The University of Nottingham

THE USE OF EXISTING DATA SOURCES TO EVALUATE THE IMPACT OF TOBACCO CONTROL POLICIES ON QUITTING BEHAVIOUR

Tessa Elisabeth Langley, BSc(Hons) MPH

Thesis submitted to the University of Nottingham for the degree of Doctor of Philosophy

JANUARY 2012

ABSTRACT

Background In England there is a comprehensive framework of tobacco control policies to reduce smoking-related harm. Policy evaluation helps to ascertain how policies may be improved so that they have the greatest impact; ineffective policies can be dropped or improved, while effective policies can be kept and improved further in order to optimise their impact. The evaluation of tobacco control policy requires high quality and timely data on smoking and smoking cessation behaviour. Time series analysis (TSA) is a robust way of evaluating policy, as it takes existing trends into account, but requires frequently collected data in large samples over long time periods.

The aims of this thesis were to investigate the suitability of a range of existing data sources for evaluating the impact of tobacco control policies in England on quitting behaviour, validate potentially suitable measures, and use validated measures to evaluate the impact of recent tobacco control initiatives in England using TSA.

Methods A range of data sources which provide information on smoking cessation behaviour were analysed to determine their adequacy for evaluating tobacco control policies, and previously unvalidated measures were validated. Different approaches to TSA – interrupted time series analysis and multiple time series analysis - were employed to evaluate the impact of the introduction of a new smoking cessation medication, varenicline, the broadening of the indications for nicotine replacement therapy (NRT) to include people with cardiovascular disease and adolescents, and the effect of anti-tobacco mass media campaigns on quitting behaviour.

Results Two key indicators of quitting behaviour are quit attempts and smoking prevalence; however, there are currently no frequently collected data from large enough samples covering a long time period on these measures. Survey data are generally not suitable for policy evaluation because they are infrequently carried out and often have small sample sizes, making it difficult to detect small and transient changes in behaviour. In contrast, routine sources of data such as electronic medical records data are often frequently collected in large samples over long time periods. A validation study showed that primary care data from The Health Improvement Network are an accurate source of data on prescribing of smoking cessation medication. Time series analyses of these data showed that both the introduction of varenicline, and the broadening of the indications for NRT, did not increase rates of prescribing for smoking cessation medication. Another study found that tobacco control mass media campaigns appear to be more effective at triggering quitting behaviour than pharmaceutical company NRT campaigns.

Conclusions Although there are significant gaps in the existing data available, there are some high quality time series data which can be used to evaluate the impact of tobacco control policies in England. There is a need for regular collection of data on key indicators of quitting behaviour, and the use of time series analysis in policy evaluation can play a vital role in strengthening the evidence for the effectiveness of policies, both in tobacco control, and in other areas of public health. The time series studies in this thesis suggest that recent changes to the availability of pharmacological smoking cessation aids have not had a significant impact on public health, and that recent cuts in tobacco control advertising are likely to have reduced quitting behaviour.

ACKNOWLEDGEMENTS

The work in this thesis was conducted under the supervision of Professor Sarah Lewis and Professor Ann McNeill in the Division of Epidemiology and Public Health, and Dr Casey Quinn in the Division of Primary Care at the University of Nottingham. It was funded by grants from the National Prevention Research Initiative and Cancer Research UK, support from Action on Smoking and Health UK and the UK Centre for Tobacco Control Studies, and by a University of Nottingham Medicine and Health Sciences Faculty Research and Knowledge Transfer Board PhD scholarship.

I would like to thank my supervisors for their ongoing advice and support, and, in particular Sarah Lewis and Ann McNeill for offering me the opportunity to enter the world of tobacco control research.

I would also like to thank Tim Coleman, who helped to supervise the NPRI-funded elements of this PhD, Jack Gibson, who set up the Nottingham Tobacco Control Database, Yue Huang who extracted much of THIN data used in this thesis, and Lisa Szatkowski, whose methodological advice has been invaluable.

My thanks go to my family and friends for their encouragement, especially those in blue and white (including one in particular) for providing the odd much-need two-wheeled distraction.

My greatest thank you is to my parents for their love and support, and for all that they do and have done for me.

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ABBREVIATIONS

ACF – autocorrelation function

AR - autoregressive

ARIMA – autoregressive integrated moving average

CHD – coronary heart disease

CI – confidence interval

CIRF – cumulative impulse response function

CVD – cardiovascular disease

ETS – environmental tobacco smoke

FCTC – Framework Convention on Tobacco Control

GHS – General Household Survey

GLF – General Lifestyle Survey (formerly GHS)

HRT – hand-rolled tobacco

HSE – Health Survey for England

IRF – impulse response function

ITC – International Tobacco Control Policy Evaluation Project

MA – moving average

MTSA – multiple time series analysis

NICE - NHS National Institute of Health and Clinical Excellence

NHS – National Health Service

NRT – nicotine replacement therapy

NTCD – Nottingham Tobacco Control Database

ONS – Office for National Statistics

OTC – over-the-counter

PACF – partial autocorrelation function

PCT – Primary Care Trust

POS – point of sale

SIDS – sudden infant death syndrome

SHS – secondhand smoke

SPC – Summary of Product Characteristics

SSS – Stop Smoking Services

STS – Smoking Toolkit Study

SVAR – Structural Vector Autoregression

TCP – Tobacco Control Plan

THIN – The Health Improvement Network

TPD – Tobacco Products Directive

UK – United Kingdom

VAR – Vector Autoregression

VECM – Vector Error Correction Model

WHO – World Health Organisation

CHAPTER 1: INTRODUCTION

1.1 The health costs of smoking

Smoking killed 100 million people worldwide in the twentieth century.[1] If current trends in smoking persist, smoking will kill one billion people in the 21st century.[2]

Cigarette smoking is the cause of approximately one in five deaths in Britain, which equated to an estimated 106,000 deaths per year between 1998 and 2002.[3, 4] Half of all regular smokers, and possibly as many as two thirds, will die as a result of their addiction.[2] The proportional impact of smoking is greatest in younger age groups and in men. One in three deaths in males aged 35–64 is caused by smoking.[3] A 35 year old male smoker shortens his life expectancy by approximately seven years; the corresponding figure for women is six years.[3]

The list of diseases demonstrated to be caused by smoking continues to lengthen. Recent reports about the health consequences of smoking have added diseases for which there was previously weak or no evidence to the list.[5, 6] This section summarises the diseases caused by smoking.

1.1.1 Cancer

Cancer is the most common cause of death in the UK, causing one in four deaths.[7] More than one in three people are diagnosed with cancer at some point in their life.[7] In 2009, over 260,000 people in England were diagnosed with cancer.[8] Relative survival for many cancers is very poor. For example, the 10 year relative survival rate for lung cancer in England and Wales has been estimated to be 5.3%.[9]

Smoking increases the risk of cancer mortality between two- and fourfold and in 2007 around 28% of over 155,000 cancer deaths in the UK were attributed to smoking.[10,11] Smoking has been shown to increase the risk of 19 cancers; these associations are summarised for the most common of these cancers below.[12]

Lung

Lung cancer is the most common form of cancer; there were over 33,000 new diagnoses of lung cancer in England in 2009.[8] Smoking causes 84% of lung cancer.[3, 7] Around a quarter of lung cancers in non-smokers are caused by passive smoking.[7] Smokers are 10 times more likely to die from lung cancer than non-smokers.[10] In heavy smokers the risks are even higher: they are 15 to 25 times more likely to die from lung cancer than non-smokers.[10]

Bladder

There were over 6000 newly diagnosed cases of bladder cancer in men in England in 2009, and nearly 2500 in women.[8] Smoking more than doubles the risk of dying from bladder cancer, and causes nearly 30% of deaths caused by the disease.[13, 14]

Pancreas

Pancreatic cancer is a rapidly fatal form of cancer accounting for approximately 3% of all cancers in England and Wales.[7] There were nearly 7000 new cases of pancreatic cancer in England in the year 2009.[8] Current smokers are approximately twice as likely to die from pancreatic cancer as never smokers.[13, 14]

Oesophagus

There were over 6500 new registrations of oesophageal cancer in England in 2009.[8] This type of cancer is strongly associated with smoking, which, when combined with alcohol, has a multiplicative effect.[7] At 10%, the survival rate for oesophageal cancer is extremely low, although it has trebled since the early 1970s.[9]

Stomach

In 1980 stomach cancer was the most common cancer in the world; its incidence has declined substantially in recent decades.[7] Current smokers are approximately twice as likely as non-smokers to get stomach cancer.[15-18]

Kidney

There were nearly 6500 new diagnoses of kidney cancer in England in 2009.[8] Smoking has been identified as a major risk factor for renal cell carcinoma and cancer of the renal pelvis. Current smokers are 50% more likely to get kidney cancer than non-smokers.[19] The risk is higher in heavy smokers, who double their risk of kidney cancer compared with non-smokers.[20]

Bowel

Bowel (colorectal) cancer is the third most common cancer in men, after prostate and lung cancer, and the fourth most common in women in England. In 2009 approximately 30,000 new cases of bowel cancer were diagnosed in England.[8]

The association between bowel cancer and smoking has only recently been demonstrated, as early studies suggested that smoking was not an important risk factor. However, there is an increasing body of

evidence, which has been able to take account of the long lag from the exposure to smoking to the onset of the disease, and the fact that colorectal cancer is common in non-smokers as well as smokers, which suggests that smoking is associated with both colon and rectal cancers.[5]

Lip, Mouth and Pharynx

In 2009 there were around 3500 and 2000 new cases of cancers of the lip, mouth and pharynx in men and women in England respectively.[8]

Pharyngeal cancer is relatively rare, but highly associated with smoking: Smokers have a sevenfold increased risk of cancer of the pharynx compared with non-smokers.[19] The risk of oral cancers is increased more than threefold by smoking.[19]

1.1.2 Cardiovascular Disease

In 2005 there were about 100,000 deaths from coronary heart disease (CHD), 58,000 from stroke and 50,000 deaths from other types of cardiovascular disease (CVD) in the UK, accounting for over a third of all deaths.[21] Cigarette smoking significantly increases the risk of CVD, as well as aggravating existing CVD conditions.[13, 22] Smoking causes one in seven deaths from heart disease.[23] The risk of CVD increases with increased exposure; however, even very light smokers have a much higher risk of CVD than non-smokers.[24-27]

Overall, smokers are 70% more likely to die from CHD than non-smokers.[28] Heavy smokers are almost three times as likely to die from CHD than non-smokers.[28]

The risk of sudden cardiac death is two to four times higher in smokers than non-smokers. [28] The risk of sudden cardiac death increases with the number of cigarettes smoked per day.[28]

Current smokers also have a two- to fourfold increased relative risk of stroke compared with non-smokers.[29, 30] People who smoke 40 or more cigarettes per day are nearly twice as likely to die from stroke than those who smoke fewer than 10 cigarettes per day.[29]

1.1.3 Respiratory Disease

In 2007 there were nearly 80,000 deaths from respiratory disease in the UK, including approximately 30,000 deaths from COPD.[11] Of all deaths from respiratory disease, 34% were attributable to smoking.[11]

It has been estimated that 25% of smokers develop clinically significant COPD, and up to 40% develop some symptoms associated with the disease.[31] However, it has also been suggested that most long-term smokers probably get COPD, but that it is often not sufficiently severe to be diagnosed, or that its diagnosis is missed if patients die from another disease, such as heart disease.[32] An estimated 69% of COPD deaths in men in the UK, and 77% in women, are attributable to smoking.[11] However, in the USA up to 80-90% of COPD deaths have been estimated to be due to smoking.[33]

Smoking is also associated with other respiratory diseases, such as pneumonia (twofold risk in smokers compared with non-smokers, and threefold risk in heavy and long-term smokers) and tuberculosis (threefold risk in smokers compared with non-smokers).[34, 35]

1.1.4 Passive smoking

Smoking does not only pose a threat to smokers themselves, but also to those who are exposed to their second-hand (SHS) smoke. It has been estimated that in 2003 11,000 adults in the UK died as a result of passive smoking in the home, and a further 617 from the effects of passive

smoking at work.[36] Because the majority of passive smoking-related deaths occur within the home, legislation prohibiting smoking in public places, which was introduced in the UK in 2006 and 2007, has only a limited, albeit an important effect on the prevention of deaths due to passive smoking. In particular, it is unable to protect a group that is particularly vulnerable to the effects of passive smoking: children. In children, passive smoking leads to over 165,000 new episodes of disease, 300,000 primary care contacts, 9500 hospital admissions, at least 200 cases of bacterial meningitis, and about 40 sudden infant deaths each year.[37]

1.1.5 Smoking in pregnancy

Passive smoking is not the only means by which a person's smoking can harm others. Smoking in pregnancy can cause harm to the unborn child. Maternal smoking has been associated with low birth weight (which, in turn, can lead to neo- and perinatal health problems), premature birth, congenital malformations, spontaneous abortion and perinatal mortality. [37-39] Passive smoking in pregnancy is also associated with increased risk of stillbirth and congenital malformation.[40] The children of mothers who smoke in pregnancy have an increase in risk of sudden infant death syndrome (SIDS), as well as a higher risk of respiratory illness and otitis media.[38, 41, 42] Exposure to secondhand smoke in early childhood also increases the risk of respiratory illness, otitis media and sore throats.[43, 44]

1.2 The economic costs of smoking

1.2.1 Individual costs

Smoking is associated with economic costs, as well as a public health burden. Smoking addiction comes with a heavy financial burden for

the individual smoker. Smoking 20 cigarettes per day costs between £1600 and £1800 per year.[45]

More deprived smokers spend a higher proportion of their income on smoking than better off smokers. In 2008, the poorest 10% of households spent an average of 2.21% of their weekly expenditure on cigarettes; for the richest 10% the corresponding figure was 0.35%.[46]

1.2.2 Costs to society

The cost of smoking to the taxpayer is also considerable. In the UK, the treatment of smoking-related disease has been estimated to cost the National Health Service (NHS) £5.2 billion per year.[47] The cost of treating childhood illnesses caused by passive smoking has been estimated at £410 million per year.[48] An estimated 34 million days are lost to absenteeism resulting from smoking-related disease in England and Wales per year.[48] It has been suggested that the societal costs of smoking in the UK outweigh the income from tobacco taxation.[49]

1.3 Trends in smoking in the UK

There has been relatively slow decline in smoking prevalence in the UK since the mid-1990s. The prevalence of cigarette smoking fell rapidly in the 1970s and early 80s, from 45% in 1974 to 35% in 1982. The rate of decline was much slower until the mid-1990s, when it levelled off at approximately 27%. Since the start of the 2000s, there has been an annual decline of around one percentage point. In 2009, 21% of British adults smoked.[50]

1.3.1 By sex

Historically, in Britain, cigarette smoking has been higher in men than in women; in 1974, the prevalence of smoking in men was 51%,

while in women it was 41%.[51] However, the gap in prevalence between men and women has narrowed over recent decades; in 2009, the General Lifestyle Survey (GLF) found that 22% of men in the UK were smokers, compared with 20% of women, but the difference was not statistically significant.[50]

1.3.2 By age

Since the early 1990s, the prevalence of smoking has been highest in adults aged 20-24. In 2009, however, the prevalence in this group was 26%, and very similar in 25-49 year olds, at 25%.[50] Adult smoking prevalence is lowest in those over 60, at 14%.[50]

Most smokers begin smoking as teenagers. The prevalence of self-reported regular smoking (at least one cigarette per week) among 11-15 year olds in England was 5% in 2010.[52] This has declined since the start of the decade, when prevalence in this group was 10%.[52] The prevalence of smoking in this age group rapidly increases with age. In 2010, smoking prevalence in 13 year olds was 5%; in 15 year olds, it was 17%.[52]

1.3.3 By socioeconomic status

There is a marked social gradient in the prevalence of smoking. In 2009, the prevalence of cigarette smoking in manual groups was 26%, compared with 16% in non-manual groups.[50] Smoking is the largest identified cause of social inequalities in health, and recent reduction in smoking prevalence has occurred predominantly in the more socioeconomically advantaged.[53] As a result, socioeconomic disparity in smoking prevalence and the prevalence of smoking-related mortality and morbidity has grown.[39]

1.3.4 In pregnancy

Survey data suggest that the rate of smoking in pregnancy has fallen in recent years, but a substantial proportion of mothers continue to put their unborn child's health at risk by smoking. In the 2010 Infant Feeding Survey (IFS) 26% of mothers in the UK reported smoking in the year before or during pregnancy, although evidence suggests that this survey, which lacks a biochemical measure to validate smoking status, underestimates the true level.[54, 55] The survey found that 12% of expectant mothers continued to smoke throughout their pregnancy. Data on smoking status at the time of delivery (SSATOD) from the Department of Health also suggest that the IFS figures are underestimates: according to these data, 13.5% of mothers were smoking at delivery.[54] The IFS estimated that the percentage of mothers smoking throughout pregnancy in the UK fell from 20% to 12% between 2000 and 2010.[54]

The survey also found that in the UK, 40% of mothers in routine and manual occupations smoked before or during pregnancy, compared with 14% in managerial and professional occupations.[54] 20% of mothers in routine and manual occupations smoked throughout pregnancy.[54] Young mothers were also more likely to smoke during pregnancy: 35% of mothers aged 20 and under smoked throughout pregnancy.[54]

1.3.5 Awareness and attitudes

Around two thirds to three quarters of smokers in Britain say that they want to quit smoking.[56] However, less than a quarter say they 'very much' want to do so.[56] In Britain, 77% of smokers say they intend to stop smoking at some point, yet only 12% say they intend to do so in the next month.[56]

The majority (85%) of smokers who want to stop smoking have at least one health reason for wanting to quit.[57] Nonetheless, survey information about smokers' knowledge as to the health risks of smoking suggests that the limited intention of British smokers to quit smoking may be attributable to a lack of awareness of the specific risks of smoking. A significant proportion of smokers in the UK continue to be unaware of the extent of the risks associated with smoking. Only 39% think smoking is the biggest cause of premature deaths in the UK, compared with 48% of ex-smokers.[56] 10% are not aware that smoking causes heart disease and 30% do not know it causes stroke.[56] There is therefore a continued need to warn of the dangers of smoking in the UK.

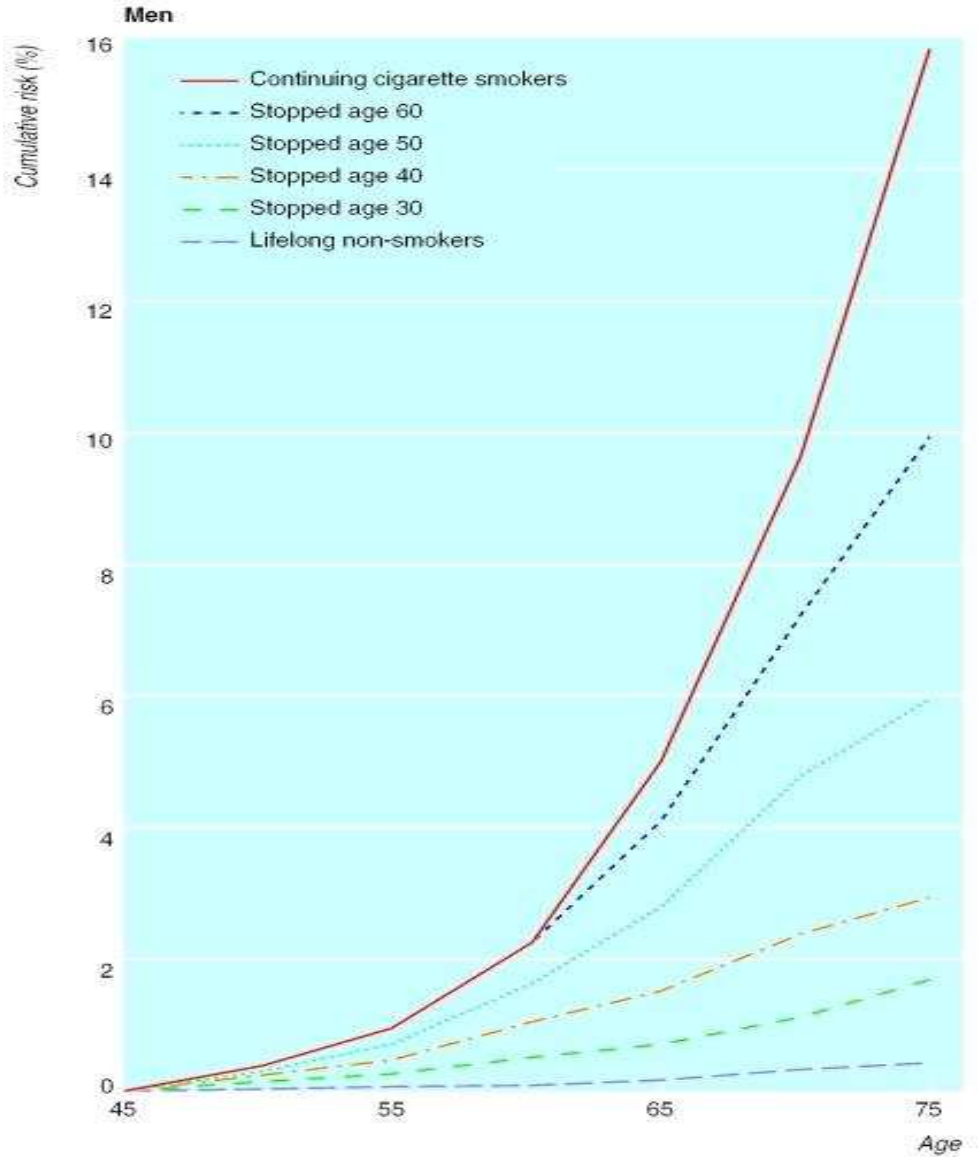
1.4 The importance of smoking cessation

1.4.1 Individual gains

The health benefits of stopping smoking are overwhelming; smoking cessation adds years to life, regardless of the age at which people quit.[2, 58] Cessation at age 60, 50, 40, or 30 years has been estimated to improve life expectancy by approximately 3, 6, 9, or 10 years respectively and, although the risk of some smoking-related diseases tends not to return to the level of lifelong non-smokers, the risk in long-term quitters is similar to that in never smokers.[2, 59]

Quitting smoking decreases an individual's risk of lung cancer compared with continuing smokers. The risk is reduced regardless of the age at which people quit, but the risk reduction is increased if the smoker stops at a younger age, as demonstrated in Figure 1-1.[60]

Figure 1-1. Effects of stopping smoking at various ages on the cumulative risk (%) of death from lung cancer up to age 75, at death rates for men in United Kingdom in 1990



Source: Peto et al. (2000)[60]

The risk of other cancers also decreases after people have quit smoking, and tends to decrease towards the risk of never-smokers over time, although for many cancers the risk never returns to the level of that in never-smoker. For example, the risks of lip, mouth and pharyngeal cancers decrease with time after cessation, although it can take two decades for the risk to return to close to that of never-smokers. Smoking cessation reduces the risk of pancreatic, kidney and bladder cancer, as well as stomach cancer and laryngeal cancer.[16, 18, 59] The evidence of the decrease in risk for some other cancers is inconsistent or inadequate.[59]

Smoking cessation also rapidly leads to a decrease in the risk of CHD. This risk continues to decline, albeit slowly, after the first year following cessation, and reaches a level comparable to that in never-smokers around 15 years after cessation.[59] Quitting smoking also reduces the risk of other types of cardiovascular disease including cerebrovascular disease, peripheral arterial disease and aortic aneurysm.[59] For example, the risk of stroke decreases significantly two years after quitting; after five years, quitters have the same lower risk of stroke as never smokers.[29]

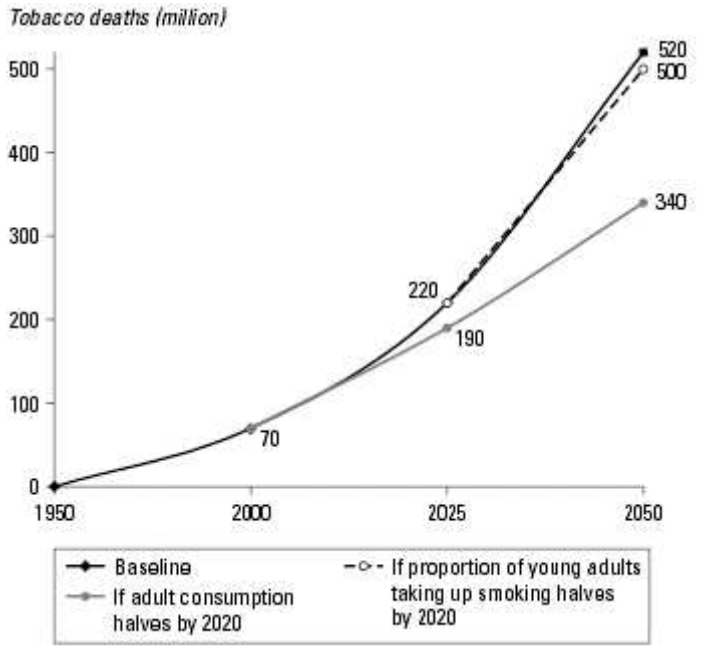
Quitting smoking is important for respiratory health, both for patients with and without existing respiratory disease. Smoking cessation is vital in preventing and decreasing the progression of COPD and respiratory symptoms.[61-63] In people without respiratory disease, smoking cessation has been shown to improve lung function by 5% within just a few months of quitting and reduces the risk of a first-time COPD diagnosis.[6, 64]

1.4.2 Population gains

The population level effects of the reduced health risk in individuals who quit smoking are substantial. As demonstrated by Figure 1-2, unless current smokers quit, tobacco deaths will rise dramatically worldwide in the next 50 years. If adult consumption halves by 2020, tobacco deaths will continue to rise, but at a much lower rate. Further to this, getting current smokers to quit now will reap benefits more quickly than preventing young people from taking up smoking; the vast majority of the projected smoking-related deaths worldwide for the first half of the current century are those of current smokers.[65]

Increasing the rate at which smokers stop smoking and remain abstinent is a fundamental aim of tobacco policy in the UK and elsewhere, and, in industrialised countries is proposed as the most important means of reducing morbidity and premature death over the next 20 years.[2]

Figure 1-2. Estimated cumulative tobacco deaths 1950–2050 with different intervention strategies



Peto and others estimate 60 million tobacco deaths between 1950 and 2000 in developed countries. The figure estimates an additional 10 million between 1990 and 2000 in developing countries. It assumes no tobacco deaths before 1990 in developing countries and minimal tobacco deaths worldwide before 1950. Projections for deaths from 2000 are based on Peto (personal communication [1998]). *Sources:* Peto, Richard and others. 1994. *Mortality from Smoking in Developed Countries 1950–2000*. Oxford University Press; and Peto, Richard, personal communication.

