocation of scarce resources, health economics is concerned with issues relating to allocation of scarce resources to improve health. This includes both resource allocation within the economy to health care system and within the health care system to different activities and individuals (Kobelt 2002). There is an increasing call for measuring the effectiveness of programs in financial terms. Cost-effectiveness analysis (CEA) is one option and was used to establish the value for money for the Swedish quitline.

A health economic evaluation is a way of establishing the “value for money” of different health care technologies (Kobelt 2002). Economic evaluations have become an important source of information to aid decision making about the allocation of resources. Economic analyses are always comparative and are applied to explicit alternatives. A treatment cannot be cost-effective by itself, but only in relation to one or several relevant alternatives, and for defined patient groups (Drummond et al., 1997). If a treatment strategy is both better and less costly, it dominates the alternatives. Outcomes are measured as health improvements expressed as either survival measured as lives saved or life years saved or as disease measures such as events avoided or delayed or patients successfully treated. Such analyses can be criticized for taking a very narrow measure of outcome and failing to include many of the potential benefits

of the health promotion intervention. Their main advantage, however, is that they allow quantification. Other measures are quality-adjusted survival expressed as quality-adjusted life years (QALYS), and monetary value, expressed as willingness-to-pay for a benefit (Kobelt 2002). There are different types of economic evaluations and these are distinguished primarily by the way in which outcomes are treated. In general, if the question being studied is whether a treatment is a good use of resources within the disease area, the comparison should be with similar treatment and the outcome measure can be disease specific. The type of evaluation will be a CEA, if there is a single outcome (Kobelt 2002). The major advantage for economic evaluation is that it explicitly values the costs and benefits of policy options.

Although the beneficial impact of quitlines has been supported by three meta-analyses (Lichtenstein 1996, Fiore 2000, Stead Lancaster 2003) and by multiple individual studies (Borland et al., 2001; El-Bastawissi et al., 2002) no evaluation of effectiveness and cost-effectiveness of the Swedish national quitline has been conducted.

2 OBJECTIVES

2.1 GENERAL OBJECTIVE

To study the effectiveness and cost-effectiveness of the Swedish quitline.

2.2 SPECIFIC OBJECTIVES

- To assess factors related to 12 months point prevalence abstinence (I)
- To describe and compare different symptoms in smokers trying to quit (II)
- To compare different characteristics of the non-responders with the responders and to assess the reasons for not responding (III)
- To assess the cost-effectiveness of the Swedish quitline (IV)

3 METHODS

3.1 STUDY POPULATION AND SETTING

The study is prospective. However, information regarding smoking behaviour before the first contact is collected retrospectively. The study population comprises all 2300 patients who called the quitline and registered for active smoking cessation support from April 1999 to October 1999 and February 2000–November 2001.

The treatment model used in the Swedish quitline was developed over a period of 12 months. During that time, questionnaires used to assess outcome for the present studies were developed through a series of interviews and pilot studies and tested for face validity.

The registration to enrol in the cessation programme is by a form sent home to the client after the first call. All smokers signing up for cessation who return the form are included in the study base. Each individual is followed up by a questionnaire 12 months after first contact. The questionnaire assesses point prevalence abstinence, and several psychological, sociological, and physiological factors that may be related to outcome. Self-reported abstinence was defined as “not a single puff of smoke during the last week”.

3.2 DATA COLLECTION AND ANALYSIS (I-IV)

The data collection was done in three stages. A) At the first call, baseline information is collected by the counsellor using a standardised computerised client record: gender, age, education, tobacco use, smoking behaviour, intention to quit, and satisfaction with the quitline. B) Clients registering for an active smoking cessation support receive a registration questionnaire to be filled in at home. C) After 12 months from the first contact, all clients who have registered for the full programme receive a detailed postal questionnaire at home about current tobacco use and factors that may affect abstinence.

Postal questionnaires are widely used in the collection of data in epidemiological studies and health research (Edwards et al., 2002). Self-completed postal questionnaires should be designed to help achieve the goals of the research and, in particular, to answer the research questions (Czaja & Blair 1996). The questionnaires used in the thesis were relatively short, included a personalised letter, and a stamped return envelope, all of which are established as effective strategies for increasing response rates (Edwards et al., 2002).

Summary facts about the different studies are shown in table 2.

Table 2: Summary of studies.

Title of study	Design & Methods	Study population (% response rate)	Study period
I. Factors related to abstinence in a telephone helpline for smoking cessation	Longitudinal survey using structured questionnaires. Self reported measures. 12 month follow up after 1 st contact assessing current abstinence, stages of change, and factors related to abstinence rates.	496 (71%) smokers calling a reactive and 629 (70%) smokers calling a proactive (contacts initiated by the counsellors after 1 st contact) quitline.	April-October 1999 February-December 2000
II. Symptoms in smokers trying to quit	Cross-sectional survey using structured questionnaires to retrospectively assess symptoms over a period of 12 months. Self reported measures. Factor analysis to explore the relationship between different symptoms.	Data based on 1131 (70%) callers. A total of 741 individuals who reported to have been smoke free for at least 24 hours 12 months from first contact.	February 2000-November 2001
III. Are non-responders in a quitline evaluation more likely to be smokers?	Cross-sectional telephone interview survey. Non-responders were contacted to assess present smoking behaviour.	Data based on 1606 callers. Of the 475 (30%) non-responders, a sample of 84 (18%) was interviewed.	February 2000-November 2001 Interviews done July -November 2002
IV. Quitline in smoking cessation A cost-effectiveness analysis	Cost-effectiveness analysis. (CEA) of the Swedish quitline over 2 years in relation to the number of quitters. Outcome was measured as cost per quitter and cost per life year saved (LYS).	Data based on 1131 (70%).	February 2000-November 2001

Note: Study II, III, and IV are all based on the same study population

3.3 STATISTICAL METHODS

Logistic regression analysis was used to calculate crude and adjusted odds ratios (OR) with 95% confidence intervals (CI) controlling for covariates in study I. The analysis of the relationship between current abstinence and predictors was done in two steps.