Source: World Bank – Curbing the Epidemic (1999) [65]

1.5 The development of tobacco control policy in the UK

The previous sections have outlined the importance of encouraging smokers to quit and preventing new smokers from starting to smoke. These are the primary aims of tobacco control policy. It also aims to reduce exposure to environmental tobacco smoke (ETS) and smoking-related health inequalities. In the UK, tobacco control policy is primarily determined by the government, with additional influence in terms of both policy and legislation from the European Union and the Framework

Convention on Tobacco Control. The role of each of these in shaping tobacco control policy in the UK is described in this section.

1.5.1 Government tobacco control policy in the UK

In 1998 the UK government published the first White Paper on tobacco control, 'Smoking Kills'.[66] It defined a strategy which has shaped the comprehensive set of tobacco control policies implemented in the UK since then. The majority of the decrease in smoking prevalence in the UK in the past decade is attributed to 'Smoking Kills'. Its objectives were to:

- Reduce smoking in children and young people
- Help adults to stop smoking
- Reduce smoking in manual groups as a step towards reducing inequalities
- Offer particular help to pregnant smokers

It detailed a range of policy measures, most of which were implemented and remain in place today. These included:

- A ban on tobacco advertising and sponsorship
- Tobacco taxes rises
- Enforcement of under-age sales
- Reducing point-of-sale tobacco advertising
- Introducing smoking cessation services
- Facilitating access to smoking cessation medication

Devolution since 1998 means that tobacco control policy is largely dealt with separately in England, Scotland, Wales and Northern Ireland, although some policy areas related to tobacco control, such as taxation, remain the responsibility of the UK government. However, 'Smoking Kills' related to the whole of the UK, and as such many of the same steps to reduce the burden of smoking have been taken throughout the UK, albeit at somewhat different times.

In March 2011, a new tobacco control strategy, 'A Tobacco Control Plan for England' was published.[67] It committed to:

- implementing legislation to end tobacco displays in shops
- looking at whether the plain packaging of tobacco products could be an effective way to reduce the number of young people who take up smoking and to support adult smokers who want to quit, and consulting on options by the end of the year
- continuing to defend tobacco legislation against legal challenges by the tobacco industry, including legislation to stop tobacco sales from vending machines from October 2011
- continuing to follow a policy of using tax to maintain the high price of tobacco products
- promoting effective local enforcement of tobacco legislation
- encouraging more smokers to quit by using the most effective forms of support, through local stop smoking services
- publishing a three-year marketing strategy for tobacco control

The implementation of this plan is in its infancy, but the measures that have already been taken are described later in this chapter.

1.5.2 The EU and tobacco control in the UK

Health policy and the organisation, financing and management of healthcare are a national responsibility of EU member states. As such, the EU has limited powers in the area of tobacco control as well as broader health policy. It nonetheless has substantial influence on tobacco control policy in the UK and other Member States.

Article 168 of the Lisbon Treaty underlines the EU's role in fostering cooperation and coordination in health policy between member states. Its most notable steps in this regard related to tobacco control have been two Council Recommendations, one on the prevention of smoking and on initiatives to improve tobacco control, and one on smokefree environments.[68, 69] These are non-binding agreements, the latter of which calls for Member States to implement legislation on smokefree public places, develop methods to protect children from ETS and encourage smoking cessation. The former calls for Member States to introduce measures to reduce sales of cigarettes to minors, prohibit most types of tobacco advertising, prevent exposure to ETS in workplaces and public places, reduce prevalence and use cigarette price as a smoking deterrent. The EU has also funded an EU-wide stop smoking campaign targeted at young people, HELP.

Due to the broad scope of tobacco control policy in the UK (which is described in detail in section 1.6), where smokefree legislation, mass media campaigns and other policies aimed at reducing smoking are in place, and the lack of power it has in health policy, it may appear that the

EU has a limited role in tobacco control in the UK. However, its most substantial contribution to tobacco control has come in other policy areas. The EU treaty states a requirement that all EU policies should protect health and, as a result, EU legislation has frequently incorporated aspects of tobacco control. Most notably, the EU single market rules have permitted (though not without resistance from the tobacco industry)[70] the EU-wide implementation of legislation banning tobacco advertising (2003/33/EC) and on the manufacture, packaging and labelling of tobacco products (2001/37/EC, known as the Tobacco Products Directive (TPD), which is currently under review).[71, 72]

1.5.3 The WHO Framework Convention on Tobacco Control and MPOWER

Tobacco control policy in the UK and the EU is in line with the tobacco control policy framework set out by the World Health Organisation Framework Convention on Tobacco Control (FCTC). The FCTC is a global public health treaty, the objective of which is "to protect present and future generations from the devastating health, social, environmental and economic consequences of tobacco consumption and exposure to tobacco smoke".[73] It was signed by the UK in 2003 and came into force in 2005.

The convention calls for parties, inter alia, to:

- enact and undertake comprehensive bans on tobacco advertising, promotion and sponsorship
- ban misleading and deceptive terms on cigarette packaging such as 'light', 'low-tar' and 'mild'

- implement rotating health warnings on tobacco packaging that cover at least 30 percent (ideally 50 percent or more) of the display areas
- protect people from tobacco smoke exposure on public transport, and in indoor work and public places
- adopt or maintain taxation policies aimed at reducing tobacco consumption
- combat illicit trade in tobacco products

Further to this, in 2008 the World Health Organisation (WHO) published a report on the worldwide tobacco epidemic which proposed six policies to be implemented in order to achieve comprehensive and effective tobacco control, collectively named MPOWER.[1] These policies are in line with the framework set out by the WHO FCTC.

- **M**onitor tobacco use and prevention policies
- **P**rotect people from tobacco smoke
- **O**ffer help to quit tobacco use
- **W**arn about the dangers of tobacco,
- **E**nforce bans on tobacco advertising, promotion and sponsorship
- **R**aise taxes on tobacco

These policies, and others, have been implemented in the UK in recent years.

1.6 Recent tobacco control policy in the UK

The key priorities for tobacco control are consistent at the national, EU and international levels, and thus the UK has been able to develop a comprehensive framework for tobacco control, the main elements of which are described in this section.

1.6.1 Smokefree legislation

As outlined in section 1.1, the risks posed by SHS exposure are high. The arguments for smokefree environments are therefore strong.

In March 2004, Ireland became the first country in the world to ban smoking in the majority of work and public places. A study by Mulcahy et al. showed that, following the implementation of the ban, ambient nicotine air concentrations in a sample of city centre bars decreased by 83%. A survey of hotel workers carried out as part of the same study showed that their self-reported exposure to SHS at work fell from a median of 30 hours per week to zero.[74] Smokefree workplaces can reduce the prevalence of smoking, and may encourage the adoption of smokefree homes.[75, 76]

Since July 2007, smoking has been prohibited in all enclosed and substantially enclosed work and public places in England. Smokefree legislation came into force in Scotland in March 2006 and in Wales and Northern Ireland in April 2007.

Smokefree legislation in the UK appears to have been successful, to the extent that it is popular, widely complied with, has improved air quality, reduced passive smoke exposure and has had a positive impact on health outcomes.[37, 77, 78] There is also some evidence that smokefree legislation has had a positive effect on quitting behaviour, although no decrease in UK smoking prevalence has been observed since it was

implemented.[50, 79, 80] Nonetheless, it has limitations. The majority of passive smoking occurs within the home, and other non-public places, such as cars. Tackling exposure to SHS in these settings, particularly that of children, is a pressing challenge for policy makers; policies to address SHS exposure in children may be developed within the next years.[37]

1.6.2 Mass media campaigns

International evidence has shown that mass media campaigns can cause positive changes or prevent negative changes in a range of health behaviours.[81] Tobacco control campaigns, which are usually funded by governments or charities, have been shown to increase smoking cessation and reduce smoking prevalence.[82-87] The existing studies are, however, heterogeneous, in terms of both the nature and intensity of the media campaigns and the populations studied, and the quality of the studies is variable.[82, 83, 86] In 2008 the UK government spent over £15 million on anti-smoking advertising. Campaigns have conveyed the dangers of smoking, the implementation of smokefree legislation and smoking cessation services, with the aim of changing smoking behaviour. Some are targeted directly at encouraging people to quit and try to help to enable quit attempts by advertising the services available to support people's quit attempts. However, this spending has recently come under threat from government spending cuts; a freeze on all Department of Health-funded public health mass media campaigns was imposed in April 2010. Although tobacco control campaigns have been re-introduced since the publication of the tobacco control plan in 2011, the rate of funding is lower than prior to the cut.[88]

Government (and charity-funded) mass media campaigns are not the only source of anti-tobacco advertising in the UK. Pharmaceutical

company-funded advertisements for nicotine replacement therapy (NRT) provide information on different types of NRT with the primary aim of increasing sales of NRT. By also conveying the health benefits of quitting these adverts may also increase the number of people who want to quit smoking and influence quitting behaviour. There is some international evidence that pharmaceutical company advertising can have a positive effect on NRT sales.[82, 89, 90] In addition, the aforementioned EU-funded HELP campaign, aimed at getting young people to stop smoking and discouraging them from taking up smoking, has had a high internet and television presence in recent years.

There is scant evidence of the effectiveness of anti-smoking mass media campaigns in the UK. Chapter 7 of this PhD thesis is a study exploring the impact of mass media campaigns on quitting behaviour in England.

1.6.3 Health warnings

Evidence from the UK and elsewhere suggests that health warnings on tobacco products are another measure that raise awareness of the risks of smoking and influence quitting behaviour, although most of the evidence is based on survey data which may be prone to recall bias.[91, 92] Health warnings have been displayed on cigarette packs in the UK since 1971. The EU Tobacco Products Directive, enforced in the UK since 2002, requires all tobacco products to display a general health warning covering at least 30% of the front of the pack, and an additional warning covering at least 40% of the back of the pack.[93] The Tobacco Products Directive, inter alia, also lays down maximum tar, nicotine and carbon monoxide yields for cigarettes manufactured or sold in the UK, and sets out regulations for labelling cigarette packs and other tobacco products.

In May 2007 Belgium became the first EU country to introduce compulsory graphic pictorial health warnings on tobacco packaging. The UK introduced compulsory pictorial health warnings, which survey evidence suggests are more effective than text warnings, in October 2008.[94, 95]

1.6.4 Bans on tobacco advertising, promotion and sponsorship

Highly effective marketing, through advertising and sponsorship, is integral to tobacco companies' marketing strategies; it encourages non-smokers, particularly young people, to take up smoking, and discourages current smokers from quitting. Advertising has been shown to have a positive effect on tobacco consumption, although the evidence is inconsistent.[96, 97] Evidence also suggests that advertising bans can be effective in reducing tobacco consumption, but to do so, must be comprehensive. Saffer et al. suggest that banning advertising in just one or a small group of advertising media leads to tobacco companies diverting resources to different marketing channels, thus preventing a reduction in advertising expenditure and tobacco consumption.[97]

Television advertising for tobacco products was banned in the UK in 1965 under the Television Act 1964, pre-empting a now amended EU Directive which did the same in 1989 (Television without Frontiers Directive (89/552/EEC). This directive was replaced by the Audiovisual Media Services Directive (2007/65/EC) adopted in December 2007).[72, 98-100] The Tobacco Advertising and Promotion Act 2002 banned most remaining tobacco advertising in the UK from 2003.[101] Tobacco advertising in the press and on billboards was banned from February 2003 and direct marketing from May 2003. Tobacco company sponsorship was phased out from July 2003, in line with the EU's Tobacco Advertising Directive (2003/33/EC) which banned cross-border tobacco advertising in all media

other than television (which had already been banned) and at events involving several Member States, such as Formula One races.[71]

Currently, however, tobacco companies continue to have other means of advertising their products in the UK: point of sale (POS) tobacco displays and branded tobacco packaging. Both of these have been identified as important marketing tools, particularly in attracting young smokers.[102, 103] In England, POS displays are set to be banned in large shops from April 2012, and in all other shops from April 2015. In Scotland, legislation to ban POS displays has been passed, but its implementation is currently being hindered by legal challenges. In Wales, a consultation of POS has taken place but final regulations and a date for implementation have not been announced. The Northern Ireland Assembly has stated that it intends to introduce a ban from spring 2012. No countries in the UK currently have plans to introduced plain packaging, but the government stated that it will consult on this measure in the tobacco control plan, and has announced that it will launch a consultation in spring 2012.[67]

1.6.5 Raising taxes on tobacco

Raising the price of tobacco has been suggested as the single most effective means of reducing tobacco consumption.[104] Evidence also suggests that it is the most effective way to reduce smoking-related inequalities in health.[105] It is estimated that, globally, on average, a 10% increase in tobacco price will reduce consumption by 4%; that is, tobacco has a price elasticity of -0.4%. [106] Poor smokers and young smokers are more responsive to price, and therefore a price increase of 10% may reduce consumption in these groups by more than 4%.[106] In the UK, tobacco has been estimated to have a price elasticity of -0.5%.[107]

In the UK, there have been rapid increases in tobacco price since the 1990s as a result of increases in the tax on tobacco. In 1993 a tobacco tax inflator was introduced, thus tobacco tax rose by 3% and then 5% above the rate of inflation. The inflator was stopped in 2001 following concerns about the contribution of increased cigarette prices to smuggling of tobacco products into the UK, but was re-introduced in April 2010. Tax currently constitutes approximately 78% of the price of cigarettes in the UK and, in 2008, the UK had the highest price of cigarettes in Europe.[104, 108]

1.6.6 Combating illicit tobacco

In the late 1990s, an estimated 20-30% of the market for tobacco in the UK was made up of illegally imported cigarettes.[109, 110] Illicit tobacco undermines tobacco control policy by reducing the price of cigarettes, thus increasing demand. Illicit tobacco also contributes to tobacco-related health inequalities; the most disadvantaged smokers are twice as likely to buy illicit tobacco as the most affluent.[111]

Since 2000, HM Revenue and Customs has taken measures to reduce tobacco smuggling in the UK, including additional customs officers, additional specialist investigators and intelligence staff; additional x-ray scanners; tougher sanctions and penalties; and a public awareness campaign. Recent estimates suggest that about 10% of the market is now smuggled.[112] However, the illicit market share for hand rolled tobacco (HRT) remains large, at about 46%.[112]

1.6.7 Rise in legal age of sale of cigarettes

On 1st October 2007 the minimum age of sale for tobacco products in England and Wales and Scotland was raised from 16 to 18 years old.

Because most adults smokers begin smoking in adolescence, this was perceived as an important measure to reduce adult smoking prevalence in the future, as well as a way of reducing adolescent smoking prevalence. This may have been effective: one study found that, in England, prevalence decreased more in 16-17 year olds following the increase in age of sale than in older age groups, although this study was limited by the fact that it was not able to take into account long term trends in prevalence in this age group.[113] This is consistent with much of the existing evidence, which suggests that restricted access to tobacco, when well enforced, reduces use in minors.[114]

1.6.8 Ban on tobacco vending machines

A more recent measure to reduce smoking in young people is a ban on cigarette vending machines, which was implemented in October 2011. Evidence has shown that adolescents in the UK were more likely to purchase tobacco from vending machines than the population as a whole, and that young people were more likely to be successful in buying cigarettes from vending machines than any other outlet.[115, 116] The vending machine ban may therefore prove to be an important measure in reducing smoking in young people.

1.6.9 The Quality and Outcomes Framework

In 2004 a new contract for GPs was introduced. The contract is voluntary, but has been taken up by most GPs.[117] Part of the contract is the Quality and Outcomes Framework (QOF), a group of pay-for-performance targets which aims to improve the management of patients with chronic disease. A group of the QOF targets are related to the management of smoking. The requirements of the QOF have changed slightly over time, but currently include:

- Recording the smoking status of patients aged 15+ in the general population at least every 27 months (except never smokers, where smoking status is to be checked annually until age 25, and ex-smokers, who are to be asked about smoking status on an annual basis until they have been a non-smoker for 3 years.)

- Recording the smoking status of patients with any of a group of specified chronic diseases at least every 15 months

- For patients with chronic diseases, offering and recording in the patients' notes smoking cessation advice or referral to specialist smoking cessation services at least every 15 months

- Providing general smoking cessation support through information provision

The QOF has been shown to improve recording of patient smoking status.[118, 119]

1.6.10 NHS Stop Smoking Services

At an individual level, UK tobacco policy is targeted at offering people the best help to quit smoking. In the UK, 67% of smokers want to stop smoking, and 53% have made a significant attempt to quit smoking in the past five years.[56] However, only 3-5% of unaided quit attempts are successful, therefore providing smokers with the support needed to increase the likelihood of a successful quit attempt is a fundamental aspect of tobacco control.[120] The UK has a comprehensive framework of support to help smokers quit. A range of interventions has been shown to be effective in yielding higher success rates, and many of these are available in the UK, some free at point of delivery.

In the UK the NHS provides access to free Stop Smoking Services (SSS) which are provided locally. These services may be provided in primary care, in pharmacies, or in community settings. NHS SSS provide counselling and behavioural support to smokers who want to quit, and are also able to provide access to smoking cessation medication. The services are effective; 14% of users have been shown to be successful quitters at 52 weeks.[121] The services are also cost-effective and may reduce socioeconomic inequalities in smoking prevalence.[122, 123] The NHS also runs a free stop smoking helpline, which offers advice and support to smokers who want to quit.

The main limitation of the SSS is their limited reach. It has been estimated that although nearly half of smokers make a quit attempt each year, only 5% of quit attempts are made with the support of the SSS.[124] By contrast, measures such as mass media campaigns, health warnings and tax increases may be less effective in individuals, but reach a much greater proportion of smokers.

The NHS National Institute of Health and Clinical Excellence (NICE) has issued guidance on how health professionals in primary care and other settings should deliver brief stop smoking interventions to patients. Health professionals are advised to offer to refer smokers who wish to quit to NHS Stop Smoking Services, or offer to prescribe one of three licensed pharmacological smoking cessation treatments.[125]

1.6.11 Pharmacotherapy

Pharmacotherapy for smoking cessation can increase the chances of quit attempt success. In the UK, three medications are licensed for smoking cessation: Nicotine replacement therapy (NRT), bupropion (brand

name Zyban) and varenicline (brand name Champix in the UK, Chantix in the USA).

NRT

NRT is the only nicotine-based pharmacotherapy licensed for smoking cessation in the UK. Six different forms of NRT are licensed in the UK: gum, tablet, patch, inhalator, nasal spray and lozenge. NRT works by providing an alternative source of nicotine during quit attempts, allowing quitters to cope without their typical smoking behaviour and rapid delivery of nicotine, while not experiencing the worst effects of nicotine withdrawal, by providing smaller quantities of nicotine. Later, NRT use is stopped.

NRT increases the likelihood of quitting by 50 to 70%.[126] The likelihood of successful quitting without pharmacological aid is low; therefore the chances of an unsuccessful quit attempt using NRT are still quite high. Nonetheless, due to the health benefits of stopping smoking, NRT is highly cost-effective as well as effective.[126] NRT has been available on NHS prescription since April 2001 and is also available over-the-counter (OTC). It became available OTC, initially from pharmacies only, in the 1980s. Since March 1999 an increasing number of NRT products have become available on general sale (i.e. over the counter outside pharmacies). In December 2005 the indications for NRT were broadened such that adolescents aged 12-17, pregnant smokers and CVD patients can also be prescribed NRT. The effect of this licensing change has yet to be evaluated; its impact is therefore investigated in Chapter 6.

Bupropion

Bupropion, which in some countries but not the UK, is licensed as an antidepressant, is licensed as a smoking cessation medication in the

UK. It has been available on NHS prescription since June 2000 and cannot be obtained without a prescription.

Bupropion is similarly effective as NRT: it increases the chance of long-term cessation by approximately 70% compared with unaided quitting.[127]

Varenicline

Varenicline is the newest medication for smoking cessation available on the NHS. Like bupropion, it is a non-nicotine smoking cessation drug, and it has been approved in the USA, in the EU, and in other countries. It was introduced in the UK in December 2006 and, like bupropion, is only available on prescription.

Varenicline is a partial agonist which eases symptoms of craving and withdrawal during smoking cessation. It also reduces the rewards and reinforcing effects of nicotine by preventing it from binding to α4β2 nicotine receptors. It increases the likelihood of a successful quit attempt between two- and threefold and is cost-effective.[128, 129] It may be more effective than NRT and bupropion in achieving continuous abstinence.[128, 129] The impact of the introduction of varenicline to the market for smoking cessation medication in England has also not been explored. Chapter 4 is a study of the impact of varenicline on prescribing of other smoking cessation medications.

1.7 The evaluation of tobacco control policy

1.7.1 Why evaluate?

Having a comprehensive framework of tobacco control policy, such as that in the UK, is clearly vital. The final element of the MPOWER framework also underlines the importance of monitoring in order to ensure

the success of the tobacco policies that are put in place. In addition to general monitoring of smoking and quitting behaviour, however, it is important to evaluate the impact of individual tobacco control policies to establish which policies are effective (and, in some cases, cost-effective) and in which circumstances and why. Policy evaluation also helps to ascertain how policies may be improved so that they have the greatest impact on reducing smoking-related harm and inequalities. In this way, ineffective policies can be dropped or improved, while effective policies can be kept and, if possible, improved further in order to optimise their impact. For example, the 2010 Royal College of Physicians Report 'Passive Smoking and Children' concluded that the primary aims of smokefree legislation - to "protect workers and the general public from exposure to the harmful effects of passive smoke exposure" - have largely been achieved in enclosed workplaces and public places.[130] However, it highlights areas in which smokefree legislation could be extended and better enforced, particularly to increase its benefit for children.[37] Evaluation may not only guide policy in the country or region in which the policy is in place; it may also aid policy development elsewhere. Following evaluation, therefore, the international dissemination of findings is also crucial.[1]

This section seeks to summarise, using examples from previous policy evaluations, the key elements of how best to carry out such an evaluation, including outcomes, study designs and data sources. It sets the background for the main body of this thesis, which explores, taking into consideration the features identified as important to policy evaluation in this section, the suitability of a range of existing data sources in England

for the evaluation of tobacco control policy, and uses existing data to evaluate a set of tobacco control policies recently implemented in England.