We first analysed the association between each factor and current abstinence separately and then adjusted the analysis for age, gender, and all factors significantly related to current abstinence in the crude analysis. When assessing the relationship between abstinence at 12 months, on the one hand, and nicotine replacement therapy or oral tobacco use on the other hand, the assessed variables were excluded from the “nicotine at baseline” index. Age was adjusted for as a three-category variable (<41 years, 41-53 years, >53 years). Cut-off levels for age and nicotine use at baseline were chosen in order to obtain approximately equal numbers of respondents (one-third) in each category. When comparing current abstinence in the reactive cohort with the proactive cohort, a two-sided p-value was calculated using Fisher’s exact test.

In study II logistic regression analysis was used to calculate crude and adjusted odds ratios with 95% confidence intervals. To analyse the relationship between withdrawal symptoms and abstinence, we dichotomised the response alternatives none, low, moderate, and high into two alternatives of low and high intensity. The dichotomisation was done so that for each variable, the two categories became as equally sized as possible. The cut-offs for the assessment of NRT use were “less than 5 weeks”, “5 weeks or more”, or “not at all”. It was also assessed as “NRT” vs. “no NRT use”. Significance levels for all tests were two-tailed.

For statistical comparison between groups in study III, we calculated Fisher’s exact test, OR, and 95 % CI on proportions and OR. In table 7 one-sided CI on the proportions was used since our main focus was on the lower limits.

In study IV cost per quitter was based on a calculation of the total cost of the quitline divided by the number of individuals who reported abstinence after 12 months. The cost per life year saved (LYS) was calculated by the use of data from the literature on average life expectancy for smokers versus quitters, the total cost of the quitline, and the cost of pharmacological treatment.

3.4 ETHICS

Participants in real world studies may sometimes be involved without their knowledge. They may also be misled about the true nature of the study. However, in this thesis, individuals call the quitline voluntarily, and all questionnaires are subject to informed consent by the participant. The quitline is run by the national health care, so that all employees are bound by the same rules of confidentiality as other health care employees. The studies presented in this thesis were ethically approved by Karolinska Institutet, Sweden (number 00-367).

4 RESULTS

Here, the main findings from studies I-IV are presented.

4.1 REACTIVE COHORT (I)

Of the 694 eligible smokers for the reactive quitline service, 71% participated in the 12 month follow-up (Table 3). No significant difference was noted in response rates between men and women. Age, gender distribution, and classification into “stages of change” at first call are presented in table 3.

Table 3. Response rate and population characteristics of 496 smokers registering for a reactive smoking cessation telephone support at the Swedish quitline.

Response rate:	71% (496/694)
Gender:	
Male	25% (125/496)
Female	75% (371/496)
Age distribution: *	
Years	
≤ 20	2% (10/492)
21-30	13% (64/492)
31-40	18% (88/492)
41-50	23% (114/492)
51-60	24% (116/492)
61-70	16% (78/492)
≥ 71	5% (22/492)
Stage distribution #	
at recruitment :	
Pre-contemplation	2% (8/494)
Contemplation	38% (189/494)
Preparation	38% (186/494)
Action	22% (108/494)
Maintenance	1% (3/494)

* Four people did not give their age. # Two people were not properly staged at baseline.

Percentages do not add up to 100% due to rounding.

Factors significantly related to abstinence in the crude analysis at follow-up included nicotine use and stage of change at first call, nicotine replacement therapy, exposure to second-hand smoke, treatment compliance, periods of depressive mood or stress, and the use of additional support (Table 4).

Table 4: Factors related to abstinence in the reactive cohort 12-14 months after first contact.

	Abstinence % (n/N) ^a	Crude OR (95% CI)	Adjusted OR (95% CI) ^b
Nicotine at baseline ^c			
>18 mg/day (ref.)	15% (19/129)	1.0	1.0
11-18 mg/day	24% (43/178)	1.8 (1.0-3.3)	1.7 (0.8-3.5)
0.1-10 mg/day	33% (49/148)	2.9 (1.6-5.2)	1.9 (0.9-4.0)
No nicotine at baseline	63 % (26/41)	10.0 (4.5-22.3)	6.4 (2.1-19.4)
Stage at baseline:			
Contemplation (ref.)	19% (35/189)	1.0	1.0
Preparation	22% (41/186)	1.2 (0.8-2.1)	1.1 (0.6-2.0)
Action	53% (57/108)	4.9 (2.9-8.3)	2.0 (0.9-4.2)
Nicotine replacement			
No nicotine replacement (ref.)	25% (48/193)	1.0	1.0
Nicotine replacement < 5 weeks	18% (33/182)	0.7 (0.4-1.1)	0.5 (0.3-1.0)
Nicotine replacement ≥ 5 weeks	46% (56/121)	2.6 (1.6-4.2)	2.1 (1.1-4.0)
Exposed to passive smoking (ref.)	23% (47/205)	1.0	1.0
Not exposed to passive smoking	33% (64/193)	1.7 (1.1-2.6)	1.9 (1.1-3.3)
No smokeless tobacco at follow-up (ref)	27% (106/400)	1.0	1.0
Using smokeless tobacco at follow-up	36% (21/59)	1.5 (0.9-2.7)	1.5 (0.7-3.3)
No previous attempts (ref.)	23% (29/127)	1.0	1.0
Previous attempts	27% (62/227)	1.3 (0.8-2.1)	1.2 (0.6-2.3)
Treatment compliance:			
Moderate/Low/No (ref.)	22% (80/358)	1.0	1.0
High	46% (50/108)	3.0 (1.9-4.7)	2.6 (1.4-4.7)
Depressed/stressed (ref.)	23% (68/296)	1.0	1.0
Not depressed/stressed	37% (65/177)	1.9 (1.3-2.9)	2.7 (1.6-4.7)
No other support (ref.)	17% (31/178)	1.0	1.0
Professional support only	22% (6/27)	1.4 (0.5-3.6)	3.5 (1.0-12.3)
Social support only	34% (79/230)	2.5 (1.5-4.0)	3.1 (1.6-6.1)
Social and professional support	34% (21/61)	2.5 (1.3-4.8)	2.8 (1.1-7.0)