1.7.2 What to evaluate

Like the International Agency for Research on Cancer's (IARC) Handbook on Methods for Evaluating Tobacco Control Policies (henceforth referred to as the IARC Handbook), on which this section draws, this thesis does not discuss the evaluation of individual-level interventions that can be tested in randomised trials, such as pharmacological smoking cessation aids or behavioural interventions.[131] Instead, this research focuses on the evaluation of the impact of population-level policy interventions which are aimed at getting smokers to quit.

1.7.3 Outcomes

The IARC Handbook states that there are five broad types of outcomes which may be included in the evaluation of tobacco control policy:

- Changes in knowledge (such as awareness of the health risks of smoking)
- Changes in attitudes and related normative beliefs (such as attitudes towards smoking in the home)
- Changes in behaviour patterns (such as smoking prevalence)
- Changes in exposures (for example, secondhand smoke)
- Changes in health outcomes (for example, the incidence of heart attacks)

Generally, it is ideal to conduct evaluations using a range of these different outcomes in order to obtain comprehensive evidence as to the impact of a policy.

Changes in knowledge and attitudes are potentially important short-term outcomes as they may act as mediators of a policy effect. In other words, they may be precursors to changes in behaviour.[132] Identifying the mechanisms through which tobacco control policies work may help to increase the effectiveness of policies.[132] However, demonstrating the impacts of policies on knowledge and attitudes alone, without showing that these changes lead to changes in behaviour, provides only weak evidence for the effectiveness of policy. Very few existing data sources provide sufficiently detailed data to enable the investigation of mediating effects, and therefore these outcomes are not used in this thesis. An exception is the International Tobacco Control Policy Evaluation (ITC) Project, which has been used to evaluate a range of tobacco control policies both in the UK and elsewhere.[132] The ITC Project is described in section 1.7.7.

The most important outcome for all types of tobacco control policy evaluations is health outcomes, as this is the best way of quantifying the public health (and potentially economic) impacts of policies. Changes in health outcomes may, however, not occur in the short-run, and evaluating these may therefore not be possible if the timescale is short. Furthermore, some individual policies may not have a detectable impact on health outcomes. Measuring changes in health outcomes as a result of tobacco control policy therefore poses a substantial challenge.

Most tobacco control policies aim to reduce the harm caused by tobacco by influencing smoking behaviours (such as quitting or initiation),

and therefore changes in behaviour are important outcomes. Furthermore, changes in behaviour are likely to occur in the short and medium term, and are therefore likely to be more sensitive to change than health outcomes. This thesis deals specifically with the effect of tobacco control policy on quitting behaviour. The most direct outcome of quitting behaviour is successful quit attempts. Smoking prevalence is also an important outcome related to quitting behaviour, although smoking prevalence is also determined by new smokers, and deaths of smokers, as opposed to just quitting. Tobacco consumption is also potentially an outcome of interest, but is probably less important for public health. This is because a decrease in consumption may not necessarily be associated with a decrease in prevalence, as it may reflect people smoking less (but potentially more intensively) rather than quitting.[133] Furthermore, some measures of consumption may not take into account illicit tobacco. However, consumption may be more sensitive to changes in policy, making it easier to detect policy effects.

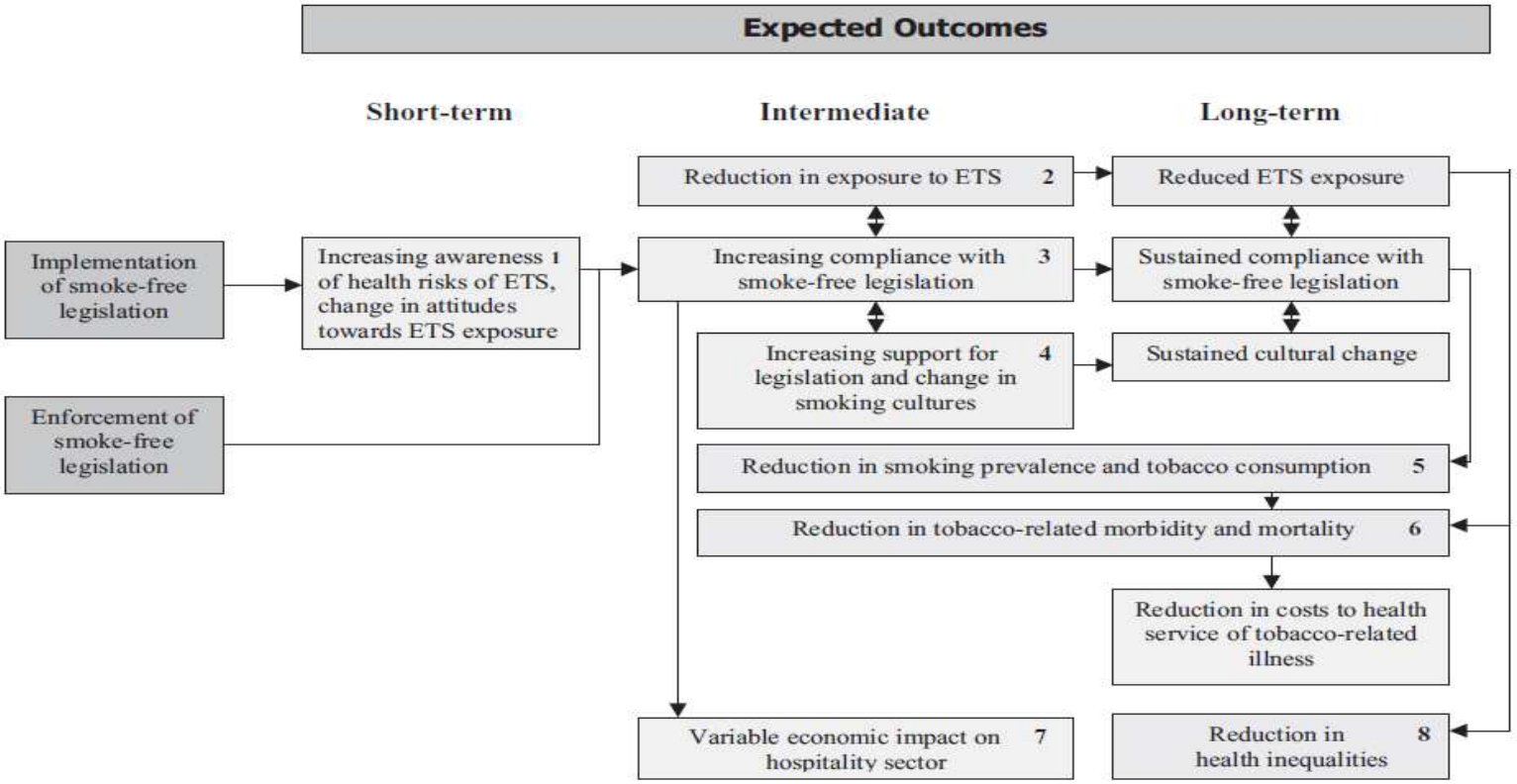
Other outcomes related to quitting behaviour include smoking cessation medication use, calls to stop smoking helplines, and attendance at smoking cessation services. They are less direct measures of quitting, but may nonetheless provide important evidence as to the impact of a policy.

Regardless of the most appropriate outcome measure, data may not be readily available or collected in a way that is adequate for analysing policy and thus relevant alternative outcomes may need to be used. At any rate, as highlighted in the IARC Handbook, in order to obtain a broad evidence base for the impact of a policy, it is desirable to evaluate using a whole range of outcomes related to the policy; consistent demonstration of

its favourable effects improves the evidence profile for the effectiveness of the policy. For example, Fowkes and colleagues and Lewis and colleagues used different outcomes (quitting and use of stop smoking medication) which both suggested that Scottish smokefree had a positive impact on quitting behaviour.[134, 135] Thus, when evaluating the impact of a policy on quitting behaviour, it is desirable to look at its effect on quit attempts, prevalence, use of cessation services, quitlines and use of smoking cessation medication.

The selection of the outcomes can be depicted using a logic model, such as that used in the (pre-implementation) planning of the evaluation of Scottish smokefree legislation (Figure 1-3).[136] A logic model helps to understand how policies have the impact they have by depicting the likely short-term, intermediate, and long-term outcomes and linking those outcomes to each other.

Figure 1-3. Logic model of expected outcomes associated with smokefree legislation



Source: Haw et al. 2006[136]

The logic model highlights that the choice of outcomes may be influenced by the time scale of the evaluation. The effects of policies may vary across the short, medium and long term, and the outcomes of interest will vary accordingly.

As mentioned above, this section, like the rest of this PhD thesis, focuses on evaluating the effect of policies on quitting behaviour. However, the majority of the study design features that are identified as important in the rest of this chapter are also relevant to the evaluation of effects on other outcomes.

1.7.4 Target populations

A final consideration in the selection of outcome measures is in whom the outcome should be measured. Some policies are not targeted at the whole population; the outcome measures should reflect the relevant population group. For example, evaluations following an increase in the legal age for buying cigarettes should focus on smoking prevalence and uptake and smoking behaviour in young people. It is also often important to explore differential impacts in different sociodemographic groups, in order to establish the implications of the policy for health inequalities, to which smoking is a major contributor.[137]

1.7.5 Study designs

The limits of a gold standard: RCTs

Randomised controlled trials are held as the gold standard in study design for the evaluation of health care interventions, because they are able to minimise both bias and confounding. They are ideally suited to establishing the efficacy of individual level or small group interventions in

controlled settings. For all that they are vital in testing interventions, however, RCTs have limitations: because they evaluate interventions in experimental conditions, they are inadequate for evaluating real-world effectiveness and dissemination.[131, 138] Implemented policies (or laws) cannot be randomised; they are natural experiments and cannot be evaluated in controlled experiments. For this reason, DiFranza states that "the evaluation of laws cannot be reasonably held to a standard that holds the randomized controlled trial to be the only valid source of knowledge".[139]

For example, elements of some current UK tobacco control policies can be evaluated using RCTs (e.g. pharmacotherapy, elements of SSS, impact of mass media campaigns) – and this is most frequently the main rationale for their implementation - but these do not tell us anything about effectiveness in real-world settings and the extent to which they will be taken up in the relevant population groups. For example, making smoking cessation medications available on prescription will not be effective in making people quit if it is not effective in practice, and/or few people choose to use it; one cannot be sure what their population-level impact, as well as their impact in specific sociodemographic groups, may be until they have been implemented in the real-world. Policy evaluations can explore these effects and therefore play a vital role that cannot be played by RCTs. The IARC Handbook underlines that because of the uncertainty surrounding real-world intervention effects, it is inappropriate to cite lack of evidence as a reason for obstructing necessary policy change.[131]

While policy cannot be evaluated using an RCT design, its evaluation can, like an RCT, seek to comprise features which address issues that are found in traditional epidemiological studies, namely bias,

confounding and chance and temporality. As far as possible, measures should be incorporated which help to rule out alternative explanations for observed effects.

The following sections describe the study design features which can be included to maximise the validity of an evaluation. They demonstrate that, due to data constraints, this is easier said than done; it is probably indeed unfair to judge evaluation studies as harshly as observational studies and RCTs. Nonetheless, the fundamental criteria on which they are judged should be similar.

Control groups

Including a control group is a common feature of epidemiological study design that is used to reduce the risk of alternative explanations for a change in an outcome following an intervention. Control groups can also be used in policy evaluation. The control group in a policy evaluation is one that has not been exposed to the policy to be evaluated. When a control group is included, the change in the outcome in the control group is compared to that in the exposure group; if the policy is effective, the difference in the policy groups will exceed that in the non-policy group.[131]

Because randomisation is not possible with implemented policies, using a control group will only improve the quality of the evaluation if the exposed and control groups are similar in features relevant to the policy (such as smoking prevalence, sociodemographics and tobacco control intensity), so that they are comparable.[131]

It is also important to consider potential confounding events. For example, if evaluating the effect of a tax decrease on tobacco consumption in country A, results may be confounded if graphic health warnings on

cigarette packs were introduced in the control country, country B, at a similar time.

It may be difficult to find a control group which adequately fulfils all these criteria; it may be particularly challenging when using existing data, which may not be available for different countries, or may not have been collected using the same methodology and may therefore not provide adequate control data. On the other hand, when collecting primary data, the inclusion of an appropriate control may be prohibitively expensive. As a result, until now, few evaluations have incorporated whole country control groups.

The main example of the inclusion of control populations in tobacco control policy evaluation until now is the ITC Project, which now includes 20 countries and therefore a range of potential control populations.[132]

Pre- and post-policy measures

The most important feature of evaluation design is that there should be a pre-policy estimate as well as a post-policy estimate. Without a pre-policy measurement, it is impossible to know what the measurement at a subsequent time point might have been, and thus it is not possible to estimate the effect of the policy.[131]

For example, in their study on the impact of smokefree legislation in Scotland, Hyland et al. reported smoking cessation figures for the year in which the policy was implemented. However, as no pre-policy measures were collected, they were not able to estimate the effect of the policy.[140]

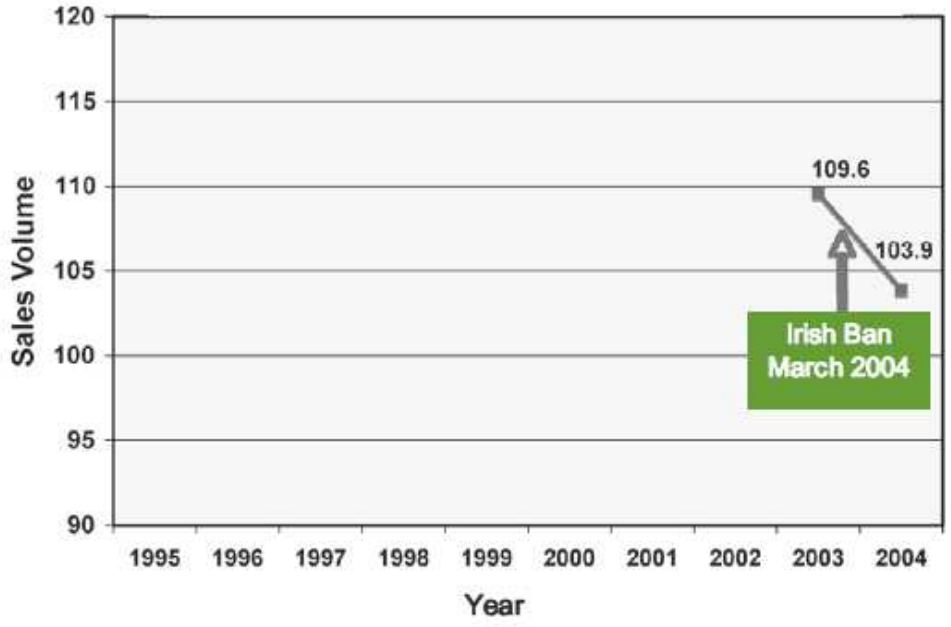
This underlines the value of planning evaluations before a policy is implemented; if primary data collection is required, this will enable the collection of pre-policy data.

Multiple pre- and post-policy measures

As is illustrated in the IARC Handbook using the example of pub sales following the introduction of smokefree legislation in Ireland, it is most useful to have *several* measurements before the policy change so that pre-existing trends and historical events (such as other tobacco control policies) may be taken into account in determining the effect of a policy.

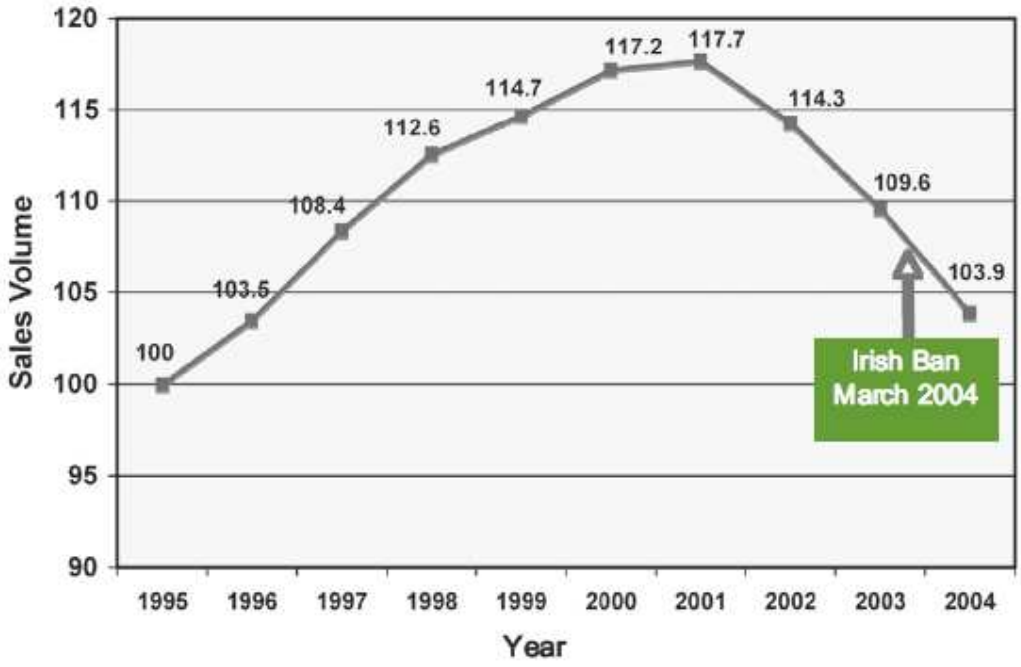
Figure 1-4 shows pub sales volumes in Ireland in the years before and after the implementation of the smoking ban in public places in Ireland. Sales in 2004 were lower than in 2003 and therefore, based on these two data points alone, it may seem that smokefree legislation caused a decrease in sales in the following year. Figure 1-5, however, shows pub volume sales for several years before the ban and one year after the ban. It clearly demonstrates that pub sales volumes were already decreasing in the years before the ban; therefore it seems likely that the ban did not in fact reduce pub sales. This shows the importance of having several measurements before the implementation of a policy. It is also valuable to have several measurements following the policy implementation in order to explore the long term effects of policy.

Figure 1-4. Pub sales volumes immediately before and after implementation of the Irish smoking ban in 2004



Source: Central Statistics Office of Ireland
Sales volumes are indexed so that sales volume in 1995 = 100

Figure 1-5. Pub sales volumes in Ireland, 1995-2004



Source: Central Statistics Office of Ireland
Sales volumes are indexed so that sales volume in 1995 = 100

A limitation of many existing evaluation studies is that they compare just one pre and post-policy measurement. For example, Hackshaw et al. found that in England, a greater percentage of smokers reported making a quit attempt in July and August 2007, when smokefree legislation was implemented, compared with July and August 2008.[79] However, this may simply reflect an existing decreasing trend in quit attempts. The results of such studies are useful, but are not conclusive. Where no data with multiple measurements are available, triangulation with other studies measuring similar or proxy outcomes is important, as this will increase the validity of the results.

Where including several pre-policy measurements is not possible, including a control group may significantly improve the validity of an evaluation by demonstrating what the change in the outcome would have been in the absence of the policy. In this case, knowledge of secular trends in the target population is not necessarily needed.

Limited pre-policy data may also underestimate the effect of a policy. Advertising and media coverage of an imminent policy may encourage behaviour change ahead of the implementation of a policy. As a result, including only data points shortly before the policy may underestimate policy effects, which may precede implementation. For example, Semple and colleagues studied changes in SHS exposure in bar workers in England following the implementation of smokefree legislation.[141] They found a significant improvement in air quality in bars (73-91% $PM_{2.5}$). However, because they took their pre-policy measurements in May and June 2007, just before the legislation was introduced in July, and because there was significant publicity surrounding

the legislation in the months leading up to July 2007, people may have begun to change their behaviour before the pre-policy measurements were taken. Their measurements may therefore have underestimated the true improvement in air quality.

As highlighted in the IARC Handbook, the benefit of having several pre-policy measurements underlines the advantage of having surveillance systems in place which collect data on outcomes of interest. When a policy is introduced with little warning, or is brought forward, there may be scant opportunities for relevant primary collection, making existing datasets all the more valuable.

Time series analysis

Time series consist of data collected at multiple, ordered, points in time, usually at equally spaced intervals, as in Figure 1-5. The importance of placing policy effects in the context of time trends emphasises why time series analysis is a particularly useful tool in policy evaluation. Interrupted time series analysis is a powerful statistical method which uses statistical modelling of data collected at regular intervals over time, to estimate the impact of an intervention introduced at a specified point in time. Multiple time series analysis (MTSA) can be used to estimate the effect of a policy exposure that is measured on a continuous scale, such as cigarette prices. These methods allow for the non-independence between data points (independence being a vital assumption of linear regression), and control for underlying trends (thus ensuring that post-intervention changes are not merely continuations of longer-term trends) and seasonal effects. Given appropriate data (time series analysis usually requires at least 50 data points) and appropriate methods, time series analysis can provide strong evidence of policy effects.[142] Time series approaches have until now rarely

been applied in a public health context, but have been successfully adopted in a small number of previous tobacco control policy evaluations.[82, 143-145] For example, Sims et al. used Hospital Episode Statistics to explore the impact of smokefree legislation in England on hospital admissions for heart attacks. They used a long monthly time series (from July 2002 to September 2008) and were able to take account of pre-policy trends and found that the legislation led to a short-term fall in admissions for myocardial infarction of 2.4%.[145]

When adequate data are available, time series analysis is able to provide high-quality evidence on policy effects. These methods are therefore used to analyse policy effects in this thesis. Chapter 4 provides a more detailed overview of the strengths and limitations and application of these methods.

Data intervals

Another important consideration in the design of a policy evaluation is the time interval between data points. Data intervals can substantially affect the flexibility of data and the strength of the conclusions that can be drawn from them.

Short data intervals make it easier to detect small and transient effects of policy; annual data may miss these effects, therefore monthly or quarterly data are preferable.[82] Shorter data intervals also increase the likelihood of reaching the required number of data points for a time series analysis, which, as described above, is an extremely valuable study design in policy evaluation. Further to this, short data intervals also make it easier to separate the (potentially confounding) effects of different policies which

may be implemented during any one year – although even with such data, disentangling these effects is often not possible.

The key limitation of monthly data is that they may be expensive, particularly if they are obtained through primary data collection. In particular, it may be costly to obtain the necessary sample sizes to ensure adequate power on a monthly basis. For example, the Opinions survey is a general survey carried out in households in Great Britain each month, and contains data on smoking prevalence.[146] However, the confidence intervals of the monthly data have been shown to be too wide to identify significant trends.[147]

1.7.6 Data and data sources

Evaluation of tobacco control policy requires high quality and timely data on smoking and smoking cessation behaviour both in the general population and in relevant sociodemographic groups. The data used should be relevant, valid and representative of the population being studied. As highlighted in section 1.7.3, it is desirable to conduct evaluations using a range of outcome measures, and therefore it is worthwhile exploring a whole variety of data sources to obtain outcome measures.

Data may be available from existing sources including national or regional surveys, or routinely collected data such as primary care data. The advantage of survey data is that they may be cheap or free for researchers to access, and are likely to be available for a long time period. However, there are significant disadvantages to this type of data, including potential reporting and recall bias (participants may not report smoking behaviour accurately or may misremember it), potentially inadequate sample sizes, and the fact that most surveys are carried out only annually.

The use of routinely collected data is likely to overcome many of the drawbacks of survey data: they may contain objective measures (thus minimising bias), and are likely to be available on a monthly or quarterly basis. Some routine data, such as electronic health care data, are also more likely to have large sample sizes, despite the short data intervals. The main disadvantages are that they may not measure exactly what needs to be measured.

In the UK, there is a range of existing data sources containing information on smoking and smoking behaviour. Many have not been used in the evaluation of individual tobacco control policies. The suitability of a group of these existing data sources for the evaluation of tobacco control policy is discussed in detail in Chapter 2.

If suitable existing data are not available, specifically-collected data may be more appropriate, as these can be tailored to the needs of the evaluation. The major disadvantages of these types of data are the substantial costs to researchers, as well as the need to begin collecting data before the implementation of the policy to enable adequate before and after comparisons. This requires the planning of data collection from the point at which discussions regarding the policy begin. This may not allow sufficient time for pre-policy data collection, and may be affected by unexpected changes in the content or timing of policies.

It may be the case that insufficient data to draw definitive conclusions about the effects of a policy are available. This may particularly be the case in countries where the infrastructure and funding for data collection and research are limited; however, as is explained in Chapter 2, even many types of existing data in England and the rest of the UK have

substantial limitations for the evaluation of tobacco control policy. Where national data and, thus, national evidence are limited, it is useful to take international evidence into account. For example, although there are few studies on improvement in health outcomes following the implementation of smokefree legislation in England, taking into consideration the reported impact of smoking bans in international settings could lend support to arguments that such bans have a positive impact on health outcomes.

1.7.7 Case study: The ITC Project

Background

The biggest tobacco control policy evaluation project undertaken to date is the ITC Project. It has many of the features described above as important to good policy evaluation; however, it also has a range of limitations. It provides a useful case study to demonstrate the importance of the various evaluation features described in this section.

The ITC Project was designed to evaluate FCTC policies and provide evidence on the impact of national tobacco control policies on psychosocial indicators (such as beliefs and attitudes and perceived risks of smoking) and smoking behaviours (e.g. quit attempts). It began in 2002 in the UK, United States, Canada and Australia, and now comprises 20 countries.

Design

The ITC Project uses a longitudinal survey design with multiple country controls and theory-based mediational models. It collects data on cohorts of approximately 2000 smokers in each country. The cohorts are replenished for each wave of data collection to ensure that the sample size is retained regardless of attrition. The survey is comprehensive, comprising questions on mediators, including policy-specific variables (such as warning

label salience) and psycho-social mediators (such as beliefs, attitudes and quit intentions), as well as questions on smoking behaviour. The conceptual model of the project assumes that each policy has an influence on behaviour through a specific chain of psychological events. In other words, it is assumed that the impact of a policy on behaviour is mediated by psycho-social factors.

Strengths

The ITC Project has several strengths which make it able to provide strong evidence of the effects of tobacco control policies in a range of countries. The longitudinal design allows the identification of temporal relationships, which would not be possible with a cross-sectional survey design. Further to this, collecting data at several time points means that temporal trends can be taken into account. The country controls help to disentangle policy effects from secular trends and confounding events. In addition, using the same method of data collection across all countries enables comparisons between them. Finally, as the surveys comprise behavioural and mediational variables, both the impact of policies and the mediators for policy impacts can be investigated.

Limitations

A key limitation of the ITC Project is that it is based on survey data, which is prone to recall and reporting bias. The results of the project would therefore benefit from triangulation with evaluations based on objective data. There is also high attrition between survey waves.[148] Further to this, the ITC data tend to have insufficiently large sample sizes to evaluate sub-national policies, which are common in some of its countries, such as the US.[132]

Perhaps the most significant limitation of the ITC Project is the frequency and regularity of data collection. In some countries, only one wave of data has currently been collected, and thus evaluations cannot incorporate longitudinal data. In the ITC countries where there have been more waves (e.g. up to 8 in the UK, Canada and Australia), the surveys have been irregular, with data collection tending to span many months. Thus it is more difficult to take accurate account of temporal trends, or to detect the effect of specific policies, which may be gradual, occur with a lag, or be confounded by other events. Further to this, the surveys are often conducted at different times of year from one wave to the next, and responses may therefore be influenced by seasonal effects on quitting behaviour and intentions. These problems are likely to be only partially mitigated by the country controls given that they are common across countries. These issues are primarily due to the significant costs of running such large, detailed surveys, and highlight the potential value of data which are routinely collected.

1.8 Summary

The burden of smoking in the UK is, despite significant decreases in smoking prevalence over recent decades, enormous. In recent years, a comprehensive framework of tobacco control policies has been implemented in the UK to reduce the burden, and that framework continues to develop. The evaluation of population-level tobacco control policy is necessary to establish which policies are effective and how they may be improved in order to maximise their impact.

A range of study design features that will improve the quality of an evaluation have been highlighted in this chapter, including the use of control groups and long time series data with multiple pre- and post-policy

observations. Time series analysis has been highlighted as a valuable statistical method in the evaluation of policy.

Various types of data may be used in the evaluation of tobacco control policy; however, all data sources have strengths and limitations. The combination of the information generated by different studies using a range of outcomes is likely to increase the validity of overall conclusions as to the effect of a policy.[131]

The ITC Project is the best attempt to date to integrate all of the features of good policy evaluation into one design, and provides extensive data on smoking, quitting behaviour and attitudes in the UK and other countries. However, it has various limitations. The work in this thesis will complement the ITC Project, by identifying other high quality data and methods that can be used to evaluate tobacco control policy in England.

1.9 Aims and objectives

The aims of this PhD thesis are to investigate the suitability of a range of existing data sources for evaluating the impact of tobacco control policies in England on quitting behaviour; validate potentially suitable measures; and use validated measures to evaluate the impact of recent tobacco control initiatives in England using time series analysis. This thesis focuses on policies in England, because tobacco control policy is largely dealt with separately in each UK country, and it is therefore beyond the scope of this research to cover each country separately. It has three specific objectives:

- To analyse and describe a range of data from existing sources which provide information on smoking cessation behaviour in terms of their adequacy for evaluating individual population-

level tobacco control policies in England, based on the criteria for good study outcomes, design and data types outlined in Chapter 1 (Chapter 2).

- To validate previously unvalidated measures identified in Chapter 2 as potentially valuable in the evaluation of population-level tobacco control policies in England (Chapter 3).
- To describe a range of approaches to time series analysis that may be used in tobacco control policy evaluation based on existing literature (Chapter 4).
- To utilise validated measures of smoking cessation activity to evaluate the impact of recent tobacco control initiatives on quitting behaviour using the time series methods described in Chapter 4. The evaluated policies are: the introduction of varenicline (Chapter 5), the broadening of NRT indications to include adolescents and CVD patients (Chapter 6), and anti-tobacco mass media campaigns (Chapter 7).

CHAPTER 2: INDICATORS OF QUITTING BEHAVIOUR IN ENGLAND – ARE ANY OF THEM SUITABLE FOR POLICY EVALUATION?

2.1 Introduction

As highlighted in section 1.7.3, it is preferable to use a selection of relevant outcome measures to evaluate any one policy, in order to obtain comprehensive evidence of its impact. When investigating the impact of a tobacco control policy on quitting behaviour, large-scale, regular data covering a long time period on quit attempts, smoking prevalence and use of smoking cessation support (such as pharmacological cessation aids and cessation advice) are all useful.

In England there are several existing sources of data on quitting behaviour which could potentially fulfil the criteria for conducting accurate tobacco control policy evaluations. This chapter seeks to establish which of the data sources in England contain data which may be appropriate for the evaluation of the impact of tobacco control policy on quitting behaviour. It takes into account the issues described in section 1.7 in order to explore the suitability of measures from the different data sources for such evaluations. Thus this chapter helps to provide the rationale for the selection of the data used in the policy evaluations in subsequent chapters of this thesis. In addition, however, it provides important information as to the breadth and quality of the data available for the evaluation of the impact of tobacco control policy on quitting behaviour in England (and, in some cases, the rest of the UK, as some data sources do not cover England alone), and highlights ways in which the data could be improved to ensure that high quality evaluation using existing data is made possible.

2.2 The Nottingham Tobacco Control Database

The data used in this thesis form part of the Nottingham Tobacco Control Database (NTCD). The NTCD was developed at the University of Nottingham by Jack Gibson, as part of a project funded by the National Prevention Research Initiative (NPRI), on which the majority of the work of this PhD project is based, and is maintained by me and Yue Huang. It contains data from a range of existing data sources (including survey data and other types of existing data) and a wide (but not exhaustive) range of measures which can be used to monitor smoking cessation behaviour, including prevalence, prescribing and sales of smoking cessation medication, and quit attempts. A full list of variables included in the NTCD is provided in Appendix 9.1. In the NTCD the data are, where possible, stratified by sex, age, region (based on strategic health authority) and socioeconomic status.

This chapter describes the data contained in the NTCD and their various strengths and limitations. Section 2.3 describes the survey data in the NTCD: The General Lifestyle Survey, the Health Survey for England (HSE), the Opinions Survey and the Smoking Toolkit Study (STS). Section 2.4 describes the non-survey data in the NTCD: Commercial OTC NRT data, national smoking cessation medication prescribing data, quitline calls data and general practice data on smoking from The Health Improvement Network (THIN).

The majority of the analysis in this chapter is descriptive, and draws on previously published work about these data sources. Where this chapter includes original graphs based on survey data, NTCD data have been used to calculate the indicators by dividing the outcome variables (e.g. the number of current smokers) by the relevant denominators (e.g. the

number of survey respondents). All of the survey data are weighted to make them representative of the general population.

2.3 Survey data

2.3.1 General Lifestyle Survey (GLF)

Overview

The GLF, formerly known as the General Household Survey (GHS), is a continuous survey carried out by the Office for National Statistics (ONS).[149] It collects information on a range of topics from people living in private households in Great Britain including around 12,500 in England each year.

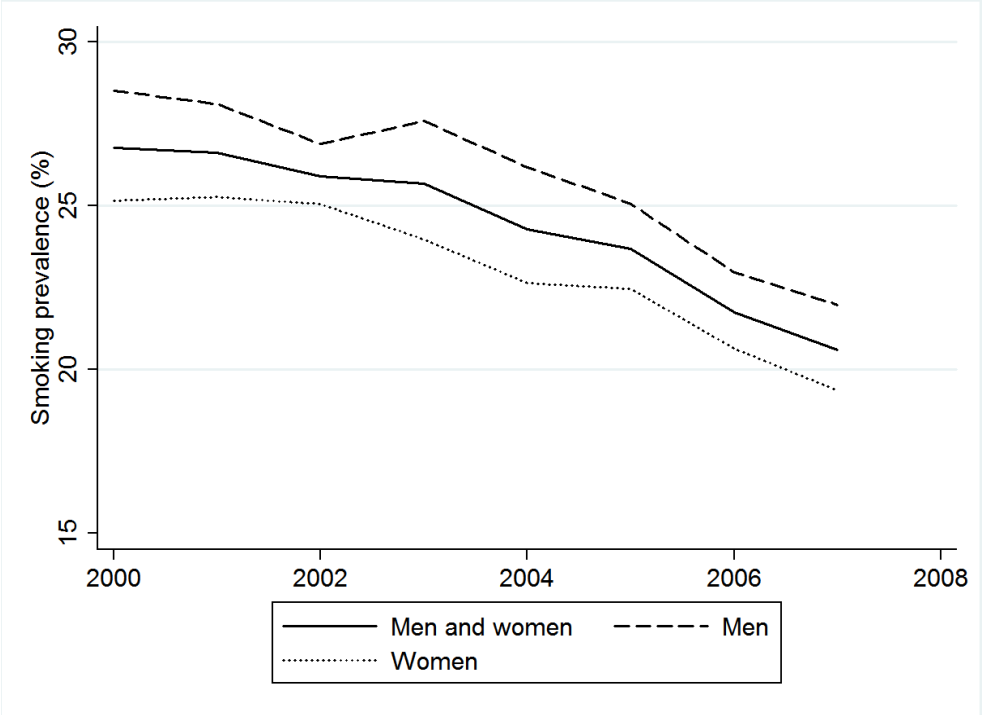
Indicators of smoking and quitting behaviour

The GLF has included questions on smoking status, as well as quitting intentions and amount and type of smoking product smoked every year since 2000; before 2000 questions on smoking were included every other year.

Strengths

The GLF's large sample size, use of well-established data collection methods and long time span make it a valuable resource in monitoring smoking behaviour over time. It is generally regarded as a gold standard measure of smoking prevalence in the UK.[150, 151] Figure 2-1 shows how the GLF can be used to monitor general trends in smoking prevalence over time.

Figure 2-1. Adult smoking prevalence, Great Britain, based on GLF, 2000-2008



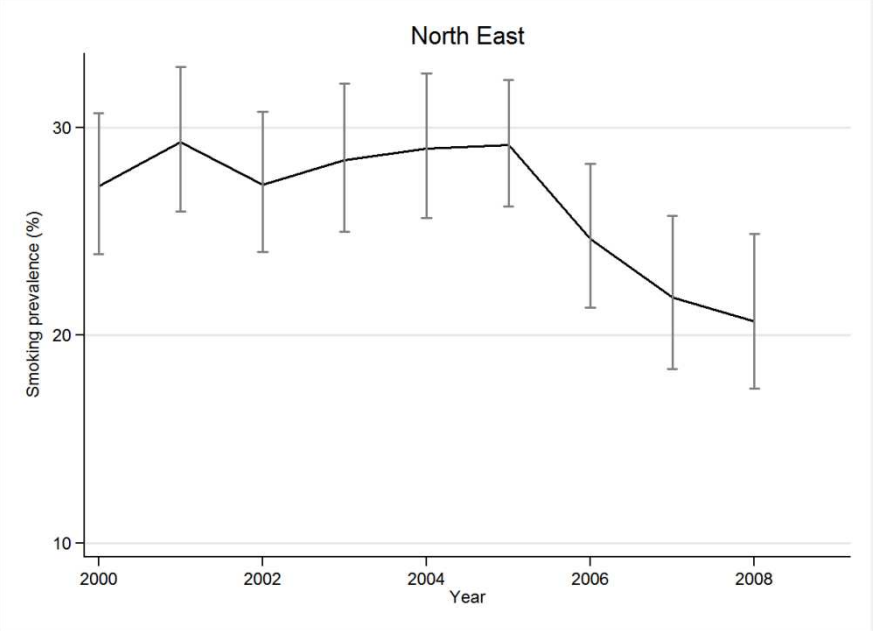
Limitations

The GLF has many of the limitations that are generally inherent in cross-sectional surveys. Like most surveys, the GLF may be prone to reporting and recall bias. In particular, it is likely that it underestimates prevalence, particularly in young people. To reduce this bias, respondents aged 16 and 17 fill in the smoking section of the survey with no one else present.

In addition to this, while the overall sample size of the GLF is large, when broken down into smaller demographic groups the confidence intervals around its estimates are extremely large, preventing accurate monitoring. This has been demonstrated at the regional level.[152] Figure 2-2 and Figure 2-3 show the GLF prevalence estimates and confidence

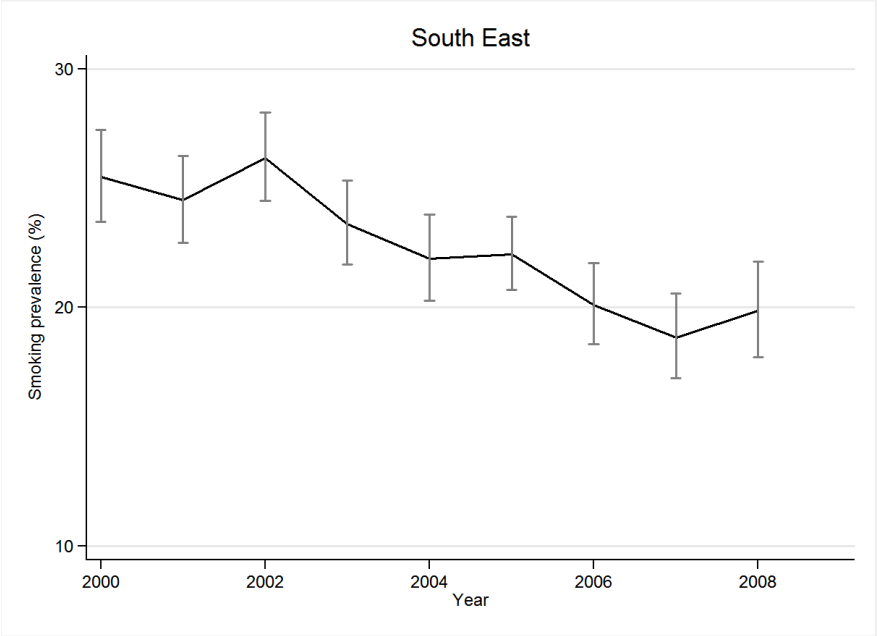
intervals for the regions with the smallest (North East – 642 in 2008) and largest (South East – 2082 in 2008) samples. For both regions, the confidence intervals around the prevalence estimates are wide.

Figure 2-2. Adult smoking prevalence, North East England, based on GLF, 2000-2008



Adapted from Langley et al. (2011)[152]

Figure 2-3. Adult smoking prevalence, South East England, based on GLF, 2000-2008



Adapted from Langley et al. (2011)[152]

Furthermore, while the GLF is an important monitoring tool, it is less suitable for the evaluation of tobacco control policy. Its major limitation in this regard is its frequency. GLF data are collected on an annual basis and therefore suffer from the limitations associated with infrequently collected data: using annual data, it is difficult to detect small and transient changes in behaviour, and the length of any lag between the implementation of a policy and the associated behaviour change. It is also particularly difficult to take account of the confounding effects of other tobacco control measures implemented during the year. A further limitation of the GLF data is the lag between the data collection and the availability of the data, which may prevent timely policy evaluation.[151]

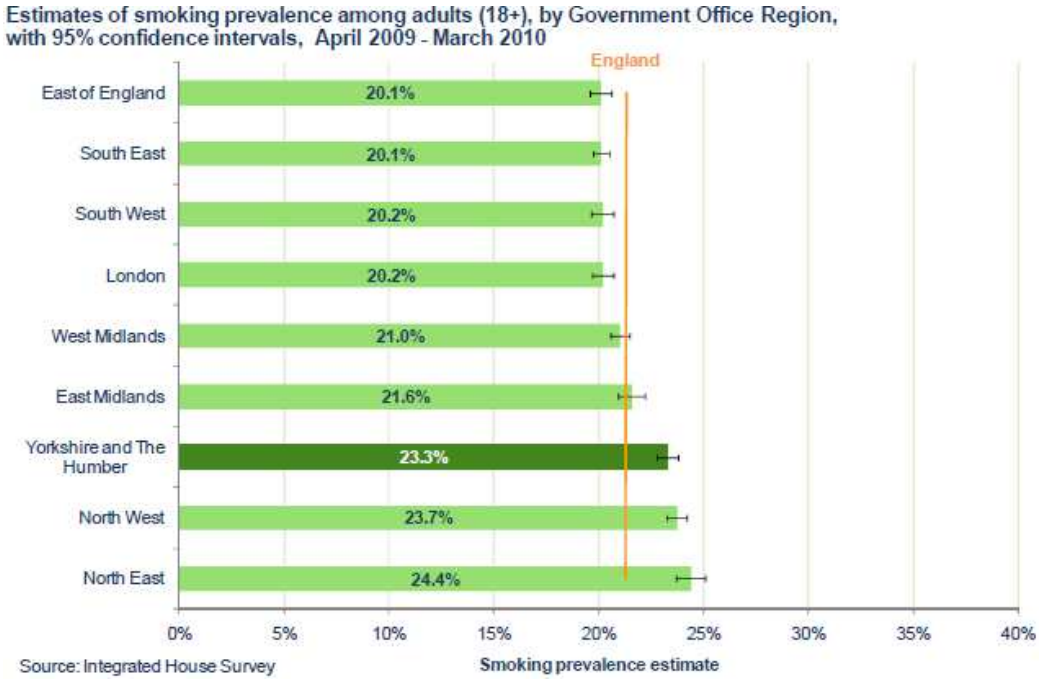
The GLF will be discontinued from January 2012, but data collection for a related, larger (though less detailed) survey, the Integrated Household Survey (IHS) has already begun.[153]

An extension of the GLF: The Integrated Household Survey (IHS)

The IHS is a continuous survey which combines key questions from a number of ONS surveys, including the GLF.[154] It began in 2008. The 'Core' questions are asked at the beginning of the included surveys: The GLF, the Living Cost and Food Survey, the English Housing Survey, the Labour Force Survey/Annual Population Survey and the Life Opportunities Survey. The survey aims to obtain data on key topics by using an extremely large sample size - over 420,000 - making it the largest UK survey after the Census. The broad topics included are economic activity, education, health and disability, identity and income. The IHS includes two questions about smoking: whether the respondent has ever smoked, and whether they currently smoke, which provides estimates of prevalence.

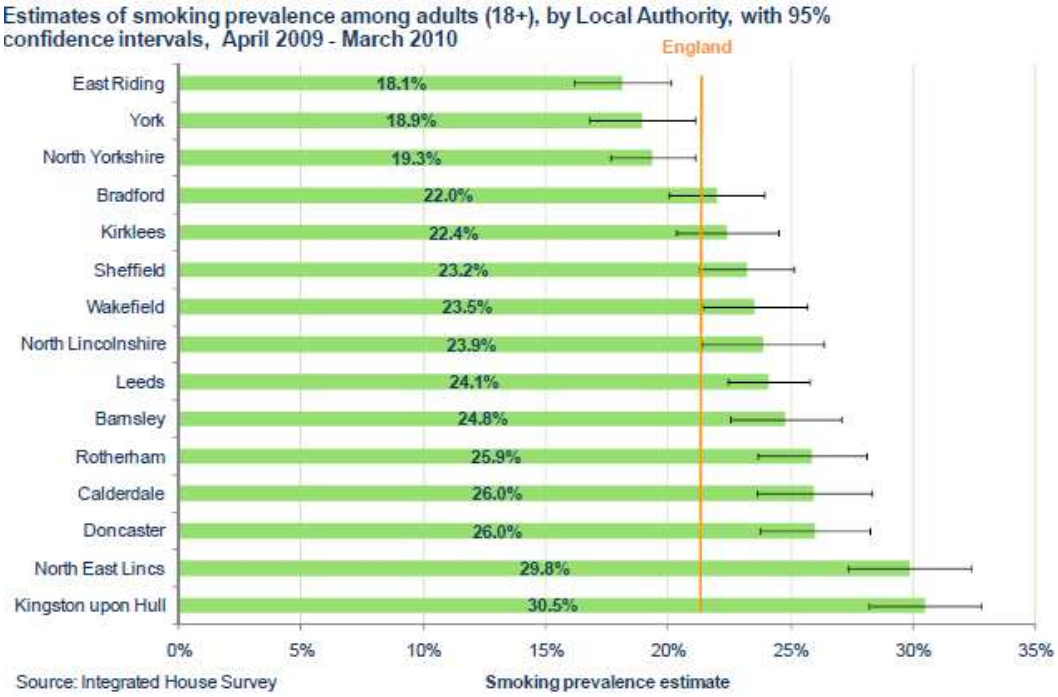
The IHS covers the whole of the UK and, unlike previous surveys, can be broken down to local authority level. The IHS has been cited in the Tobacco Control Plan as an important source of prevalence data, particularly for planning tobacco control at a local level.[67] As shown in Figure 2-4 below, results from the 2009-10 survey suggest that the survey provides prevalence estimates with very narrow confidence intervals down to the regional level. However, at the local authority level, accuracy appears likely to be poor, at least in smaller authorities, due to the much reduced sample sizes. As an example, Figure 2-5 shows the wide confidence intervals of the estimates from the April 2009-March 2010 survey for estimates of smoking prevalence for Yorkshire and Humber local authorities.

Figure 2-4. Adult smoking prevalence by Government Office Region, Great Britain, based on the IHS, April 2009-March 2010



Source: Smoking prevalence by local authorities in Yorkshire and Humber, Yorkshire and Humber Public Health Observatory (2010)

Figure 2-5. Adult smoking prevalence by Local Authority, Yorkshire and Humber, based on the IHS, April 2009-March 2010



Source: Smoking prevalence by local authorities in Yorkshire and Humber, Yorkshire and Humber Public Health Observatory (2010)

The data are currently classified as experimental (new official statistics undergoing evaluation), and ought therefore to be used with caution. Annual data are to be published on a quarterly basis (e.g. annual data April 2009 - March 2010 followed by July 2009 - June 2010), although the time lag to publication is currently not known.