The full table is available in paper I p. 308

a: Variations in denominators are owing to missing information.

b: The analysis is adjusted for age, gender and all variables significantly related to outcome in the crude analysis.

c: ref. = the reference group for the OR analysis.

* Difference statistically significant

Most of these relationships remained statistically significant in the adjusted analysis. The importance of access to additional professional support became more apparent in the multivariate analysis. In all cases assessed in the telephone interviews, the additional professional support alluded to being referred to the quitline by a physician, a nurse, a dentist, dental hygienist, or pharmacy personnel after brief advice. The positive association of abstinence with referral by a health care professional on abstinence rate persisted when the analysis excluded clients with severe smoking-related symptoms.

Of those who were in the pre-contemplation stage, five out of ten had advanced to contemplation or action/maintenance. Those who were in preparation at first call, five out of ten had regressed to contemplation or pre-contemplation, and four in ten had progressed to the action/maintenance stages. Of those who were in action/maintenance at first call, seven out of ten were still there at follow-up, while three in ten had regressed to an earlier stage.

4.1.1 Proactive cohort

Of the 900 smokers treated with a proactive approach, 629 (70%) returned the follow-up questionnaire. The 12-month overall abstinence was somewhat higher in the proactive group compared with the reactive group, 33% and 28% respectively, but the difference was not statistically significant $p=0.08$. However, when men and women were assessed separately, women were significantly more likely to be abstinent in the proactive group compared with the reactive group, 34% and 27% $p=0.03$ respectively. No change was noted for men between the two treatment protocols. There were no significant differences between the reactive and proactive cohorts in any of the assessed background variables that may explain the difference in 12-month abstinence. Comparing available variables gathered at first call including age, gender, stage of change, and nicotine use did not show any statistically significant differences between responders and non-responders in the present study. This was true for both reactive and proactive cohorts.

4.2 PREVALENCE OF SYMPTOMS AND ABSTINENCE (II)

Of the 1131 subjects who participated in study II, 66% (741/1131) reported abstinence symptoms. A total of 43% reported high craving and 34% high restlessness. Other relevant symptoms that were reported by approximately one in four subjects included: apprehension/anxiety 25%, irritability 24%, difficulties concentrating 24%, and depressed/depressed mood 24%.

High intensity of symptoms related to unsuccessful quitting attempts included craving, irritability, apprehension/anxiety, difficulties concentrating, restlessness, depressed/ depressed mood, and insomnia (Table 5).

Table 5. Symptoms versus abstinence. Presenting percentage and proportion reporting to be abstinent. (N=741)

Symptoms	Low intensity	High intensity ^(ref)	OR 95% CI
Craving	49% (207/421)	32% (103/320)	2.0 1.5-2.8*
Irritability	45% (163/362)	39% (147/379)	1.3 1.0-1.7*
Apprehension/ Anxiety	47% (177/375)	36% (133/366)	1.6 1.2-2.1*
Restlessness	49% (142/291)	37% (168/450)	1.6 1.2-2.2*
Difficulties concentrating	46% (175/384)	38% (135/357)	1.4 1.0-1.8*
Depressed/depressed mood	48% (196/412)	35% (114/329)	1.7 1.3-2.3*
Insomnia	45% (155/341)	39% (155/400)	1.3 1.0-1.8*
Mouth ulcers	40% (238/601)	51% (72/140)	0.6 0.4-0.9*

Note: Dichotomisation was done so that for each symptom, the two categories became as equally sized as possible.

* Difference statistically significant

The full table is available in paper II p 11.

4.2.1 Factor analysis

Three factors whose eigenvalues (i.e., the sum of the squared factor loadings) were greater than 1 were identified and accounted for 49% of the variance. Factor loadings greater than 0.35 were considered in the interpretation of the factors. The greater the loading, the more the variable is considered a pure measure for the factor (Comrey & Lee 1992). *Factor 1 (psychological)* comprised symptoms that were mainly psychological and to some extent neurological in nature. Assigned to this group were craving, irritability, apprehension/anxiety, restlessness, difficulties concentrating, and depression/depressed mood. The two latter symptoms also included in factor 3 (Table 6). *Factor 2 (physiological)* included symptoms that were primarily physical (somatic) and partly neurological including mouth ulcers, dizziness, (also included in

factor 3), sweating, muscular pain, cramps, constipation, and other stomach trouble (Table 6). *Factor 3 (neurological)* comprised mainly symptoms that may be termed neurological as well as some symptoms that are more psychological in nature including headache, insomnia, sleepiness/drowsiness, nightmares, dizziness, difficulties concentrating and depression/ depressed mood. The two latter also included in factor 1 (Table 6). A comparison between the mean values of the factor scores in successful versus unsuccessful quitters revealed that high factor scores on factor 1 (psychological) was significantly related to unsuccessful quitting attempt.

Table 6. Factor analysis including items of distinctive groups, psychological, physiological and neurological.

	Factor		
	1	2	3
Craving	.701	.176	-.238
Irritability	.714	.090	.175
Apprehension/anxiety	.741	.045	.328
Restlessness	.738	.085	.220
Difficulties concentrating	.713	.085	.367
Depressed/depressed mood	.546	.046	.444
Headache	.182	.192	.647
Insomnia	.257	.195	.625
Sleepiness/drowsiness	.136	.209	.633
Nightmares	.155	.274	.576
Dizziness	.107	.453	.432
Mouth ulcers	.056	.583	.080
Sweating	.209	.575	.317
Muscular pain	.047	.693	.151
Cramps	.053	.726	.017
Constipation	.093	.533	.205
Other stomach trouble	.037	.526	.276

Note: Factor loadings greater than 0.35 are boldface.

4.2.2 Nicotine replacement therapy and symptoms

The tendency of increased prevalence for users of NRT for less than 5 weeks, but not for users of NRT for 5 weeks or longer, was seen for all symptoms comprising the psychological factor Figure 1 not shown here but in paper II (p.14). When compared with those reporting *not* having used nicotine replacement therapy (NRT), using NRT for less than 5 weeks was significantly correlated with an increased prevalence of craving, irritability difficulties concentrating as well as mouth ulcers, and a decreased

prevalence of cramps. With the exception of mouth ulcers, these correlations did not persist when comparing non-users of NRT to users of NRT for 5 weeks or longer.

4.3 NON-RESPONDER BEHAVIOUR (III)

Of the 84 subjects not responding to the original questionnaire at the 12 month follow-up (non-responders) recruited for the study base, 55% (46/84) participated in a telephone interview. Of the remaining 38 subjects who did not participate, 61% (23/38) could not be reached, 29% (11/38) declined, and 10% (4/38) were either sick or dead.

4.3.1 Abstinence

Of the 46 subjects participating in study III, 39% reported to have been smoke-free at the time they received the original follow-up questionnaire (abstinent at 12 months) compared with 31% of responders in the original study population (Table 7). No significant difference in abstinence was noted between the present study population and the original study population (Table 7).

Table 7. Percentage and proportions of abstinence in the original study population (responders) and the present study population (non-responders) at the 12 month follow-up, and at the time of the telephone interview.

	Original study population	The present study population participating in the telephone interview	
	Abstinent at 12 months	Abstinent at 12 months	Abstinent at the time of the tel. interview
	% (n/N)	% (n/N)	% (n/N)
	One-sided 95% CI	One-sided 95% CI	One-sided 95% CI
Men	30 (69/226)	63 (5/8)	38 (3/8)
	≥25	≥29	≥11
Women	31(285/905)	34 (13/38)	26 (10/38)
	≥29	≥22	≥15
Total	31 (354/1131)	39 (18/46)	28 (13/46)
	≥29	≥27	≥18

4.3.2 Reasons for not returning the postal questionnaire

The most common reason for not having returned the original questionnaire was the claim to have returned it. Approximately one in ten participants further stated that they had believed that abstinence was a prerequisite for answering and therefore had not returned the questionnaire since they were smoking at the time.

4.3.3 Population characteristics

The non-responders comprising the study base in the present study were somewhat younger than the responders in the original study population (Table 8). The mean ages were 47 for the responders and 42 for the non-responders. Men and women were equally represented among both responders and non-responders. Non-responders tended more often to having been abstinent when they first called the quitline (Table 8). They were also significantly more likely to have been totally nicotine free at first call compared with the responders (Table 8).

Table 8. Population characteristics of responding and non-responding subjects. Comparing 46 non-responders participating in the non-response analysis with the 1131 responders in the original study population.

Total	Total sample of non-responders	Non-responders not participating in the telephone interview	Non-responders participating in the telephone interview	Responders in the original study	Comparison ¶	
	% (n) 100 (84)	% (n) 100 (38)	% (n) 100 (46)	% (n) 100 (1131)	OR	95% CI
Sex						
Male (Ref)	20 (17)	24 (9)	17 (8)	20 (226)		
Female	80 (67)	76 (29)	83 (38)	80 (905)	1.2	0.5 – 2.6
Age distribution:						
≥ 41 (Ref)	58 (49)	61 (23)	57 (26)	67 (755)		
≤ 40	42 (35)	39 (15)	43 (20)	33 (376)	1.5	0.9 – 2.8
Smoke-free at first call:						
No (Ref)	73 (61)	76 (29)	70 (32)	77 (875)		
Yes	27 (23)	24 (9)	30 (14)	23 (256)	1.5	0.8 – 2.8
Using nicotine* at first call:						
Yes (Ref)	82 (69)	87 (33)	78 (36)	89 (1010)		
No	18 (15)	13 (5)	22 (10)	11 (121)	2.3	1.1 – 4.8

*Total consumption of nicotine, including smoked and smoke-free tobacco and NRT

¶Comparing non-responders participating in the telephone interview with responders

4.4 COST-EFFECTIVENESS (IV)

4.4.1 Cost per quitter

In study IV, a total of 4,021 individuals received tobacco cessation counselling over the study period, February 2000-November 2001. Often, they were advised on single aspects such as nicotine replacement therapy or smokeless tobacco. Of these, 1,131 subjects enrolled in the evaluation. After one year, 354 (31 percent) smokers reported abstinence. The cost per quitter for the Swedish quitline was between 1,052 and 1,360 USD. Table 9 provides examples of the relative cost-effectiveness, expressed in cost per year of life saved, of different smoking cessation measures.

Table 9. Cost-effectiveness of Smoking Cessation Interventions

Smoking cessation intervention	Cost per life year gained in USD year 2002
Telephone counselling	311-401 (current study)
Swedish quitline	
Quit and Win	235-1528 ^a
Community antismoking campaign	950 ^a
Brief advice	282 ^a
Advice + self material	358 ^a
GP counselling	949 ^a
Bupropion (SR)	10 520
NRT	12 047
NRT + Bupropion (SR)	19 492

a: Recalculated according to CPI; Source: Department of Labor, Bureau of Labor Statistics, &

OECD Main Indicators CPI.