If monthly data are also made available, the continuous nature of the data collection may provide sufficiently large monthly samples to provide accurate monthly prevalence estimates. It is not clear, however, whether the sampling method creates representative samples on a monthly or quarterly basis. If so, when sufficient data points are available, the data may be appropriate for time series analysis and evaluating the impact of policies.

The IHS seems likely to provide accurate and regular estimates of prevalence for the UK as a whole and at the regional level. However, currently, only one year of data is available, and it can therefore not be used in the context of this PhD.

2.3.2 Health Survey for England (HSE)

Overview

The HSE is an annual survey which seeks to measure health and health-related behaviours in adults and children living in private households in England.[155] It has been carried out every year since 1991. It regularly collects information on knowledge, attitudes and behaviour related to smoking, alcohol, diet and physical activity, as well as having a varying key topic. The sample size varies across survey years, from around 7000 to 16000 adults. Generally, a large survey in one year is followed by a smaller survey in the next year.

Indicators of smoking and quitting behaviour

The HSE contains questions on smoking prevalence, amount smoked and attitudes to quitting in a range of sociodemographic groups in England.

Strengths

The HSE is regularly carried out, and every second year has a large sample size. Its major strength is that it provides information on a range of health issues not covered by other surveys; however, the information it contains about smoking appears to be less reliable than that in other surveys, as discussed in the following section.

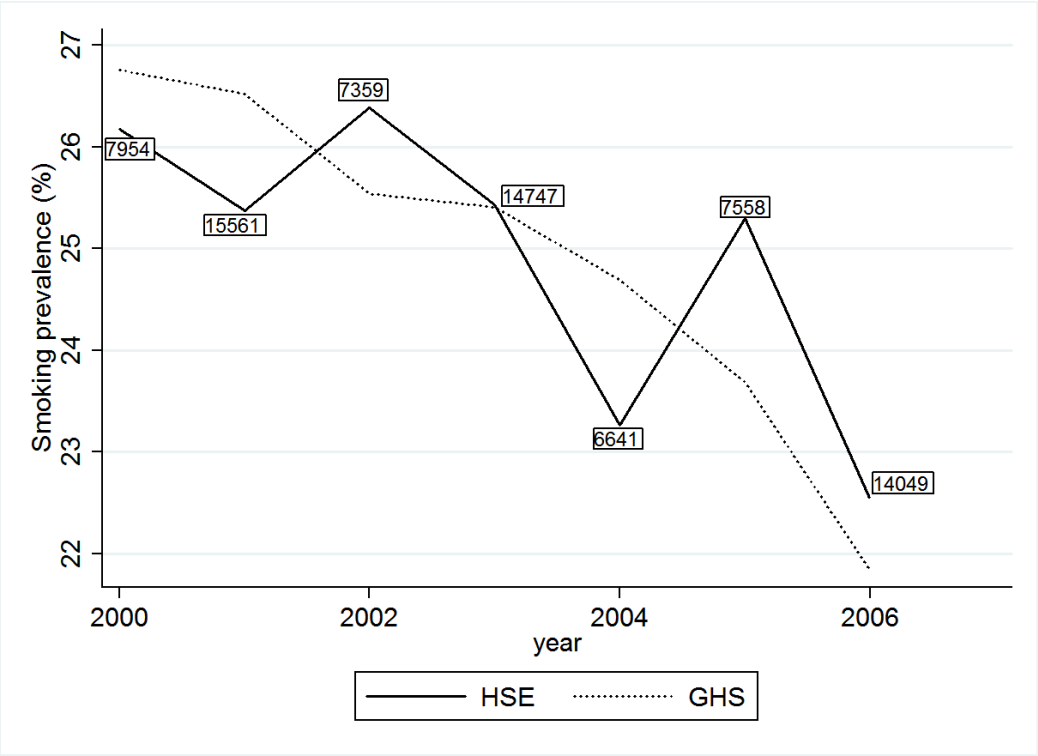
Limitations

Generally, the limitations of the HSE are similar to those of the GHS. For example, it is also prone to underestimates of smoking prevalence and takes similar steps to the GLF to overcome them. Evidence suggests that self-reported cigarette smoking status using the HSE underestimates true smoking prevalence by approximately 2.8% compared with biochemically-validated estimates.[156] This is not necessarily a limitation when exploring trends, assuming that the error is consistent over time, but may lead to underestimates of the public health burden of smoking. In addition to this, the HSE is also annual, which is a substantial limitation in the use of these data in the evaluation of individual tobacco control policies.

A major limitation of the HSE smoking data is its sampling error. Comparing the standard errors for the GLF and the HSE underlines the higher sampling error of the HSE. In the 2007 and 2009 surveys, years with relatively small sample sizes, the standard error of the smoking prevalence estimates in the HSE was around 1; for the GLF it was around 0.5.[157-159] The standard error will be higher still in estimates based on questions asked to smokers only, due to the much reduced sample size. The impact of this error on HSE estimates, and thus the potential impact on observed trends, can be demonstrated using graphical analysis. In Figure 2-6 below, prevalence estimates from the HSE and the GLF are overlaid. It shows that HSE estimates are highly variable from one year to the next. This contrasts with the GLF estimates, which show a fairly smooth decreasing trend over time. The variability in the HSE estimates suggests that the often smaller sample size compared with the GLF results in substantial sampling error. Figure 2-6 also shows the HSE sample size in

each year. Unsurprisingly, it appears that the HSE estimates are generally further away from the GLF estimates in years with smaller sample sizes, although the estimate for 2001, when the sample size was over 15000, is nearly two percentage points lower than that from the GLF.

Figure 2-6. Adult smoking prevalence, England, based on HSE and GLF, 2000-2006



2.3.3 ONS Opinions Survey

Overview

Like the GLF, the Opinions Survey (previously known as the ONS Omnibus Survey) is carried out by the ONS and is a regular, multi-purpose survey which was carried out in eight months of the year until April 2005, after which it became a monthly survey.[146] Approximately 1800 adults in private households are surveyed each month.

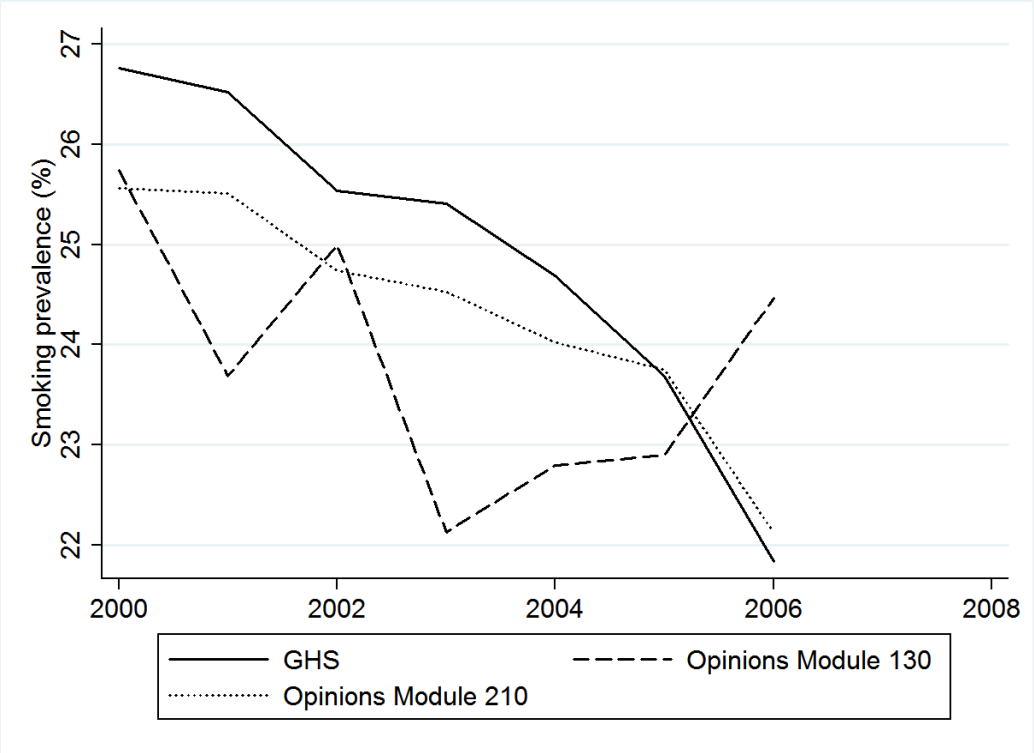
Indicators of smoking and quitting behaviour

Opinions Survey data on smoking and quitting behaviour come from two different survey modules about smoking behaviour. Module 130 (Smoking) is comprehensive and contains a variety of questions about quit attempts, support used, attitudes to smoking and restrictions on smoking, and occasional topical questions about proposed policy changes. However, this module is only included once or twice a year. Module 210 contains fewer questions, covering smoking status, use of cigarettes vs. roll-ups and differences between weekday and weekend consumption, but is included on an almost monthly basis.

Strengths

The Opinions Survey prevalence data up to 2000 have been compared with GHS prevalence estimates on an annual basis and found to be similar to these both overall and in different sociodemographic groups.[147] This is likely due to the large annual sample size of over 20,000. Figure 2-7 shows that since 2000 too, the annual prevalence estimates based on Module 210 have been similar to those from the GHS. By contrast, those from Module 130 are much more variable. This is due to the smaller denominators for this part of the survey, which is included less frequently than Module 210.

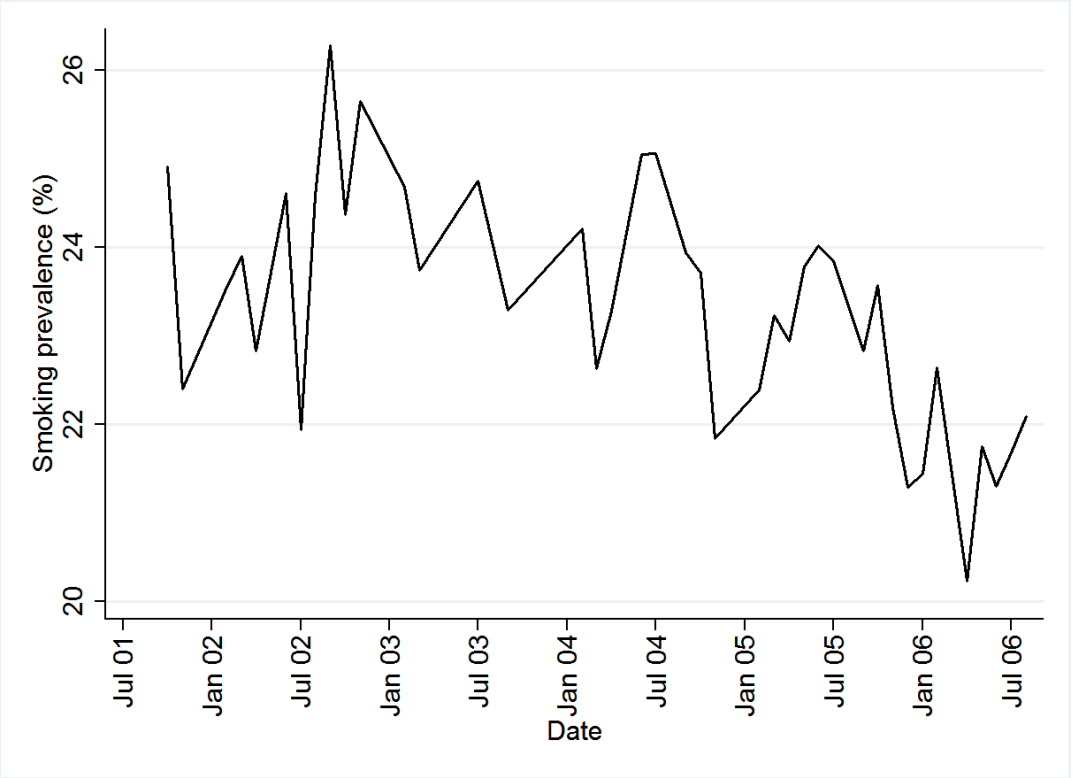
Figure 2-7. Adult smoking prevalence, England, based on Opinions survey and GLF, 2000-2006



Limitations

A potential advantage of the Opinions Survey is that it provides monthly data, and hence a long time series which allows trends to be taken into account in policy evaluations. However, a previous study, which looked at data to 2000, found that confidence intervals for the monthly data were too wide to allow accurate monitoring of monthly prevalence.[147] Figure 2-8 demonstrates that this is also the case for more recent years of the survey: There is significant fluctuation in estimates of smoking prevalence from month to month, suggesting extremely high standard errors and confidence intervals. This would make it very difficult to accurately identify the effect of a policy. This is an even more significant problem for all questions asked to smokers only, such as those related to quit attempts, as the denominators are further reduced.

Figure 2-8. Adult monthly smoking prevalence, England, based on Opinions survey, October 2001-August 2006



2.3.4 Smoking Toolkit Study (STS)

Overview

The STS involves repeated cross-sectional household surveys of national samples of smokers and recent ex-smokers in England.[150, 160] The surveys have been carried out on a monthly basis (with a small number of months with no survey) since November 2006 and include around 500 smokers.

Indicators of smoking and quitting behaviour

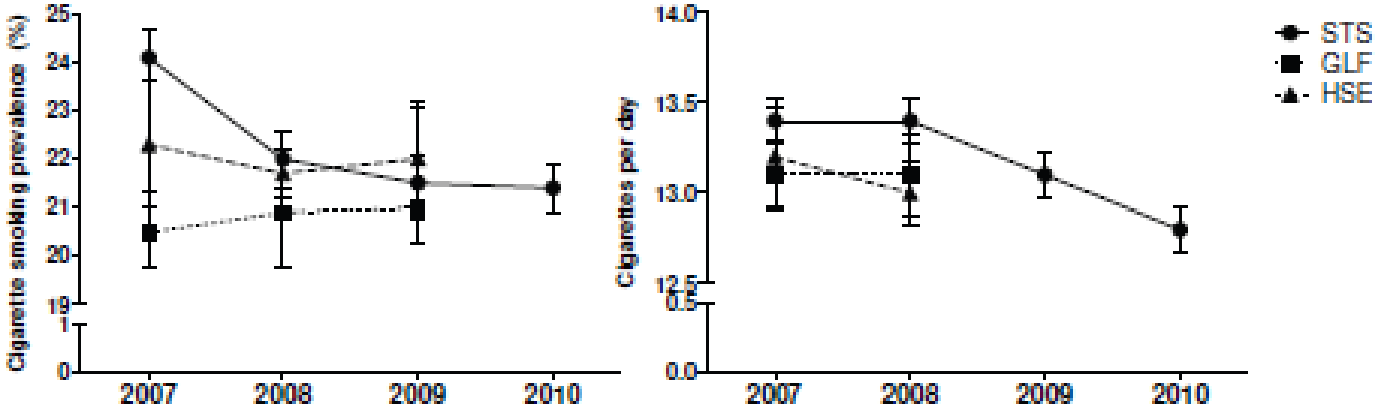
The STS covers a wide range of parameters related to smoking and quitting behaviour, including prevalence, quit attempts, ways of quitting and attitudes to smoking and quitting.

Strengths

Aside from the ITC Study, the STS is the only ongoing survey that specifically focuses on smoking and quitting behaviour in England. As such it provides extremely detailed data over five years on a wide range of measures, including direct measures of quitting, and a variety of sociodemographic data. This means that it can be used to answer a wide range of questions related to tobacco control. The data are also made available soon after collection.

The STS is nationally representative, and pooling results from several waves of the survey yields large sample sizes. The survey has been shown to generate annual estimates of smoking prevalence comparable to those from the GLF and HSE in 2008 and 2009, as shown in Figure 2-9.

Figure 2-9. Adults smoking prevalence and cigarettes per day, England, based on the Smoking Toolkit Study, GLF and HSE, 2007-2010



From: Fidler et al. (2011)[150]

Data from the STS have been used to investigate a range of issues related to smoking cessation, including the affective impact of quitting, sociodemographic differences in triggers to quitting smoking, and the social gradient in quit attempts, use of aids to cessation and the success of quit attempts.[161-163]

Limitations

Despite its many strengths and the wealth of useful data that it provides, the STS has some specific limitations (in addition to those inherent in surveys) which reduce its adequacy as a dataset for evaluating the effects of specific tobacco control policies on quitting behaviour.

The availability of monthly data on a range of measures is potentially valuable in that it could permit the examination of possible intervention effects more easily than annual surveys; however, the monthly sample of smokers is small at around 500. [150] As a result, monthly estimates will have high standard errors, making accurate formal statistical analysis of the monthly data, particularly using time series analysis, difficult.

2.4 Non-survey data

2.4.1 Commercial OTC NRT data

Overview

Increases in sales of OTC NRT may mirror increases in the number of people quitting smoking, and OTC NRT has therefore been used as an indicator of quitting activity.[135, 164, 165] The OTC sales data used in the NTCD are monthly Electronic Point of Sales scanner data obtained from Information Resources Inc. (IRI, now Symphony IRI).[166] They include data from all stores except Boots stores in Great Britain, and are available at the regional level, and broken down by brand and product.

Strengths

These data have a range of strengths which make them suitable for the evaluation of policies which may influence quitting behaviour. They are available at four-weekly intervals over several years, resulting in the sort of long time series that is ideal for such evaluations. OTC sales are also an objective measure, i.e. they are not prone to the same recall or reporting biases as survey data. Furthermore, because they are population level data, they ought to be completely representative of national and regional sales. Finally, OTC sales may be more sensitive to policy than, for example, prevalence, making it easier to detect small or short-term effects on quitting behaviour.

Limitations

These data also have certain limitations. Firstly, they can be expensive to obtain. Furthermore, although there are numerous sources of such data, because of the cost of these data, it can be difficult to compare them with other data sources for the purposes of validation. In addition, the IRI data do not contain data from Boots stores. It has not been

possible to obtain information as to the proportion of total OTC NRT sales Boots sales account for, or whether the trends in Boots sales are different from those in other stores; it is therefore not clear how great a limitation this is.

Furthermore, OTC sales of NRT is an indirect indicator of quitting; NRT may be purchased for cutting down, or for use in situations where people may not smoke, as opposed to for use as part of a quit attempt, and changes in NRT sales may therefore not truly reflect changes in quitting behaviour. Nonetheless, it seems likely that increases in sales indicate efforts by smokers to reduce or cease smoking, thus, particularly in the absence of extensive high quality data on direct indicators of quitting, such as quit attempts, OTC NRT sales appears a useful outcome. To enhance the validity of results, studies using these data as a marker of quitting behaviour should be triangulated with those using other data.

A final limitation of these data is that, although regional data are available, further sociodemographic data are not. As a result, these data cannot be used to explore variations according to, for example, age, sex and socioeconomic status.

2.4.2 National smoking cessation medication prescribing data

Overview

Prescribing of smoking cessation medication may also be a good indicator of quitting behaviour. One source of data on prescribing is national dispensing data. Within the NHS, pharmacies dispense prescriptions and are then reimbursed for the products that they dispense. NHS Prescription Services (previously the Prescription Pricing Division) process NHS prescriptions dispensed in England for reimbursement and

remuneration, and collect information on what is prescribed and the cost of prescriptions via their ePACT system.[167] Prescriptions written in hospitals, prescriptions dispensed in hospitals, dental prescribing and private prescriptions are not included. The NTCD contains ePACT data from August 2003 to July 2008 for the three smoking cessation medications licensed during this period – bupropion, NRT and varenicline. The ePACT data in the NTCD are not published, and can be obtained on request from the NHS Information Centre, listed by drug name and by region.

Strengths

ePACT processes all GP, nurse and other non-medical prescriber prescriptions dispensed in England, and is therefore likely to be a source of accurate primary care dispensing data, and a useful resource in the evaluation of tobacco control policy that may be expected to have an impact on prescribing of this group of medications in England. The ePACT data have many of the same advantages as the OTC NRT data described above: they are an objective measure of the provision of stop smoking medication, and they are available at monthly intervals and over a long time period.

Data on prescribing of smoking cessation medication may be a more accurate indicator of quitting behaviour than OTC sales of NRT, as it seems more likely to be provided as part of a planned quit attempt, as opposed to for cutting down or for use in situations where one may not smoke.

Limitations

A limitation of the ePACT data is that they are not available in sociodemographic strata. Although trends can be examined by region, it is

not possible to look at trends according to sex, age or socioeconomic status, as is desirable in many evaluations. As such, ePACT is not an optimal source of data on prescribing of smoking cessation medication; a potential alternative measure, which includes sociodemographic data, primary care data on prescribing, is described in section 2.4.4. Furthermore, while the ePACT data seem likely to be a sensitive measure of quitting behaviour, they may not be an accurate measure of medication use, as dispensed medication may not necessarily be used. Previous studies have estimated that between 5.2% and 20% of patients do not redeem their prescriptions.[168-172]

2.4.3 Quitline calls

Overview

The NHS runs a variety of free stop smoking helplines where people seeking advice on smoking cessation can speak to a trained smoking cessation advisor. There are UK-wide services, as well as nation-specific services, a pregnancy smoking helpline, and helplines in a range of languages. Quitlines have been shown to be effective in helping smokers quit, and quitline calls are therefore an important measure of smoking cessation activity.[173-175] In a recent trial comparing 'proactive' (repeated calls from a cessation advisor to the client) with 'reactive' (responding only to smokers calls) telephone counselling in England (PORTSSS) approximately eight per cent of study participants had quit at six months follow-up.[176] However, there was no significant difference between those receiving standard reactive support and proactive support, and the study also found that offering free NRT via the quitline did not increase quit success. The NTCD contains monthly quitline calls data from the NHS stop

smoking helplines in England from November 2004 to December 2009. The data are available from the Department of Health.

Strengths

Quitline calls seem likely to be a good proxy measure for quit attempts, although we cannot extrapolate what proportion of callers go on to make a quit attempt. The major strengths of these data are that they are objective, and that they are available on a monthly basis over a long period of time. The quitline data are population level data, and therefore ought to be completely representative of national calls. Finally, quitline calls also seem likely to be more sensitive to policy than prevalence, making it easier to detect small and short-term effects on quitting behaviour.

Limitations

The quitline data have several limitations. Firstly, they do not contain information about the length of calls; therefore we do not know how many recorded calls were hoax calls or extremely brief calls that were unlikely to include adequate cessation advice. Further to this, the calls are provided as aggregated data; the data therefore contain no sociodemographic information. In addition, although there is international evidence for the effectiveness of quitline calls, there have been no recent studies of the effectiveness of the quitlines in increasing quit attempts and quit success in England. Thus although it is likely that increases in quitline calls indicate a behavioural action to seek support, we cannot be sure that increases in calls translate to increased quit attempts and success.

2.4.4 General practice data

Overview

A further, more comprehensive source of non-survey data on smoking and quitting behaviour is primary care data. The primary care data in the NTCD are from THIN. THIN is a database containing the primary care records of approximately 8 million patients from 446 UK general practices, including 329 practices in England. 3.2 million patients are currently registered with a practice and can be followed prospectively; retrospective data are available for the remaining patients who have since either died or transferred from THIN practices.[177] Prospective medical records are recorded using the Vision general practice computer system software (In Practice Systems, London, UK), and serve as the primary medical record for the practice. GPs are able to record diagnoses, demographic information, lifestyle characteristics and other medical information. Prescriptions are automatically recorded when the relevant details are entered into a computer to generate prescription forms.

The validity of THIN data has been demonstrated for major events.[178-183] Studies have demonstrated the accuracy of recording of death[178], hepatitis C[179], gastrointestinal ulcer[180], lymphoma[181] and skin cancer[182]. A further study was able to replicate well-established associations between diseases (for example hypertension and stroke) and between diseases and drugs (for example aspirin and colon cancer) in case control studies.[183]

Indicators of smoking and quitting behaviour

THIN contains data on a range of measures of smoking and quitting behaviour. It contains data on recorded smoking status, prescribing for smoking cessation medication, brief stop smoking advice provided by GPs,

and referrals to stop smoking services. As explained in section 1.6.9, the QOF provides incentives for GPs to record smoking status in all patients and offer smoking cessation advice and referrals to smoking cessation services to smokers with certain chronic diseases.

Strengths

There are several general advantages to using THIN data compared with national survey data. THIN data are routinely collected, are released three to four times per year, and have a lag of only three to eight months before data becomes available.[184] THIN also has an extremely large sample size, and data are available on a monthly basis. Data are available over a long time period (since January 2000), and, contrary to the data on sales and dispensing of smoking cessation medication described above, can be broken down into different sociodemographic groups. These data are therefore potentially an extremely valuable source of data for policy evaluation, fulfilling the majority of the criteria described in section 1.7.

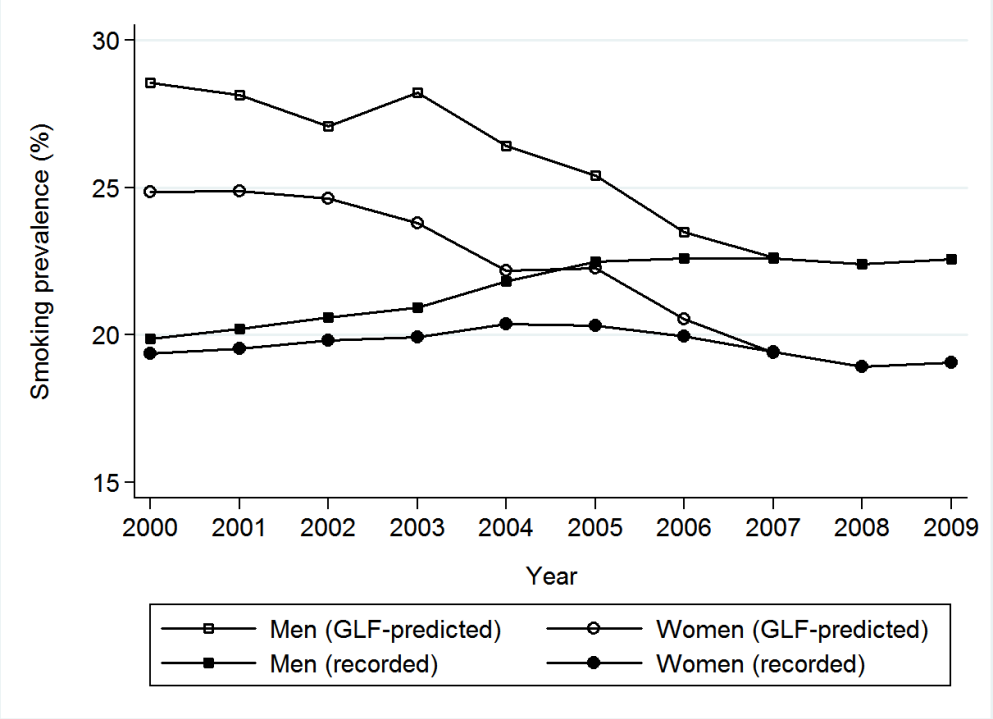
Limitations

Not all the indicators of smoking and quitting behaviour have been validated. Those that have, however, have been shown to be of varying and variable quality; care must therefore be taken in using the data and drawing conclusions from such work. The validity of the prevalence, GP advice and referrals data has been explored in previous studies, which are summarised below.[185] The smoking cessation medication prescribing data have, until now, not been validated; therefore a validation study of these data follows in the subsequent chapter of this thesis.

Prevalence data

The data on smoking status can be used to generate estimates of smoking prevalence. Szatkowski et al. compared estimates of smoking prevalence from THIN with those from the GHS between 2000 and 2007.[184] They found that from 2006 there was good agreement between THIN and GHS estimates. However, as shown in Figure 2-10, there was disparity in estimates of up to five percentage points in the previous five years. This suggests that recording of smoking status has improved in recent years, probably as a result of the incentives provided by the QOF to record smoking status, which previous studies have shown to improve recording of patient smoking status.[118, 119] The authors concluded that THIN can possibly be used to identify current smokers with sufficient accuracy to monitor national smoking prevalence (though recording of ex- and never-smokers is less complete), although a limitation of these data is that, like survey data, they are self-reported.

Figure 2-10. Adult smoking prevalence, England, based on THIN, 2000-2009



Source: Lisa Szatkowski, PhD thesis

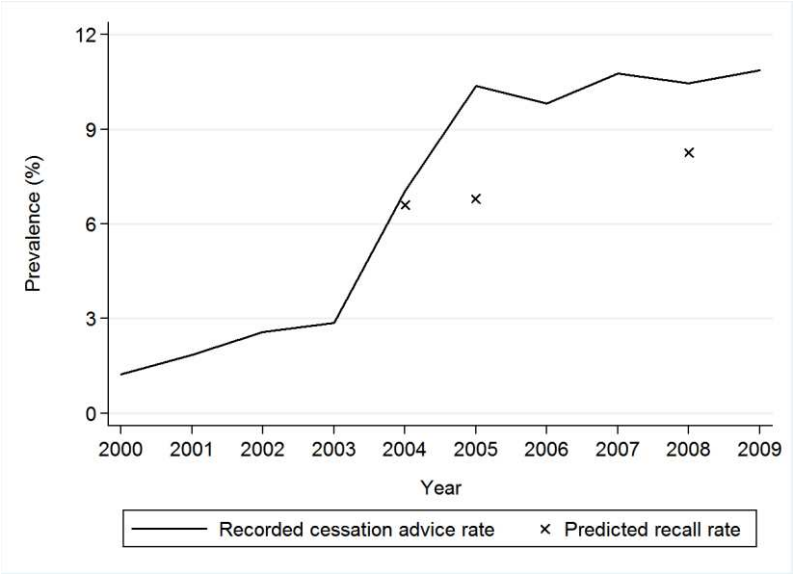
A further study has replicated these results at the regional level.[152] This study formed part of a medical sciences student project designed and supervised by me and Sarah Lewis. It has subsequently been published in BMC Public Health and is also included as an appendix in this thesis (Appendix 9.2). Despite the diminished sample size of the THIN data at the regional level, the results of this study were broadly consistent with those of the study of these data carried out at the national level. As at the national level, prevalence estimates based on THIN from most regions were found to be similar to those based on the GLF from 2006 onwards.

Brief advice data

Brief stop smoking advice in a general practice setting has been shown to be an effective and cost-effective way of getting people to quit smoking.[186, 187] Brief advice recorded in primary care records is therefore a potentially valuable indicator of quitting behaviour. The introduction of the QOF provided a financial incentive for GPs to record that they had offered smokers smoking cessation advice.[188] In the year following the introduction of the QOF, rates of advice giving tripled; however, this may have been due to GPs' increased propensity to record advice as opposed to reflecting a genuine increase in advice giving.[189]

Szatkowski et al. compared advice recorded in THIN with that recalled in a survey of NHS patients in England, the Primary Care Trust (PCT) Patient Survey to explore agreement between these two data sources and to establish whether THIN may be a good source of data on advice giving.[190] The researchers found that, as previously reported, the proportion of patients with a record of cessation advice increased during the study period, particularly in the year of and following the implementation of the QOF. As Figure 2-11 shows, there was good agreement between recording of cessation advice in THIN and recall rates in 2004. In 2005 and 2008, however, recall rates were much lower. This may reflect recall or reporting bias in the Patient Survey, recording of advice that was refused, or the recording in THIN of advice that was not actually given. Regardless of the reason for the discrepancy, if GP advice is not recalled by patients, it seems likely that smokers are not responding to advice. Therefore, recording of brief advice in THIN is probably not a good indicator of quitting behaviour.

Figure 2-11. The proportion of THIN patients aged 16+ with recorded cessation advice and predicted recall rates, 2000-2009



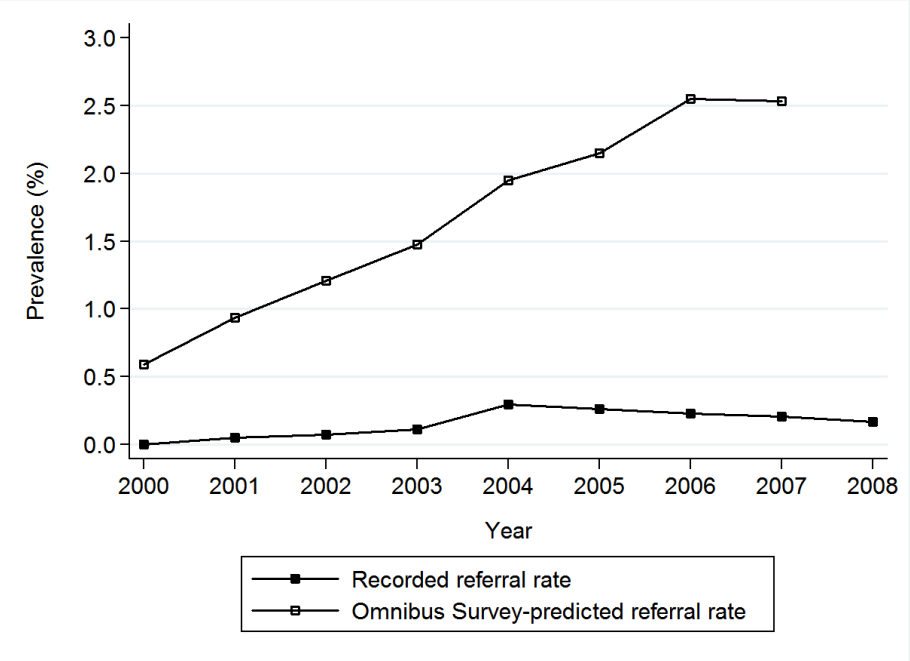
Source: Szatkowski et al. 2011

Referrals data

As described in section 1.6.10, the NHS SSS are highly effective at helping people to quit smoking.[191] As a result, GP referrals to smoking cessation services are a potentially useful measure of quitting behaviour. Szatkowski found that there was no source of data that was directly comparable to the THIN data for validation, but used Omnibus survey data on the number of self-reported smokers who also self-reported having been referred or self-referred to a stop smoking group, clinic or service in the past year. As shown in Figure 2-12, the proportion of patients with a referral to a smoking cessation service recorded in their records is extremely low. The number of people predicted to recall referral based on the Omnibus data increased until 2006 and then levelled out, and is much higher than recorded referral. This discrepancy may be due to the differences between the two data sources. Nonetheless, there remains

significant uncertainty about the quality of the smoking cessation service referral data in THIN, and it therefore seems inappropriate to use them in policy evaluation.

Figure 2-12. The proportion of THIN patients aged 16+ with recorded referral and predicted referral rates, 2000-2009



Source: Lisa Szatkowski, PhD thesis

2.5 Conclusions

Comprehensive evaluation of the impact of tobacco control policy on quitting behaviour benefits from having high quality, regular data over a long time period in a large, representative sample with extensive sociodemographic data. Key indicators are successful quit attempts and smoking prevalence, and combining these with other indicators of quitting behaviour such as the use of pharmacological smoking cessation aids and smoking cessation support services can provide a broad evidence base as to the impact of a policy on quitting behaviour. This chapter has

summarised a large group of data sources which can provide data on these indicators in England.

The key characteristics of the data sources described in this chapter are summarised in Table 2-1 and Table 2-2. This chapter has demonstrated that surveys are a valuable source of data for the monitoring of smoking behaviour in the UK; they are generally less appropriate for evaluating the impact of specific tobacco control policies. These data are often collected on an annual basis, and those that are more frequently collected tend to have small sample sizes. The inability to take into account confounding by other policies and/or the presence of large standard errors, particularly in smaller demographic groups, limits the level of evidence that can be obtained from these data sources. The IHS may prove to be a valuable source of data in the future, but currently the non-survey sources described in this chapter seem to provide more appropriate data for the evaluation of tobacco control policy.

Some of the non-survey data have the disadvantage (compared with surveys), of having little sociodemographic data, which makes them inadequate for exploring differential impacts of policy across demographic groups. However, they provide long time series with short data intervals based on large sample sizes. This makes them suitable for the evaluation of individual policies.

Of all the data sources described in this chapter, THIN primary care data appear to be best suited to the evaluation of policy – THIN provides time series data based on an extremely large sample size, even on a monthly basis. There is, however, uncertainty about the quality of THIN data on the delivery of cessation advice and referral of smokers to

cessation services. THIN also, however, has large-scale smoking prevalence data which, though seemingly only valid from 2006, may prove to be an extremely valuable source of prevalence data which can be used to accurately estimate policy impacts in the future. The availability of detailed demographic data in such a large sample over a long time period makes primary care data uniquely suited to the evaluation of the impact of tobacco control policy on quitting behaviour.

Overall then, it seems that the data available for tobacco control policy evaluation in England have significant gaps and limitations, with no validated monthly measure of quit attempts or success, and no validated monthly measure of smoking prevalence which covers a long time series. There are, however, good data on a group of proxy measures for quit attempts, such as smoking cessation medication sales and dispensing, and quitline calls, although these lack sociodemographic data. Unfortunately, the incomplete nature of the data for much of the period for which data are available means that THIN prevalence data cannot be used in this PhD thesis. The next chapter of this thesis, however, turns to the validation of the final indicator of smoking and quitting behaviour, prescribing of smoking cessation medication, which has, to my knowledge, not previously been validated.

Table 2-1. Summary of characteristics of quitting behaviour data sources: Survey data

	Key measures of quitting behaviour	Geographical coverage	Sociodemographic data	Sample size	Data intervals	Date data first available
GHS	- Smoking prevalence - Attitudes to quitting	Great Britain	- Sex - Age - Region - SES	16000	Annual	1971
Omnibus	- Smoking prevalence*	Great Britain	- Sex - Age - Region - SES	18000	Monthly. Smoking data in most months*	Oct 1990
HSE	- Smoking prevalence - Attitudes to quitting	England	- Sex - Age - Region - SES	7000-16000	Annual	1991
Smoking Toolkit	- Prevalence - Quit attempts - Medication use - Attitudes to quitting	England	- Sex - Age - Region - SES	2000	Monthly	Nov 2006

*Refers to Module 210. Module 130 is more detailed but is only carried out 1 to 2 times per year

Table 2-2. Summary of characteristics of quitting behaviour data sources: Routine data

	Type of data	Key measures of quitting behaviour	Geographical coverage	Sociodemographic data	Sample size	Data intervals	Date data first available
OTC NRT data	Scanner data	- Unit sales of OTC NRT	Great Britain	- Region	Population level	Monthly	Oct 2003
ePACT	Dispensed NHS prescription data	- Dispensed prescriptions for stop smoking medication	England	- Region	Population level	Monthly	Aug 2003
NHS Stop Smoking Helpline	Quitline calls data	- Number of quitline calls	England	- None	Population level	Monthly	Nov 2004
THIN	Primary care data	- Smoking status - Prescriptions - Brief stop smoking advice - SSS referrals	UK	- Sex - Year of birth - SES - Region	6 million	Monthly	Jan 2000

CHAPTER 3: VALIDATION STUDY OF THIN DATA ON PRESCRIBING OF SMOKING CESSATION MEDICATION

3.1 Introduction

Whether prescriptions recorded in primary care can provide an accurate indicator for monitoring trends in prescribed smoking cessation medications and evaluating tobacco control policy depends on the completeness of the primary care data. Comparing prescribing records with dispensing records provides a means of assessing this. I carried out a validation study comparing secular trends in monthly rates of prescribing for smoking cessation medications based on THIN data with monthly rates of dispensing of these treatments based on national dispensing data for January 2004 to December 2005. Due to their likely completeness, I compared the THIN data with the ePACT data from NHS Prescription Services described in section 2.4. The aim was to assess whether THIN data are complete and can therefore be used to monitor trends in prescribed smoking cessation medications and identify changes in prescribing following the implementation of a tobacco control policy. This study has been published in Pharmacoepidemiology and Drug Safety.[192]

3.2 Methods

NHS Prescription Services collect data on prescriptions dispensed in England only; therefore, only data from the 329 English practices in THIN were used in the analyses this chapter.

The outcome measures were rates of prescribing of all NRT and bupropion per 100,000 of the population per month based on THIN, and rates of dispensing of the same medications per 100,000 of the population per month based on the ePACT data.

The total number of NRT and bupropion prescriptions in all patients for each month between January 2004 and December 2005 were extracted

from the THIN database. The combined total was used as a measure for total smoking cessation medication prescriptions. Varenicline did not become available in the UK until December 2006 and is therefore not included in this analysis. The denominator for each month was the total number of live individuals contributing data to the THIN database throughout the month. It was assumed that those contributing data within each month provided one person-month of follow-up, and the numbers of prescriptions were divided by the total person months to derive the rate of prescribing per 100,000 of the population per month.

The total number of dispensed NRT and bupropion prescriptions for each month of the study period was also extracted from the ePACT data. The monthly population denominators for these data were calculated using the Office for National Statistics mid-year population estimates for England for each year, increasing by one twelfth of the annual increase per month.[193] The monthly dispensing rates were calculated in the same way as the prescribing rates.

The rates of prescribing of smoking cessation medications in THIN and of dispensed prescriptions for these treatments from ePACT were compared for each month for the period January 2004 to December 2005. This period was selected due to the lack of major tobacco policy changes which may have influenced behaviour or prescribing in these two years. The analysis had no age limits due to the lack of age-stratification in the ePACT data.

Monthly prescribing and dispensing rates were compared graphically for the study period to assess whether THIN smoking cessation medication prescribing data are similar to NHS Prescription Services dispensing data.

All analysis was carried out in Stata Version 10.0 (Stata Corp, College Station, TX).

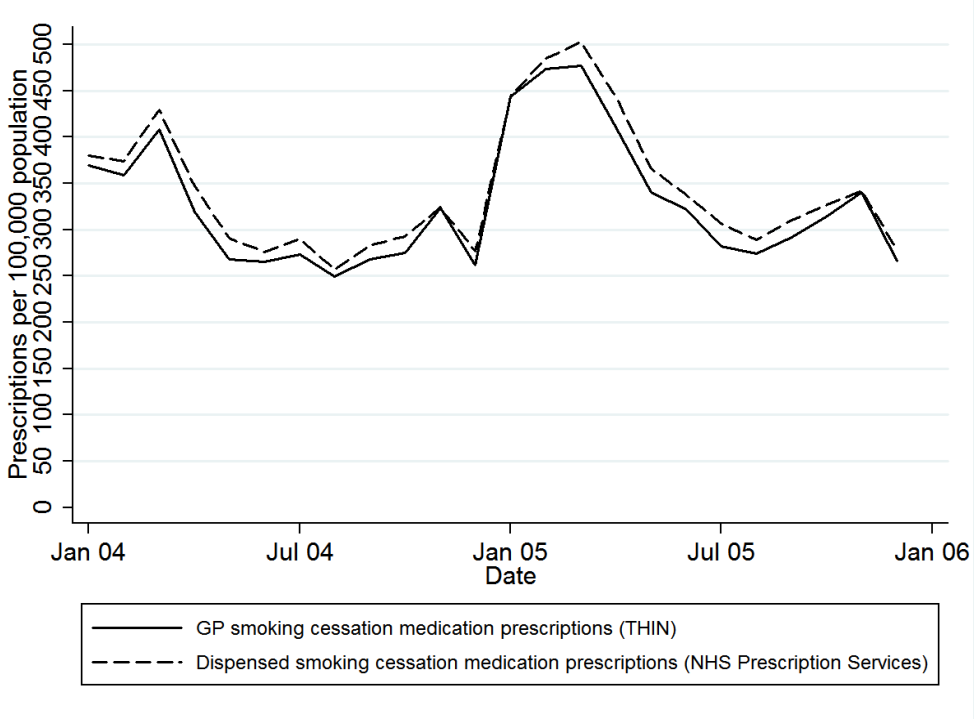
The difference between the rates of prescribing and dispensing was estimated as the percentage difference between the mean rates of prescribing and dispensing over the study period.

The analysis of THIN data for this study was approved by the Derbyshire ethics committee.

3.3 Results

Figure 3-1 shows the rate of total prescribing of smoking cessation medication in THIN between January 2004 and December 2005, as well as the rates of dispensing of smoking cessation medication from ePACT. Throughout this period the rates were very similar for these two sets of data, although numbers of dispensed prescriptions tended to be very slightly higher than prescriptions written in general practice. There were peaks in written and dispensed prescriptions in January and March of both years, coinciding with New Year and No Smoking Day. The agreement between rates of prescribing and dispensing remained consistent during the period studied.

Figure 3-1. Rates of prescribing of smoking cessation medication, England, based on THIN and ePACT, January 2004-December 2005



NRT products made up the majority of prescriptions. A discrepancy between dispensing and prescribing of NRT products, which was largely consistent over time, was observed (Figure 3-2). Across the two years studied, NRT dispensing exceeded GP prescribing by 5.5% on average. For bupropion, which was much less frequently prescribed than NRT, the rate of prescribing tended to exceed the rate of dispensing (Figure 3-3). Bupropion prescriptions exceeded dispensing by 5% on average across the study period. Here too, the small amount by which prescribing and dispensing differed was largely consistent over time.

Figure 3-2. Rates of prescribing of NRT, England, based on THIN and ePACT, January 2004 to December 2005

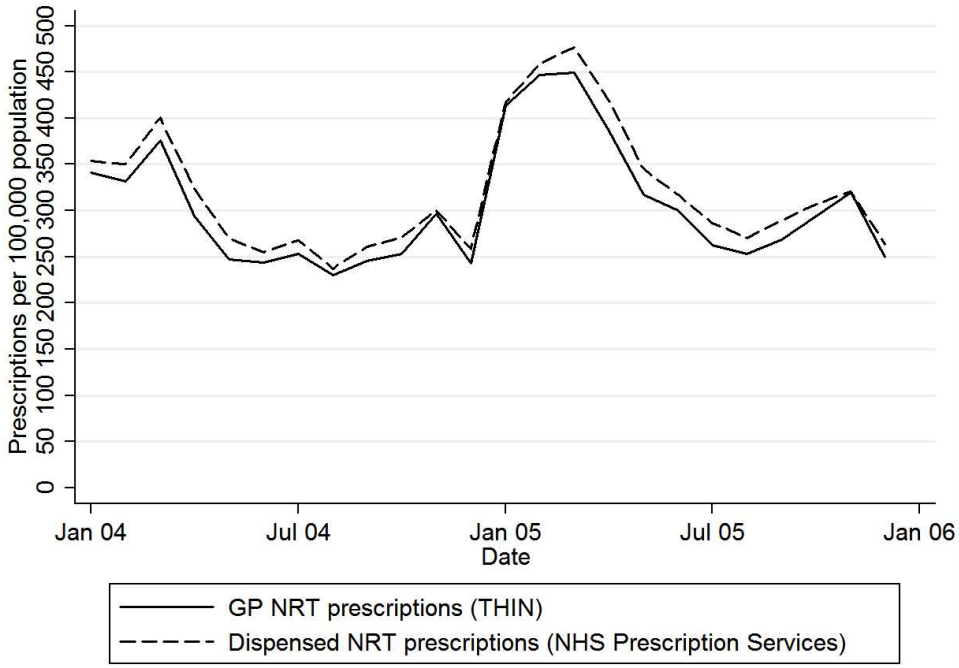
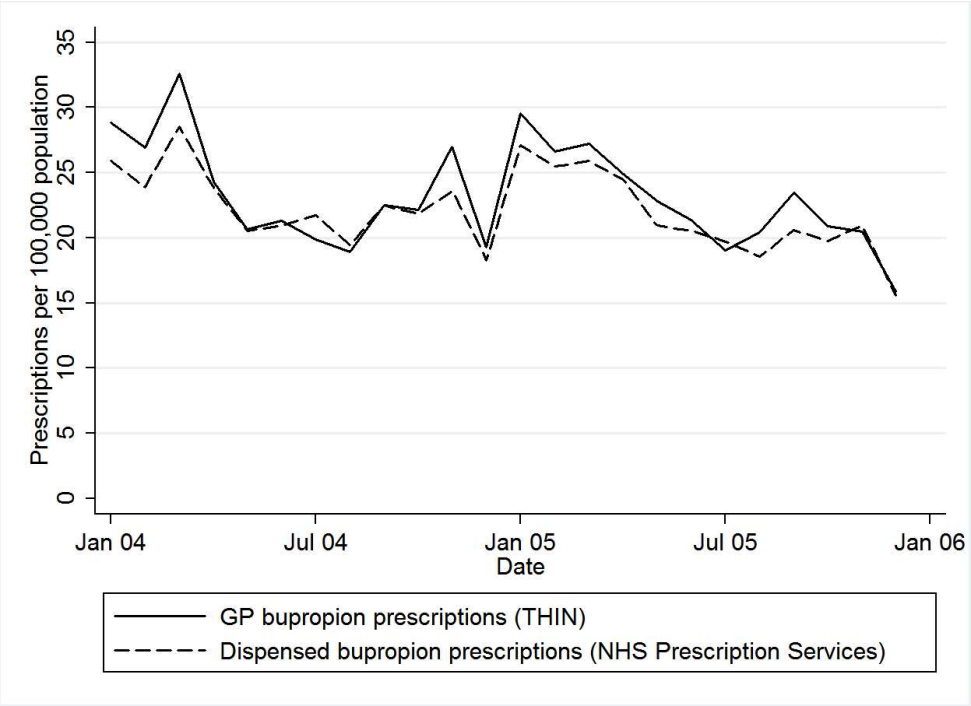


Figure 3-3. Rates of prescribing of bupropion, England, based on THIN and ePACT, January 2004-December 2005



3.4 Discussion

These results show that the rates of prescribing of smoking cessation medication recorded in THIN are highly comparable to the rates of dispensing of prescriptions based on data from ePACT, and remain consistently so over the time period studied. To my knowledge, this is the first study to assess the validity of THIN prescribing data for specific drugs and, as these data are a valuable source of information on prescribing patterns, finding them to be consistent with dispensing patterns is important.