SR: Sustained Release

4.4.2 Cost per Life Year Saved

The accumulated total of life years gained was 2,400, (not shown here but in paper IV, Table 5, p473 and the cost per life year saved is equivalent to 311- 401 USD. The sensitivity of the data on life years saved (LYS) was tested by calculating the effects of 2, 4, and 6 LYS, instead of an average of 8 LYS. The lower value, 2 LYS, increased the cost of the quitline from 311 USD to 1, 056 USD per LYS. When changing to 4 years, the cost per LYS was 526 and for 6 years, 355 USD.

In the sensitivity analysis we also recalculated the cost-effectiveness of reducing the rate of quitters from 30 percent down to 6 percent. As shown in Table 10, the lowest quit rate corresponds to 1,607 USD per LYS and the highest to 311 USD. For outcomes down to 20 percent abstinence, the cost per year of life saved changed modestly (from 311 to 482 USD).

Table 10. Sensitivity analysis

Abstinent after 12 months (%)	Cost per Life Year Saved USD
6%	1, 607
7%	1, 375
10%	963
15%	642
20%	482
25%	385
30%	321
31%	311

5 DISCUSSION

The Swedish quitline proved to be a cost-effective public health intervention with approximately one out of three clients being smoke-free after 12 months. This supports findings from United States (Zhu et al., 1996; El-Bastawissi et al., 2002) and Australia (Borland et al., 2001) all of which showed effectiveness. It is widely acknowledged that the majority of smoking cessation methods are cost-effective (Fiore et al., 2000; Parrot et al., 1998; World Bank 1999) but no cost-effectiveness study has been found which focused on a national telephone-based tobacco cessation service.

Being referred to the quitline by a health professional proved to be an important factor for enhancing the quit rates. Previously reported findings (Fiore et al., 2000; Wadland et al., 1999) showed that combining doctor's brief advice and a quitline service appear to have a synergetic effect and health care providers are natural partners for quitlines and can play a major role in increasing their utilisation (World Bank 2004).

5.1 METHODOLOGICAL CONSIDERATIONS

In many fields of applied research, the randomized controlled trial (RCT) is viewed as the gold standard, that is the method of choice if you seek to do quality research.

However, study design cannot suffice as the main criterion for the credibility of evidence about public health interventions (Rychetnik et al., 2002).

The notion that real world phenomena are best studied outside the laboratory needs justification. An experiment is realistic if the situation which it presents to the subject is realistic, if it truly involves the subjects as interactive agents, and has an impact upon them (Robson 2004). There are several disadvantages in carrying out field experiments: 1) random assignment: there are practical and ethical problems in achieving random assignment to different experimental treatments or conditions (e.g., in withholding the treatment from a no-treatment control group). Random assignment is also often feasible only in atypical circumstances or with selected respondents, leading to questionable generalisability. Treatment-related refusal to participate or continue can bias sampling. 2) Validity: the actual treatment may be an imperfect realization of the variable of interest, or a restricted range of outcomes may be insensitively or imperfectly measured, resulting in questionable validity. A supposed no-treatment control group may receive some form of compensatory treatment, or be otherwise influenced (e.g., through deprivation effects). 3) Participant availability: it is not easy to ensure that participants will come into the laboratory. You have to rely on them turning up.

This thesis is conducted in a real world setting with its shortcomings but also its advantages. Participant availability was never a problem. Random assignment was not used since few smokers calling a quitline would expect to be assigned to a control group. Also, to impose control in this setting would jeopardize ethical standards. Measures based on recall such as in study II and III may lead to problems with validity. The design in these two studies was cross-sectional survey which is relatively inexpensive and easy to perform, as well as ethically sound. However, this method can

not establish causation (only association) and is susceptible to bias such as recall bias and confounding (Badenoch & Henegan 2002). As a predictive measure, a quit attempt that lasted a week or longer in the last year appears less biased by recall than any attempt for a day or longer in the last year (Gilpin & Pierce 1994). However, the 24-hour time frame of abstinence used for symptom assessment in study II was selected to achieve better statistical power in the analysis. The questions used to assess depression in study II were not standardised. There are studies where these kinds of simple questions have been compared with standardised scales and it was found that both specificity and sensitivity of simple questions is very high (Watkins et al., 2001). It simply was not practical to include validated scales in this real world setting. The retrospective assessment of smoking behaviour in non-responders in study III may also have been affected by recall bias. However, when comparing responders' with non-responders' smoking behaviour at the time of the telephone interview (Table 7) the main results did not change.

Confounding is an important issue that has to be considered in all epidemiological studies. Only factors logically and empirically linked to the proposed outcome and exposure were explored (Rothman 2002). In this thesis potential confounders were retained for adjustment in multivariate analysis only if they were statistically associated to the outcome in univariate analysis.

Nevertheless, the natural setting has several advantages 1) Generalisability: the laboratory is necessarily and deliberately an artificial setting, set apart from real life by the degree of control and isolation that applies. If we are concerned with generalizing results to the real world, the task is easier when experimentation is based in a natural setting which is the case with the Swedish quitline. 2) Validity: the demand characteristics of laboratory experiments, where subjects tend to do what they think you want them to do, are heightened by the artificiality and isolation of the laboratory situation. In a real world setting you are more likely to be measuring what you think you are measuring. 3) Participant availability, it is easier to get participants involved in real life experiments which was true in our case.

All data collected using a questionnaire may incorrectly categorise subjects. The magnitude of this potential bias is dependent on the validity and reliability of the modules. The modules were developed through a series of in-depth interviews and pilot studies to enhance validity of the questions. Another disadvantage to postal and self-administered surveys is ambiguities in, and misunderstandings about the survey questions that may not be detected (Robson 2004). However, the questionnaires were tested for face validity.