Only data up to 2006 were analysed to avoid the period since 2006 when major changes in tobacco policy, including the introduction of smokefree legislation, may have served to change the underlying patterns

of prescribing. Appendix 9.3 shows that the agreement between the two data sources is in fact also consistent after December 2005, including the period after varenicline was introduced.

Previous studies have suggested that prescriptions are well recorded in electronic primary care records. In a systematic review of the quality of electronic patient records, Thiru et al. found that prescribing data tended to be more complete than diagnostic or lifestyle data.[194] In particular, prescribing data from the General Practice Research Database (GPRD), of which approximately 50% of contributing practices also contribute to THIN, have also been demonstrated to be of high quality.[168, 195, 196] In computerised medical records systems, where prescription forms are generated from within electronic medical records, as is the case in THIN, prescription records would be expected to be complete. The high level of consistency between rates of smoking cessation medication prescriptions in THIN and ePACT data provides support for the convergent validity of these data. THIN prescriptions data cannot, however, provide direct estimates of actual medication use, as this is dependent on medication compliance. Assessing the latter is difficult without surveying recipients, and that was beyond the scope of this study.

The rate of dispensing slightly exceeds that of prescribing, overall, and specifically for NRT prescriptions. These data might therefore be seen to indicate that the recording of written prescriptions in THIN is incomplete. However, THIN data include only prescriptions written within family physician's premises, whilst the ePACT data also include prescriptions written by community-based nurses and pharmacists, which are also dispensed in community pharmacies. During the study period a minority of specially-trained nurses and pharmacists were permitted to

prescribe nicotine replacement therapy (but not bupropion). Between April and September 2005 three brands of NRT were in the top twenty dispensed products prescribed by nurses, accounting for 6.7% of all NRT prescribed in this period.[12] These prescriptions may not always be recorded in THIN. A limitation of this study is that it is not known what proportion of dispensed prescriptions are written by community-based nurses (and therefore would not be recorded in THIN), but as non-GP prescribing for stop smoking medication may occur in unique settings, such as in stop smoking groups, it seems likely to be high. Overall, the discrepancy between NRT prescribing and dispensing seems likely to be largely caused by the inclusion of prescribing outside of general practice in the dispensing data.

For bupropion, contrary to the results for NRT, the rate of prescribing exceeded the rate of dispensing. The major factor which is likely to have led to the discrepancy between rates of prescribing and dispensing is the non-use of prescriptions. As stated in section 2.4.2, previous studies have estimated that between 5.2% and 20% of patients do not redeem their prescriptions.[168-172] The lower rate of dispensed compared to written prescriptions for bupropion seems likely to be attributable to this cause. Over the two years included in this study, the rate of prescribing was 5% higher than the rate of dispensing for bupropion. This figure may provide some indication of the proportion of written bupropion prescriptions that are not dispensed. It is at the lower end of the range of unredeemed prescriptions found in other studies, and may be an underestimate, if recording of prescriptions in THIN is not entirely accurate. Failure to use bupropion prescriptions could be a consequence of reports of sudden deaths associated with bupropion.[197]

Subsequent research studies demonstrating a favourable safety profile for bupropion may not have fully allayed these fears in the public arena.[198]

That dispensed prescriptions exceed written prescriptions for NRT suggests that the proportion of unused prescriptions is lower for NRT. A limitation of this study is that it is not possible to separate this effect from that of the other factors, previously described, that may contribute to the discrepancies.

Because THIN prescription data and national dispensing data are highly comparable and small differences between these are relatively consistent over time, THIN prescription data could be used to monitor longitudinal trends in prescribing for smoking cessation medications. As sociodemographic information is also available in THIN, these data could also be used to investigate variation in prescribing across different demographic and socioeconomic groups and provides a means for monitoring the smoking cessation behaviour of the population in response to tobacco control policy. In doing so, it would be important to take into consideration the fact that these medications may not necessarily be prescribed for smoking cessation. In particular, NRT may be used for cutting down or temporary abstinence so that its use for smoking cessation may be overestimated. In non-UK settings, bupropion may be prescribed for depression, but in the UK it does not have a license for treating depression, therefore all bupropion prescriptions will be for smoking cessation.

3.5 Conclusions

THIN appears to be a source of highly valid data on prescribing of smoking cessation medication. It is arguably the best measure of quitting

behaviour in the NTCD, because it is valid on a monthly basis, includes extensive sociodemographic data, and covers a long time period. THIN prescription data could therefore be used to monitor longitudinal trends in prescribing for smoking cessation medications and can be a useful tool in studying the smoking cessation behaviour of the population in response to tobacco control policy.

The smoking cessation medication data in THIN lend themselves to the evaluation of several policies that have recently been implemented in England which aimed to increase access to smoking cessation medication. The THIN prescribing data are therefore used as outcome measures throughout this thesis.

CHAPTER 4: TIME SERIES METHODS FOR THE EVALUATION OF TOBACCO CONTROL POLICY

4.1 Introduction

The concept of time series analysis and its potential value in the evaluation of tobacco control policies has been discussed in the introduction. This chapter takes a more detailed look at why time series analysis is needed, and at the different types of time series analysis that may be employed when estimating the effect of health policies. Section 4.2 describes why specific methods are needed to analyse time series. Section 4.3 deals with interrupted time series analysis – a method which looks at the impact of a policy introduced at one point in time. Section 4.4 explores multiple time series analysis – a method for measuring the impact of a policy exposure which changes over time. For each method the following questions are considered:

- What questions will the method help to answer?
- What data are required?
- How is the model specified?
- How are the results interpreted?
- What are the strengths and limitations of this approach?

The Stata commands needed for all the time series models described in this chapter are presented in Appendix 9.4.

The remainder of this thesis uses these different methods to evaluate a range of different tobacco control policies introduced in England in recent years.

4.2 Why we need time series analysis: autocorrelation

In time series data, instead of fluctuating randomly from one period to the next, successive observations tend to be close to each other; this is

known as autocorrelation. Autocorrelation may also be seasonal. In this case, in a monthly time series, a value of the series at one point in time is related to that 12 (and in some cases 24, 36 and so on) months previously.

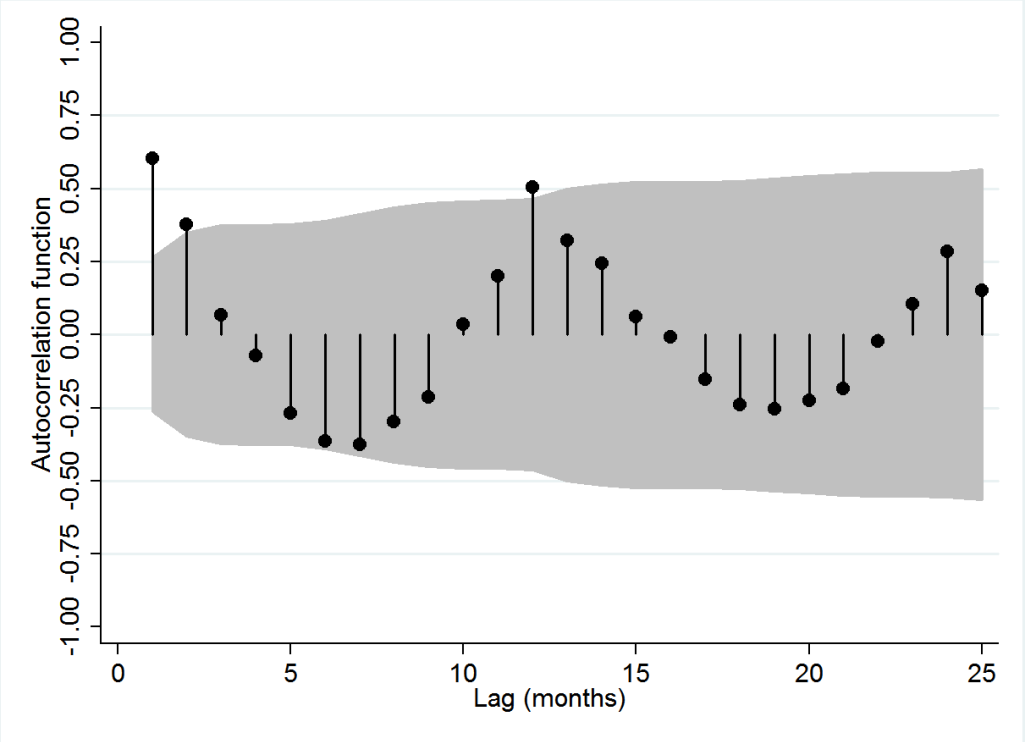
Autocorrelation in a time series violates a central assumption of linear regression, namely independence between data points. This causes standard errors to be underestimated (if the autocorrelation is positive), or overestimated (if the autocorrelation is negative).[199] Therefore, modelling the impact of an intervention without taking account of the autocorrelation in a time series may lead to making either a type one (rejecting a true null hypothesis) or type two (accepting a false null) error. Thus, if time series data are autocorrelated and we do not take account of the autocorrelation, we may make inaccurate inferences about the effect of policies. For example, we may incorrectly conclude that a policy was effective, or incorrectly conclude that a policy was not effective. Such errors could lead to an inefficient use of resources, for example through trying to improve a policy that is in fact meeting its objectives, or through encouraging policymakers in other regions or countries to implement a policy that is unlikely to be effective. Time series techniques accommodate autocorrelated errors and avoid these problems.

4.2.1 Identifying autocorrelation

An autocorrelation function (ACF) can be used to demonstrate graphically whether autocorrelation is present in a time series. Figure 4-1 below shows the average autocorrelation between data points in one of the time series that was validated in Chapter 3 – prescribing of NRT in THIN. It shows that the correlation between data points and their one-month lags is

high and significant, at 0.6, and decreases as the lag increases. The ACF also suggests that there is seasonal autocorrelation, as there is also high correlation with the value at the 12 month lag.

Figure 4-1. Example of an autocorrelation function

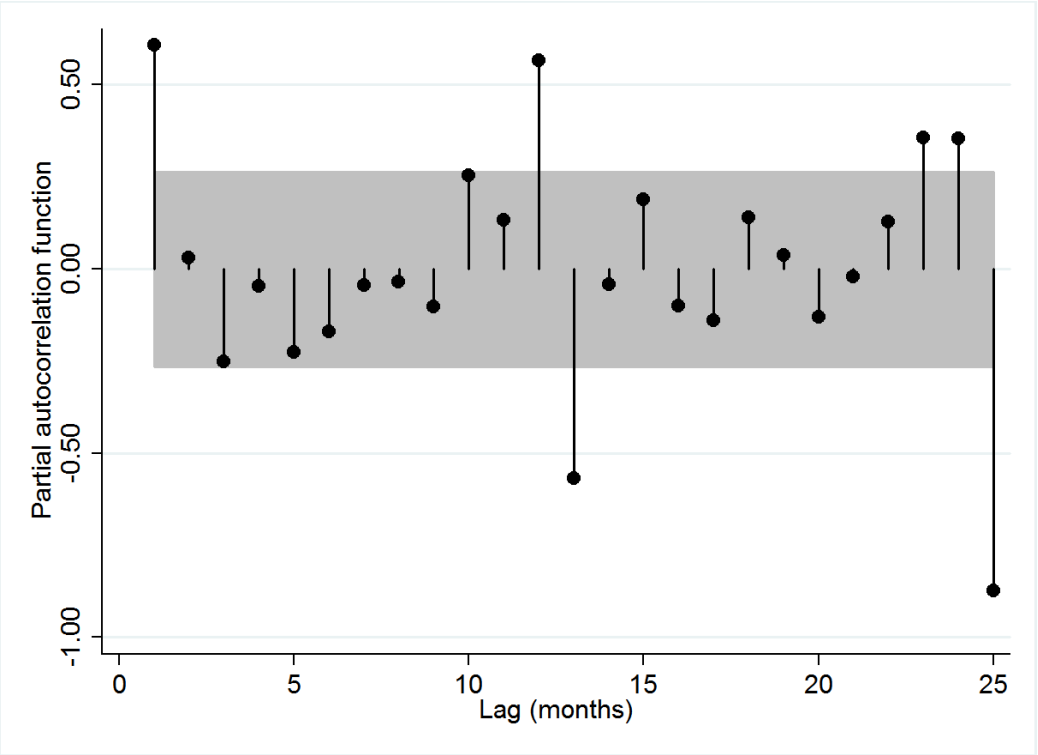


4.2.2 The partial autocorrelation function and types of autocorrelation

Partial autocorrelation is the correlation between a value at a point in time and lag of itself that is not explained by correlations at lower-order lags, and can be seen in a partial autocorrelation function (PACF). Thus if the PACF has a significant spike at lag 1 only, the higher-order correlations are almost entirely due to the lag 1 autocorrelation. Figure 4-2 shows an example of a PACF using the NRT prescribing data from THIN. The PACF

can be used in conjunction with the ACF to identify the type of autocorrelation that is present in a time series.

Figure 4-2. Example of a partial autocorrelation function



There are two types of autocorrelation: autoregressive (AR) and moving average (MA).

If there is autoregressive autocorrelation in a time series, the value of the series at a point in time is a function of the value of the series at a previous point in time, plus an error component. In an autoregressive process of order one – AR(1) – the value at one point in time, t, is a function of the value of the series at the point in time immediately prior to it, t-1.[200] The order of autoregressive autocorrelation is rarely greater than two.[201]

If there is moving average autocorrelation in a time series, the value of the series at a point in time is a function of the error component from the series at an earlier point in time and the error component at the current point in time. In a moving average process of order one – MA(1) – the value at one point in time, t, is a function of the error component other the series at the point in time immediately prior to it, t-1, and the error at the current point in time.[200] As for AR processes, the order of MA autocorrelation is usually not greater than two.

There are rules of thumb for identifying the order of autocorrelation present in a time series using ACFs and PACFs. As will be explained in this chapter, these autocorrelation terms are then fitted in the time series model. Table 4-1 contains a summary of practical recommendations for identification by Pankratz.[202]

Table 4-1. Recommendations for identifying the autocorrelation process

Process (order)	ACF	PACF
AR(1)	Exponential decay	Spike at lag 1, no correlation for other lags
AR(2)	Sine-wave pattern or set of exponential decays	Spikes at lags 1 and 2, no correlation for other lags
MA(1)	Spike at lag 1, no correlation for other lags	Damps out exponentially
MA(2)	Spikes at lags 1 and 2, no correlation for other lags	Sine-wave pattern or set of exponential decays
AR(1) and MA(1)	Exponential decay starting at lag 1	Exponential decay starting at lag 1

Adapted from ARIMA methodology: http://www.statsoft.com/textbook/time-series-analysis/#arima (Accessed 29th October 2011)

These rules can also be applied to identify seasonal autocorrelation. For example, if there is seasonal autoregressive autocorrelation in monthly data, there will be significant autocorrelation at lag 12 with exponential decay in the ACF and a spike at lag 12 with no correlation for other lags in the PACF.

4.3 Interrupted time series analysis

Interrupted time series analyses are methods used to determine whether an intervention, such as a public health policy, affects a time series of outcome measurements. In interrupted time series analysis, the intervention must be introduced at a single, known point in time so that the data can be separated into pre– and post-interruption series. This chapter presents two approaches to interrupted time series analysis, each with strengths and limitations. One is a regression framework, and one is a class of mathematical models called Autoregressive Integrated Moving Average (ARIMA) models. Both of these methods and their application to the evaluation of public health policy have been described in detail elsewhere; therefore, this section provides a brief overview of the key points related to each method.[185, 203]

4.3.1 Segmented regression analysis

What questions will the segmented regression help to answer?

Segmented regression analysis is one approach to comparing pre- and post–intervention series; this method has increasingly been used to estimate the effects of health services and policy interventions, but is still rarely used to evaluate the impact of national public health policy.[203-207]

The segmented regression approach can be used to assess how much an intervention, such as the introduction of smokefree legislation,

changed an outcome of interest, such as the national prevalence of smoking, immediately and over time. Segmented regression analysis estimates the trend in a time series before an intervention, and step changes in the level and changes in the trend of the series at the time point immediately following an intervention, taking into account any seasonal patterns in the data.[203]

Data requirements

Segmented regression analysis requires data to be in regular, equally-spaced time intervals.[203] Segmented regression can be undertaken with relatively short time series, although recommendations as to the minimum length of the time series vary. Cochrane's Effective Practice and Organisation of Care Group recommend that interrupted time series models (but not ARIMA models, for which the recommendations are longer) have at least three observations prior to the intervention and at least three in the post-intervention period.[208] However, a more appropriate recommendation when using monthly data is for at least 12 data points prior to and after the intervention.[203] This allows seasonal variation to be taken into account. This recommendation is not based on power, however, and the power of the model is more likely to depend on the complexity of the autocorrelation.[209] Power calculations for this type of analysis are in their infancy.[209]

Fitting a linear segmented regression model

Wagner et al. describe in detail how to fit a segmented regression model.[203] Simple segmented regression models can be fitted as linear regression models that include terms to describe the trend in the outcome in the pre-intervention period, any immediate step change in the level of outcome following the intervention, and any change in the trend in the

outcome in the post-intervention compared to pre-intervention data, as shown in equation (1).[210]

$$Y_t = \beta_0 + \beta_1 * \text{time}_t + \beta_2 * \text{intervention}_t + \beta_3 * \text{time since intervention} + \varepsilon_t \quad (1)$$

In equation (1), β_1 is the trend prior to the intervention, β_2 is the change in level immediately after the intervention, and β_3 is the change in the trend following the intervention. Thus (β_{1+} β_3) is the post-intervention slope. A parsimonious model is built by eliminating non-significant terms from the model. Table 4-2 shows an example of how one would structure a dataset to investigate a change in prescribing following an intervention introduced at time point 16.

Table 4-2. Structure of data for segmented regression analysis

Time ($time_t$)	Level ($intervention_t$)	Slope (time since $intervention_t$)	Prescriptions (Y_t)
1	0	0	31.91
2	0	0	30.71
3	0	0	36.70
4	0	0	37.68
5	0	0	50.95
6	0	0	44.92
7	0	0	50.79
8	0	0	50.76
9	0	0	46.62
10	0	0	45.73
11	0	0	40.69
12	0	0	29.69
13	0	0	38.64
14	0	0	41.38
15	0	0	71.75
16	1	1	50.93
17	1	2	99.27
18	1	3	58.88
19	1	4	86.35
20	1	5	55.83
21	1	6	61.62
22	1	7	52.05
23	1	8	32.36
24	1	9	39.38
25	1	10	51.23
26	1	11	79.52
27	1	12	39.11
28	1	13	39.99
29	1	14	108.36
30	1	15	111.28

Interpreting the results

Running a segmented regression model generates estimates of coefficients, confidence intervals and p-values for the pre-intervention trend, immediate change in level and change in trend of the time series. The values of the outcome variable predicted by the model can also be obtained and plotted against the original time series to demonstrate, graphically, any changes in the trend and/or level of the time series following the intervention.

Dealing with autocorrelation in segmented regression models: General Additive Models

Simple linear regression does not, however, account for autocorrelation. If the ACF of the residuals of the model reveals AR autocorrelation at one lag, Prais-Winsten estimation can be used to take this into account.[211] However, the Prais-Winsten method is not able to correct for MA autocorrelation or AR autocorrelation of an order higher than one. Thus if these types of autocorrelation are present in a time series, we risk drawing incorrect conclusions about the impact of a policy. Alternative models can be used to take account of more complex autocorrelation structures.

When autocorrelation structures in data are found to be more complex than AR(1), more flexible types of model can be used: Generalised Additive Models (GAMs) and Generalised Additive Mixed Models (GAMMs). GAMs enable the fitting of seasonal smoothing terms, and therefore allow seasonal autocorrelation to be taken into account.[212] GAMMs can also fit AR and MA autocorrelation terms, thus ensuring that all autocorrelation is taken into account.[210]

GAMs and GAMMs can both be fitted in the statistical package ***R*** by first running a linear regression model as described above, and then using stepwise elimination to obtain a parsimonious model. If there is evidence of seasonal autocorrelation in the residuals of the model, a smoothing term is included to model any regular seasonal pattern in the outcome. The ACFs and PACFs of this model are then used to establish which autocorrelation terms are required.

These methods have recently been used to evaluate the impact of smokefree legislation in England on hospital admissions for myocardial infarction.[145] The code required to conduct a segmented regression analysis using GAMs and GAMMs in ***R*** is presented in Appendix 9.5.

Strengths and limitations of segmented regression analysis

The key strength of segmented regression analysis is that it can control for underlying trends, which is important for ensuring that correct conclusions are drawn. By using GAMs and GAMMs, seasonal effects and autocorrelation can also be taken into account. Further to this, segmented regression can be used to estimate two key parameters – immediate changes in the mean of a series and changes in the trend following an intervention, which gives a useful indication of the immediate and longer term impact of an intervention.

The main strength of segmented regression is that it can be used with relatively short time series. This is particularly important in public health research where long series with regularly-spaced data are not always at hand for the variables of interest.

Segmented regression also has several limitations. A fundamental limitation of all analysis that investigates the effect of a policy introduced at one point in time is that it is not possible to reliably separate the effects of different policies that are introduced at the same time or in proximate time. For tobacco control policies this is often the case, and care must therefore be taken in interpreting the results.

A further limitation of segmented regression analysis is that it may fail to capture effects that occur prior to the intervention (for example, people trying to quit smoking in the run up to smokefree legislation). It may also fail to detect any transient effects on the trend of a time series. This may be overcome by shortening the time series, so that a shorter time period following the introduction of a policy is analysed, but this will reduce the power of the model. Autoregressive Integrated Moving Average (ARIMA) models provide a more flexible method for investigating the effects of policy changes which does not have these limitations.

Finally, because segmented regression involves fitting linear regression models, it can only be used when the trends before and after the policy change are linear. ARIMA models can be used when there are non-linear trends in the time series.

4.3.2 Autoregressive Integrated Moving Average (ARIMA) modelling

What questions will the ARIMA approach help to answer?

ARIMA models are frequently used by econometricians to make economic forecasts, and have also be used for forecasting the incidence of diseases.[213, 214] However, they are also an alternative approach to interrupted time series analysis, and allow changes in the outcome variable

before and after the intervention to be explored. As such, ARIMA models are increasingly being employed in public health evaluation.

Like segmented regression analysis, the ARIMA model can be used to assess whether there were changes in an outcome of interest, such as the rate of prescribing of stop smoking medications, after the introduction of an intervention, such as smokefree legislation. Changes are expressed relative to the underlying level of the outcome variable, taking long-term and seasonal trends into account. Unlike segmented regression, however, ARIMA models can be used to investigate, in detail, the nature of the change: whether it pre-empted the policy, and whether the effects are transient or permanent.

The ARIMA method models the behaviour of the time series and establishes whether an intervention has a statistically significant impact on the time series by assessing whether the data-generating process of the time series has changed between the pre-and post-policy period. In other words, ARIMA modelling tells us whether the intervention component helps to predict the behaviour of the time series over and above the seasonal and serial correlation components.