5.2 ABSTINENCE

Self-reported point prevalence abstinence was used as outcome measure. This has previously been found to be an accurate measurement (Patrick et al., 1994; Caraballo et al., 2001) and was preferred for several reasons. First, the majority of existing trials

present their primary outcome data as point prevalence (Fiore et al., 2000). Second, guideline analyses show that studies with, and without, biochemical confirmation yield similar meta-analysis results (Fiore et al., 2000).

Point prevalence rate has several advantages. If measured sometime after the event or intervention, such as 6 or 12 months later, it can include smokers who take delayed action to quit. This smoking cessation measure therefore captures the dynamic process of quitting and reflects better how people change in their natural environments than does a continuous abstinence measure. Point prevalence rates also allow lapses (brief returns to smoking) or relapses (extended returns to smoking) to occur following treatment without making it necessary to categorize the smoker as a permanent failure. The immediacy of the measure avoids the problems inherent in measures that rely on recall of past events.

But point prevalence also has several disadvantages. Given the high rates of relapse during the first three months following quitting, it is possible that some individuals who were counted as former smokers at baseline will be current smokers at the follow-up. Point prevalence rates are not as stable as continuous abstinence rates since they depend on the minimum duration of abstinence used to define former smokers and the point in time that participants are assessed. The rates may be difficult to interpret in relation to certain abstinence symptoms that develop over time such as weight gain as well as the health effects of smoking cessation (study II). Smokers who have not smoked for 1 or 7 days obviously demonstrate only the more immediate abstinence symptoms and health benefits of quitting while those not smoking for a longer period of time allow for analysis of the longer-term consequences of cessation (Velicer & Prochaska 2004).

5.3 TRANSTHEORETICAL MODEL (TTM) – STAGES OF CHANGE

In accordance with previous studies (Curry et al., 1995; Rohren et al., 1994) stage of change at baseline in study I was associated with abstinence at follow-up. The majority of callers were mainly in contemplation and preparation stage (study I) which shows a more prepared group of individuals similar to other investigated quitline populations (Borland et al., 2003). Among those in action stage, the median amount of time between stated quit date and first call was five days. In addition treatment from the California quitline, it was found that 60% relapsed already in the first week (Zhu & Pierce 1995). This implies that the high success rates of those who were in the action stage at baseline could to a great extent be explained by selection. It may also be an indicator of high motivation at first call (study I).

One of the major claims of investigators who use the TTM is its ability to guide stage-matched interventions, thus tailoring strategies to individual stage of readiness and needs. There is evidence that the stages of smoking cessation are related to levels of nicotine dependence and number of cigarettes smoked (Andersen et al., 1999). In a literature review, it was concluded that the TTM applies well to tobacco cessation and better enables practitioners and researchers to understand tobacco users and helping them quit (Spencer et al., 2002). The correct identification of a smoker's stage of change is fundamental to the TTM. A test/retest reliability was performed in one study of Australian smokers and almost 80% of subjects provided the same response at two

measurement points that were less than a week apart with a reliability coefficient of .72. This was considered to be a moderate, but not strong, reliability given the close proximity of the two measurement points. A better way of assessing the reliability of a single-item measure is through the use of a quasi-simplex, a method that adjusts for potential confounding factors in a test/retest situation. This method has demonstrated a high level of reliability.

Furthermore, a review of a number of longitudinal, prospective experimental, and quasi-experimental studies on TTM and tobacco use, support the validity of the stage of change construct (Spencer et al., 2002). This leads to a more specific question as to whether stages are better measured by a continuous scale than a categorical measure. Some evidence suggest that this might be the case (Kraft et al., 1999; Pierce et al., 1998) but this was demonstrated mainly among early-stage smokers.

The probable existence of subtypes emphasizes the need to address the validity of the model within specific contexts. Also, in studies, of populations outside the United States suggest that the stages of change construct can be applied accurately and usefully. Location may not have an effect, the differences lies with the motivation to quit, or stage of change distribution, of a sample (Borland et al., 2003). Further, it has been observed that when smoking cessation recommendations are matched to an individual's needs and readiness to change, the potential impact to the population of smokers increase long after the end of treatment (Velicer et al., 1999).

In the review cited above a significant challenge to the model was related to the stages of change; specifically it has been questioned whether they exist, how they should be defined, and measured (Spencer et al., 2002). Another criticism of the stages of change construct is that it might not represent true stages that can be discreetly categorized, where forward movement from one stage is caused by different variables than those that cause forward movement from another stage (Sutton 2000).

A recent editorial (West 2005) however, challenged researchers and clinicians to abandon the TTM as it was seen as flawed, especially criticising the concept of "stage". Stages here were seen as theoretical constructs being far too artificial to describe the more dynamic flow of behavioural change. Reviews comparing stop-smoking interventions designed using the stages of change approach with non-tailored treatments found no benefit for those based on the model (Reimsma et al., 2003; van Sluijs et al., 2004). According to Sutton, the reviews of stage-based intervention that have been published until now have included studies that were not proper applications of the TTM (Sutton 2005). This should stimulate a debate and hopefully more research for a better understanding of behavioural change.

The Swedish quitline has used the stages of change, TTM from the outset and found it to be a useful tool. Whether TTM will be replaced by other constructs at the quitline in the future can only be answered by further analyses and/or the development of better models.

5.4 PROACTIVE/REACTIVE COUNSELLING

The results from the Swedish quitline with approximately one out of three reporting abstinence after one year (study I) are convincing and in line with these supportive results from the three reviews mentioned before in 1.3.1 and 5. However, there are

substantial differences depending on stage of change at baseline. Those who were in the contemplation stage at first call reported 12 month abstinence in 19% of the cases compared with 22% for those in preparation and 53% for people who were in the action stage at first call.

Among women the proactive quitline service enhanced abstinence rates compared to the reactive service (study I). When further analyses were done on an extended proactive material, the difference between groups disappeared. The results in study I may have occurred by chance. On the other hand, about 40% (197/496) of those belonging to the reactive cohort were exposed to a fast track evaluation about 6-8 months after the first call, which may be seen as a proactive intervention. This was required by the funding agencies. An ad hoc assessment had to be performed before a decision for further monetary contribution could be taken. This contamination probably had a diluting effect.

The positive association of abstinence with referral by a health care professional on abstinence rate (study I) is supported by a recent article assessing the effect of the Swedish quitline on general practitioners' smoking cessation activities. It was concluded that the quitline had a positive effect on GPs' engagement in smoking cessation (Boldemann et al., 2005). Such services probably support and encourage GPs to do more (Marcy et al., 2002).

Evaluations involving reactive services have been more likely to compare variants in service than to use a no intervention control (Balanda et al., 1999; Davis et al., 1992). In general reactive quitlines respond only to client initiated calls, but in some models smokers may request counselling calls which are made from the call centre (Zhu 1996 et al., 1996; Zhu et al., 2000) and there is then some overlap with the proactive call. Proactive services have been more widely evaluated because they can more easily be compared with a minimal intervention. Findings from systematic reviews (Lichtenstein et al., 1996; Fiore et al., 2000; Stead et al., 2003) provide support for proactive telephone counselling as the main intervention and suggest that telephone counselling as the sole intervention, or added to self-help materials alone, increases the odds of quitting. No direct comparison of quitline models is available, thus there is no evidence for greater effectiveness of any of the models over others.

A threat to generalisability is the use of meta-analysis which in this context would be comparing results from different studies that may combine programmes with quite different levels of quality and advice and/or schedules of advice. These different results may be difficult to compare because of the various services provided, different follow-up periods, inconsistent definitions of callers, smokers, or quitters, and different numerators and denominators. However, when stability of meta-analytic findings was determined with respect to only one population characteristic, that is, whether patients sought cessation treatment "self-selected" or whether treatment was delivered without the patient seeking it "all comers" such an approach yielded similar findings (Fiore et al., 2000).

It has been found that quitlines also have the benefit of being a supportive treatment for those who are close to relapse, thus not only generating calls but promoting cessation in the general population (Borland et al., 2001). There may be unanticipated effects that apply to our results as well. Evaluative research outcomes may be intended or

unintended. Unintended effects may be as desirable as, or even more desirable than, the intended effects of the evaluation (Rychetnik et al., 2002).

5.5 SYMPTOMS AND ABSTINENCE

The majority of subjects trying to quit reported symptoms and high intensity of symptoms related to unsuccessful quitting attempts (study II). All symptoms comprising factor 1 (psychological) were correlated to abstinence at 12 months, and these symptoms are largely those reported to be related to abstinence in other studies (West et al., 1989; Xian et al., 2003).

The expectation that cessation of tobacco use will result in many aversive symptoms may serve as a barrier to making attempts to quit. Moreover, given that the intensity of tobacco withdrawal symptoms often peaks during the first week post-quit (Hughes et al., 1990; Kottke et al., 1989) and some 65% of self-quitters relapse during the first week (Hughes 1992), it is tempting to posit a relationship between withdrawal severity and abstinence. However, this relationship has not been consistent (Patten et al., 1996; Surgeon General 1990). This lack of consistency may reflect a true lack of association or it may also be based on methodological shortcomings. One problem with design in study II was that baseline data on symptoms was not assessed, and this should routinely be collected (Shiffman et al., 2004). Obviously, gathering base-line information on the prevalence of symptoms allows us to distinguish between abstinence induced symptoms and the baseline prevalence. Unfortunately, those smokers who were never abstinent or abstinent for less than 24 h did not answer the symptoms assessment questions. This information (had that been available) could have served as some sort of base-line for the prevalence of these symptoms in smokers. However, it could be expected that many of these people had at least attempted to quit and therefore may report higher prevalence compared to smokers not trying to abstain. The frequency and intensity of symptoms varied across subjects (study II). This variability may be explained by the fact that successful quitters report fewer symptoms whereas those being unsuccessful quitters overestimate symptom discomfort. We need to document these symptoms in a representative cohort of smokers not trying to quit as well as in non-smokers. Overall, this area is complex and the literature has conflicting results and conclusions.

5.6 NON-RESPONSE REGARDED AS SUCCESS

In contrast to commonly held beliefs and practices, results in this thesis show that non-responders in smoking cessation programs should not automatically be regarded as treatment failures (study III). There is often a tendency to view non-responders as a homogenous group with common characteristics, but studies have not confirmed this to be the case (Etter & Perneger 1997).

Studying non-responders acts as a control for the validity of the results of a study (Rothman 2002). In this case non-responders reported higher abstinence rates at the time when they were supposed to return the follow-up questionnaire (study III). This finding is in agreement with other studies (Kaper et al., 2005; Rupp et al., 2002; Tillgren et al., 2000; Rodes et al., 1990). There are studies, however, where differences were found (Kotaniemi et al., 2001; Boström et al., 1993; Hill et al., 1997; Rönmark et

al., 1999). In evaluation of smoking cessation programs including surveys and clinical trials, the tradition has been to treat non-responders as smokers. However, the existing empirical data on differences in smoking between responders and non-responders is often based on public health surveys (Boström et al., 1993). Caution is needed when comparing these studies to our study since it is possible that non-responders in general health surveys may differ from non-responders in studies assessing abstinence rates after smoking cessation treatment. It is also known that bias is increased when response rate is low (Siemiatycki & Cambell 1984). The possibility exists that non-responders in studies with lower response rates may differ from our study population and our results may only apply from studies with a similar (70%) or higher response rate.

5.7 COST-EFFECTIVENESS

The resultant cost of 311-401 USD per life year saved (LYS) as shown in study IV represents excellent value for money by any standards (Tengs et al., 1995; Stapleton 2001). Smoking cessation services show good return on investment (Miller et al., 1993) and compared with medical interventions that require 30 000 USD to 150 000 USD per LYS (Warner 1993), the results from the Swedish quitline, even when applying the most conservative quit rates contribute to public health.

Although it was concluded that the cost-effectiveness of the quitline could have been underestimated due to the omission of future benefits (study IV), it may be argued that there are a number of important methodological features pointing to the opposite. It can be seen in Table 9 that the year of analysis ranged from 1993 to 2002, although all estimates were converted to 2002 prices for the purposes of comparison. However, this does not allow for the fact that there may have been technological advances and shifts in relative prices over the time period that could have affected the ranking (Drummond et al., 2003). More importantly, differences also exist between countries in clinical practice, the relative prices of health care resources and the incentives given to health professionals and institutions. This suggests that considerable care should be taken when extrapolating cost-effectiveness results from one country to another, or including them in the same league table. However, clinical data from studies employing a “pragmatic” protocol as study IV are often more generalisable and hence preferable for economic evaluation (Drummond & Jefferson 1996).

As well as direct health benefits, there may be public health outcomes as well. Some authors suggest that evaluations have usually ignored the latter and paid too much attention to individual health outcomes. Interventions may bring non-health benefits to individuals such as increasing the knowledge and future capacity to make informed choices. An intervention may have a social diffusion effect. A successful attempt to quit smoking with the Swedish quitline may spread to family, friends and colleagues. Community interventions aimed directly attempt to foster such diffusion (Rosen & Lindholm 1992). These are all valid concepts, although measurement of them may be difficult.

The most straightforward way to estimate costs and consequences is to use resource utilization and efficacy data from a randomized clinical trial. This approach retains the high internal validity of the trial, ensuring that both the costs and effects are measured within the same setting, and allowing variability in cost and effect estimates to be

explored using confidence intervals for the incremental cost-effectiveness ratio. However, there are several reasons why this approach may not be suitable in practice as was discussed before in chapter 1.6.2, and economic evaluations attempt to address questions set in real situations, rather than theoretical abstractions (WHO 2004).

Finally, decision makers should realize that cost-effectiveness estimates should not be used in a mechanistic fashion and that they at best represent merely a useful aid for decision making (Drummond 1993).

6 CONCLUSIONS AND POLICY IMPLICATIONS

The Swedish quitline significantly increased 12 month abstinence rate, especially in motivated smokers. Treatment efficacy may be further enhanced by focusing on factors identified in the different studies as being related to 12 months abstinence. (I). Symptoms that are psychological and/or neurological in nature are interrelated and appear to be the most significant obstacles for successful quitting attempts. These symptoms may be successfully treated with Nicotine Replacement Therapy (II). Non-responders in smoking cessation programs offered to a general population of smokers outside the stricter rules of clinical trials, should not automatically be regarded as treatment failures as in contrast to commonly held beliefs and practices (III). The Swedish quitline represents good value for money and is a cost-effective public health intervention compared with other smoking cessation interventions (IV).

- The Swedish quitline provides direct service to help smokers quit and efforts shall be made to expand its utilisation.
- Even a small percentage increase in quit rates translates into significant public health effects.
- The quitline offers an opportunity for health professionals in the primary health care to use this service as an adjunct. Efforts should be made to facilitate this tobacco prevention activity.
- National tobacco guidelines should be developed with increased support for the Swedish quitline.

7 REFLECTIONS FOR THE FUTURE

“The burden is greatest among those who can least afford it and who will have the least support to either prevent or treat its use” (Leischow et al., 2000). Although not a part of my thesis I find this an essential issue to be tackled in future tobacco prevention work. The challenge is not only evident in rich countries but even more in low and middle-income countries. In the context of comprehensive tobacco control efforts, a quitline may help to advance larger goals of the program, such as normalizing cessation and elimination disparities in tobacco use or access to treatment (World Bank 2004). Its applicability in resource poor settings remains to be studied.

Recalling that “the typical caller of the Swedish quitline is a women of 47 years of age with 12 years of education”, one important strategy is to find new ways to improve the impact of quitline services so that they reach much larger numbers of individuals also in Sweden. However, increasing patient flow must always be weighed against possible drops in quit rates. Other options include identifying and reaching priority sub-populations and especially to identify priority populations in Sweden such as low socioeconomic groups, adolescents, minority groups, and hospitalized patients is a future challenge for the Swedish quitline. Assessing the possible benefits of linking quitlines to web-based technologies and the newer generations of mobile telephones is another future prospect.

Even though my thesis is about a quitline in Sweden I would allow myself some reflections related to a wider context. Smoking is a global problem. The real challenge is in countries such as China and Viet Nam with the highest smoking prevalence in the world (WHO 2004). I have some limited experience from these countries and more from their “small” neighbor Lao PDR (Tomson et al., 2003). Actions to be considered in tobacco policy programs include price measures, legislation, bans on tobacco, information and advocacy campaigns, health warnings, control of smuggling, restricting access of minors to tobacco, crop substitution, and elimination of government subsidies for tobacco farming. Could quitlines play a role here? The first reported quitline in Asia was in Hong Kong (Abdullah et al., 2004) with quit rates comparable to those in West. Hong Kong, however, is not representative of the whole of China. Recalling the exponential growth of telecommunication systems in China becoming the world’s biggest cell phone market with nearly 200 million subscribers, one wonders if this could pave the way for quitlines in China.

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