Data requirements

Recommendations as to the length of time series required for ARIMA modelling vary. The Cochrane Effective Practice and Organisation of Care Group recommend that at least 20 observations prior to the intervention are required, but this appears unlikely to enable accurate modelling if there are seasonal effects in the time series.[208] Other authors recommend at least 50-100 observations, though some simulations suggest 250 or more observations are needed for accurate modelling.[215]

The number of observations needed increases if a series exhibits seasonality, which is often the case for monthly data. If it is likely that a policy will take time to have an effect, enough post-intervention data are required to ensure that the lag in effect is captured. Methods to calculate the power of interrupted time series analysis using ARIMA models have recently been developed.[216]

Preparing the data

The first step in an ARIMA analysis is to check the time series for outlying values. Outliers can bias the results of time series analysis, and can be replaced by imputed values.[200] If they appear at the beginning of a time series, and the time series is long enough, they can be omitted from the analysis.

ARIMA modelling needs to be carried out on stationary data; the mean and variance of a series must be stable over time.[215] If the variance of the time series is not stable, it is typically log-transformed to stabilise the variance.[215] When a log-transformation is not possible, for example, when the series contains zero values, an alternative transformation, such as an inverse hyperbolic sine, can be used, as shown in equation (2) below.[217]

$$\text{arcsinh } z = \log\left(z+\text{sqrt}(1+z^2)\right) \qquad (2)$$

Next, any trend in the data must be removed to ensure that the mean of the time series is constant over time. This can be achieved by differencing the time series: the value of the series at each point in time is replaced by the value of the difference between that point and the value of the time series in the previous month, as shown in Table 4-3.

Table 4-3. Example of differenced data

Date	Original series	Value of logged series	Differenced series
Jan-03	247.254952	5.51042	-
Feb-03	225.789918	5.419605	-0.09082
Mar-03	242.645857	5.491603	0.071998
Apr-03	231.211066	5.443331	-0.04827
May-03	204.722008	5.321653	-0.12168
Jun-03	188.828085	5.240837	-0.08082
Jul-03	201.394969	5.305268	0.064432
Aug-03	159.277028	5.070645	-0.23462
Sep-03	193.894074	5.267312	0.196667
Oct-03	220.104845	5.394104	0.126793
Nov-03	198.322005	5.289892	-0.10421
Dec-03	182.240091	5.205325	-0.08457

The ACF and plots of the time series (and differenced time series) can be used to establish whether the series needs to be (further) differenced. A correctly differenced series will fluctuate around a well-defined mean and the ACF will decay fairly rapidly to zero.[218] A time series which needs to be differenced once to become trend stationary is said to be integrated of order one (I(1)).

If there is significant autocorrelation at seasonal lags, the time series must also be seasonally differenced: in a monthly time series each value is replaced by the difference between that value and the value of the data point in the same month the previous year.

Model identification and diagnosis

The next step is to identify an appropriate ARIMA model. This is done using the pre-intervention data only.[215]

An ARIMA model is conventionally described using the general syntax:

ARIMA (p, d, q)(P, D, Q)s

where:

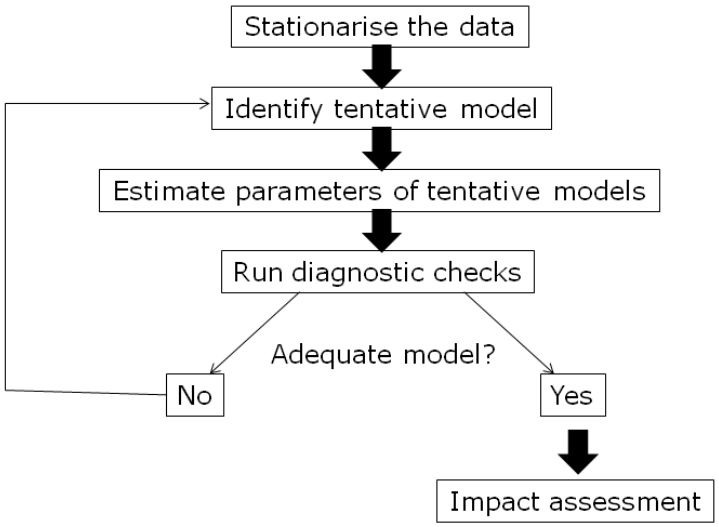
p = order of non-seasonal autoregressive autocorrelation
d = order of non-seasonal differencing needed to obtain non-seasonal stationarity
q = order of non-seasonal moving average autocorrelation
P = order of seasonal autoregressive autocorrelation
D = order of seasonal differencing needed to obtain seasonal stationarity
Q = order of seasonal moving average autocorrelation
s = seasonal order of series (number of seasons in a year)

The autocorrelation and partial autocorrelation functions of the (if necessary, logged, differenced) series are examined to help determine the order of moving average (MA) and autoregressive (AR) terms and seasonal MA and AR terms needed to model the autocorrelation in the stationary series. The rules of thumb described in section 4.2.2 are used to identify a tentative model.

This tentative model is then estimated, and several diagnostic checks carried out to ensure that the model is parsimonious and valid. Firstly, the autocorrelation terms included in the model must be statistically significant. This is checked based on the output from the model. Secondly, the model residuals must be normally distributed and random and independent (i.e. should display no autocorrelation). This can be checked by estimating the residuals of the model, and then examining the distribution of the data and the ACF and PACF.

As shown in Figure 4-3, if the tentative model is inadequate, the process is repeated until a valid model is found.

Figure 4-3. Stages involved in using ARIMA to assess the impact of an intervention on a time series



Intervention analysis

When a valid, parsimonious model has been selected, it can be applied to the whole time series to estimate the effect of the intervention on the time series. The intervention is included as a dummy variable, which can be used to model an immediate, permanent step change in the outcome – in which case the dummy takes the value 0 before the intervention and 1 from the time the intervention was introduced. Alternatively, the dummy variable can be used to model a pulse effect, which lasts for either only one time period (e.g. one month) or a small number of time periods, in which case the dummy takes the value 0 before the intervention, takes the value 1 for the pulse effect period and 0 thereafter. If it is anticipated that an intervention may have an effect prior to its implementation, or have a lagged effect, the dummy can also take the value 1 prior to implementation or take the value 0 for a time after implementation. Thus a study found that smokefree legislation increased prescribing of smoking cessation medication for six months prior to the

implementation of the policy and up to ten months after implementation, but that there was no permanent increase in prescribing.[184]

Confounding events can also be fitted as dummy variables, but it may not be possible to disentangle the effects of different interventions. For example, graphic health warnings may be introduced six months after smokefree legislation. It is possible to include a dummy variable for the effect of the health warnings in an evaluation of the impact of smokefree on quitting behaviour, but there may be a delayed impact of smokefree legislation; thus it will not be possible to differentiate between the effect of the smoking ban and that of the health warnings.

Interpreting the results

Running the ARIMA model for the whole time series with a dummy variable for the intervention generates a coefficient and corresponding confidence intervals and p-value for the effect of the intervention. If the time series has not been log-transformed the coefficient is interpreted as the absolute level change in the outcome as a result of the intervention. If the time series has been log transformed, the ARIMA model coefficients provide estimates of the percentage change in the outcome following the intervention.

Strengths and limitations of ARIMA modelling

ARIMA modelling has many of the same advantages as segmented regression, and these have been discussed in section 4.3.1: underlying trends can be taken into account and seasonal effects and autocorrelation can be modelled.

The main advantage of ARIMA modelling over segmented regression is its flexibility. The dummy variable can be changed to model

different effects of a policy: changes prior to the implementation of the policy, permanent effects and transient effects. Thus much more detailed and potentially more accurate information can be obtained from an ARIMA model. In addition, as previously mentioned, ARIMA models can be used when there are non-linear trends in the time series.

As mentioned in section 4.3.1, an inherent limitation with methods that explore the impact of a policy introduced at one point in time, is that it is difficult to take account of the confounding effects of simultaneous policies. In addition, as also previously mentioned, a potential limitation of ARIMA is the need for a long time series, which may not be available for the outcome of interest.

4.3.3 Conclusions

Segmented regression analysis is a powerful quasi-experimental approach for the evaluation of policy that can be used with relatively short time series. Where longer-term series of data are available, however, ARIMA modelling provides a more flexible approach to interrupted time series analysis. The relative power of the two methods is unclear; methods have been developed for computing the power of interrupted time series analysis using ARIMA models, but power calculations for segmented regression analysis are underdeveloped. ARIMA models allow both immediate and delayed, and transient and sustained, effects of interventions to be investigated.

In this thesis, both types of analysis are used in order to illustrate how they are applied.

4.4 Multiple time series analysis

Multiple time series analysis (MTSA) is a method frequently used in econometrics to investigate the relationships between economic time series measured on a continuous scale, for example income and consumption, or price and sales. Until now, this method has rarely been used in a public health context, but may be needed to deal with continuous exposure data such as cigarette price or health policy expenditure over time. There are a range of different multiple time series models, and the choice of analysis depends on the statistical properties of each time series and the nature of the temporal relationship between the time series. These properties and relationships are identified prior to fitting the models. This section describes two approaches to MTSA: dynamic regression analysis, and vector autoregression (VAR).

4.4.1 Dynamic regression analysis

What questions will dynamic regression help to answer?

A standard MTSA approach is dynamic regression modelling (also known as ARMAX/ARIMAX or transfer function modelling).[215] Dynamic regression is an extension of ARIMA modelling – whereas in an ARIMA model the impact of an intervention is explained by a dummy variable, in dynamic regression models the time series of the outcome (output) series is explained in terms of current values and lags of one or more predictor (input) time series.[215] This approach has previously been used in a study exploring the impact of tobacco price and mass media campaigns on smoking prevalence.[82]

Data requirements

Dynamic regression requires two time series which cover the same period at the same temporal frequency of data collection. This author has not been able to identify explicit recommendations as to the number of data points required, but as these models are specified in a similar way to ARIMA models, it seems reasonable to assume that the same recommendations as outlined in section 4.3.2 apply.

Preparing the data

Like ARIMA modelling, dynamic regression analysis must be carried out on stationary data.[215] If necessary, therefore, both time series should be transformed and differenced as described in section 4.3.2. If one time series needs to be transformed or differenced to achieve stationarity, the same should be done to the other time series to preserve the relationship between them.[215]

Dynamic regression analysis assumes weak exogeneity between the input (X_t) and output (Y_t) series i.e. Y_t must depend on the lagged values of X_t, but the reverse must not be the case.[215] In other words, there must be a unidirectional relationship between the time series. If the relationship is bi-directional, it is said that there is feedback between the series, and an alternative method of analysis must be used.[215] To confirm that there is weak exogeneity between the time series, each must be regressed on lagged values of itself and the other; statistical significance should only be found in one direction.[219] This can be done using the Granger Causality test.[215] If weak exogeneity is confirmed, dynamic regression can be used. If this assumption is violated, vector autoregression can be used. This method is described in the subsequent section.

Model specification

If weak exogeneity is confirmed, the model is specified as follows. A basic ARIMA model is specified in which the output series is regressed on sequential lags of the input series. Initially enough lags are included so that the proper lag can be determined by dropping lagged terms if they are non-significant to leave a parsimonious model. If the residuals of the model exhibit autocorrelation, autocorrelation terms are added to the model. The residuals of a correctly specified model should exhibit no autocorrelation and be normally distributed. Thus the general procedure for specifying a dynamic regression model is similar to that for ARIMA models.

Interpreting the results

Running the dynamic regression model estimates coefficients and corresponding confidence intervals and p-values for the effect of the input series on the output series in the contemporaneous time period and at lagged time periods, depending on the lags included in the model. If the time series has not been log-transformed, the coefficient is interpreted as the absolute change in the outcome as a result of a one-unit increase in the input series. If the time series has been log transformed, the model coefficients provide estimates of the percentage change in the outcome following a one percent increase in the input series. For example, in a study of the impact of price on sales, the coefficients provide estimates of the percentage change in sales following a one percent increase in price.

Strengths and limitations of dynamic regression

The key strength of dynamic regression analysis is that it is able to take account of the complexities of time series data, including autocorrelation and seasonality, as well as any lags in effect. In a public

health context, the main limitation of dynamic regression can be the availability of data – like ARIMA models, dynamic regression requires regular time series data over a long time period.

A further limitation of this method is the weak exogeneity assumption, which can mean that other multiple time series modelling approaches, such as VAR, must be used.

4.4.2 (Structural) Vector Autoregression

What question will vector autoregression help to answer?

When the weak exogeneity assumption of dynamic regression is violated, an alternative approach to estimate the impact of one time series on another is vector autoregressive (VAR) modelling.[215] VAR is a framework developed to model a set of two or more dependent variables within a single model.[220] These models were developed in order to capture the complex and often multi-directional relationships between macroeconomic variables and are often used in economic forecasting and policy analysis. To my knowledge, these methods have until now not been used in a public health context.

However, VAR uses only lags of the input series, and can therefore miss valuable information when there is instantaneous causality (simultaneity) between two time series. There is instantaneous causality when the current value of Y_t (output) is better 'predicted' when the current value of X_t (input) is included in the 'prediction' of Y_t.[221] This can occur when data are temporally aggregated or are recorded at insufficiently frequent time intervals to detect the temporal relationship between them. An extension of VAR, structural VAR allows assumptions to be made about the direction of causality in order to unpick the temporal relationships

between variables – the relationships between time series within the current time period as well as any lagged effects in subsequent time periods. It is also possible to put appropriate restrictions on the model so that the relationship which is modelled is unidirectional.

In evaluations of tobacco control policy, it is likely that any causal relationship runs from the policy to the outcome, rather than vice versa, at least in the short run; therefore it is appropriate to build a unidirectional model. Furthermore, there may be very little lag in the impact of tobacco control policies on certain outcomes; therefore, when using monthly or less frequent data that impact may appear to be, at least in part, instantaneous. SVAR models are likely to better capture this effect than VAR models, and this section therefore focuses on this type of model.

Due to the likely rapid impact of tobacco control policies on quitting behaviour, this chapter describes short-run SVAR models. There are VAR and SVAR methods which model the long-run relationships between time series, but these are not dealt with here.

Data requirements

Like dynamic regression, SVAR modelling requires at least two series of data measured on continuous scales that cover the same period at the same frequency of data collection.

Preparing the data

SVAR (and VAR) modelling requires stationary data so the time series may need to be transformed and differenced to ensure stationarity.[217, 222]

Model specification

SVAR models are estimated as follows, and the Stata commands required are included in Appendix 9.4.5.[223]

First, matrices containing the constraints are specified; these determine the directions of causality in the model by restricting some parameters. (Normal VAR models are estimated in the same way but without this first step.) To explain this, an example of SVAR model looking at the effect of tobacco price (x) on smoking prevalence (y) is used.

In this example, there are just two variables, and therefore the matrix to be estimated is a simple 2x2 matrix which represents the parameters in the SVAR model:

[a b]
[c d]

Where:

a = The effect of a change in x on x
b = The effect of a change in y on x
c = The effect of a change in x on y
d = The effect of a change in y on y

Hence:

[x→x y→x]
[x→y y→y]

Intuitively, the effect of a variable on itself is one. Therefore, in the SVAR model, we assume that the effect of price (x) on price is one, and that the effect of y on y is one, and that prevalence has no effect on price, thus y→x = 0. The only parameter that needs to be estimated in the model is the effect of x on y. Thus the matrix is specified as follows:

[1 0]
[. 1]

The '.' will be estimated in the model. By specifying the model in this way, we are setting up a model which models the effects of price on prevalence without allowing for an effect of prevalence on price.

Information criteria - measures of the relative goodness of fit of a statistical model - are used to identify the optimal number of lags to include in the model; the lags account for any autocorrelation in the model. This is done by fitting models with different numbers of lags, and choosing the model which minimises the information criteria. Factors such as seasonal effects can be fitted as exogenous variables (variables which are independent from the other variables in the model). For example, if they improve the fit of the model (again, this is tested using information criteria), seasonal dummy variables can be added to the model. Once optimised, the model is run and diagnostic testing undertaken to establish that the model has been properly specified.[223] These include tests for autocorrelation, stability (stationarity) and normality of the model residuals. If there is autocorrelation in the model, it should be respecified with a different number of lags to remove the autocorrelation. The tests for normality of the residuals can behave poorly in small samples and should therefore only be used as rough check of normality.[224]

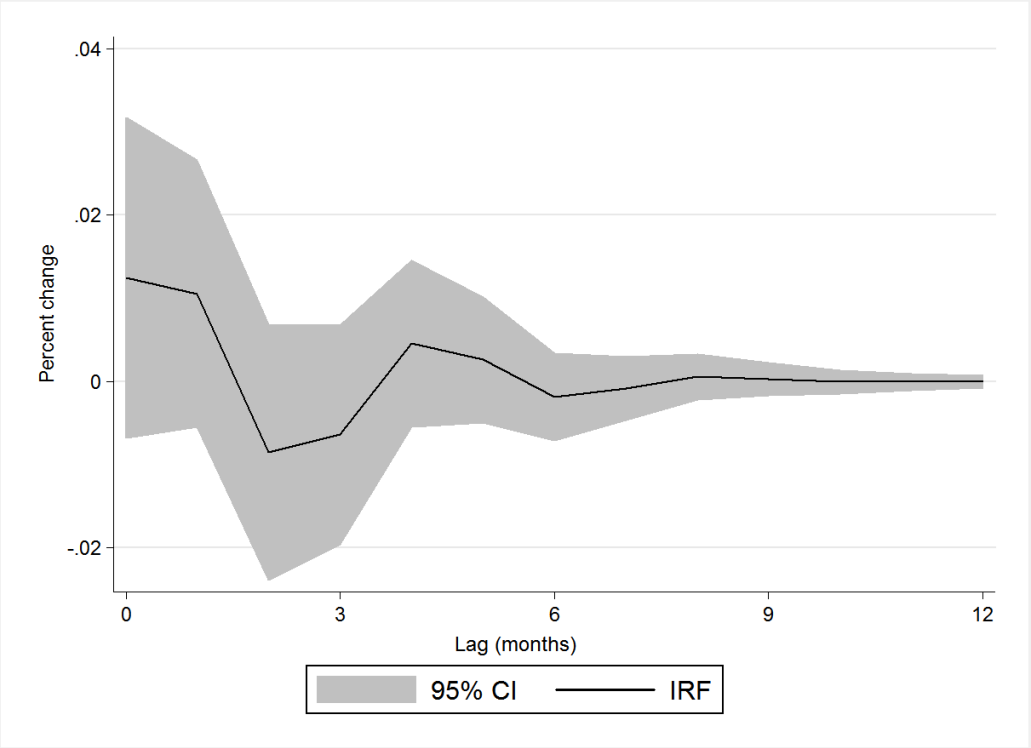
The final step in a policy analysis using a SVAR is obtaining the impulse response function (IRF) – this tells us how a shock (change) to one variable (the impulse variable) affects future values of the second variable (the response variable).

Interpreting the results

A graphical example of an IRF is shown in Figure 4-4. IRFs show the change in the output variable (for example, smoking prevalence) in

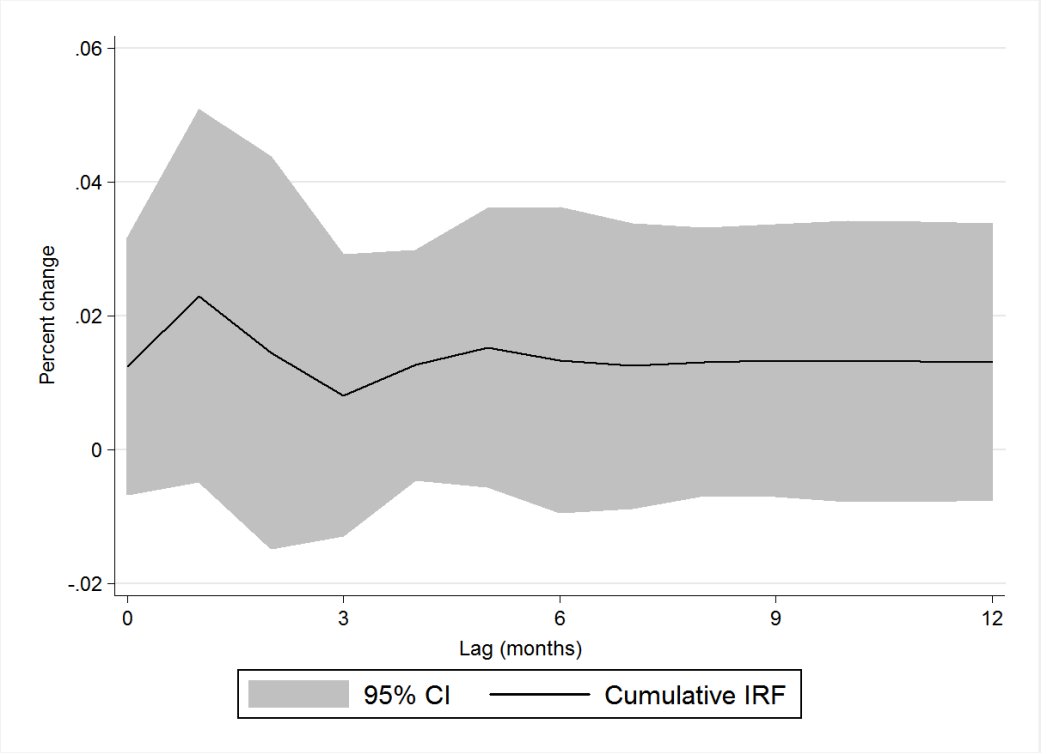
response to a change in the input variable (such as price) in the same month and in the subsequent months. The solid line represents the IRF estimate at different time lags, and the shaded area the 95% confidence interval. Modelling transformed-differenced data provides the percentage change of each series; therefore the results can be interpreted directly as elasticities i.e. the percentage change in the outcome variable following a one percent change in the explanatory variable. Modelling non-transformed data provides level changes – the absolute change in the outcome following a one unit rise in the exposure.

Figure 4-4. Example of an Impulse Response Function (IRF)



Cumulative IRFs (CIRFS) which show the overall effect of a shock can also be obtained, as shown in Figure 4-5. Thus the solid line in the CIRF represents the total change in the response variable following a change in the input variable at different time lags.

Figure 4-5. Example of a Cumulative Impulse Response Function (CIRF)



Strengths and limitations of vector autoregression

VAR and SVAR models have broadly the same strengths and limitations as dynamic regression – they are able to take account of autocorrelation, seasonality and lags in effect, but also require long time series. They offer an alternative to dynamic regression when the weak exogeneity assumption is violated.

4.4.3 Conclusions

Given the availability of appropriate data, multiple time series analysis is a robust way of investigating the relationship between a continuous exposure and a continuous outcome over time, and may

therefore be extremely valuable in the evaluation of tobacco control policies such as price increases and mass media campaigns.

In Chapter 7 of this thesis, SVAR modelling is used to investigate the impact of anti-smoking mass media campaigns on quitting behaviour.

CHAPTER 5: PRESCRIBING OF SMOKING CESSATION MEDICATION SINCE THE INTRODUCTION OF VARENICLINE

5.1 Introduction

The role of pharmacotherapy in increasing the success of quit attempts has been described in section 1.6.11. Smokers who make unsupported quit attempts have only a small chance of success, and smoking cessation medications are one way of increasing the rate of quit success.

Until 2006, only two pharmacological smoking cessation aids were licensed in the UK: bupropion and NRT. Bupropion has been available on prescription as a smoking cessation aid from the NHS since June 2000. NRT has been available on NHS prescription since April 2001, and is also available over-the-counter. Varenicline became available on NHS prescription in December 2006, and NICE published guidance related to its use in July 2007.[129] The introduction of this new cessation medication gave motivated smokers trying to quit a new treatment option. This could have stimulated a general interest amongst smokers in attempting cessation and might have increased smokers' overall quitting activity, which one would expect to be reflected in greater use of cessation medications. Alternatively, varenicline's introduction may have only stimulated interest in using this medication, such that overall numbers of quit attempts and total use of cessation medications remained unchanged.

The THIN prescribing data that were validated in Chapter 3 provide a mechanism for investigating whether or not the introduction of varenicline has added to total prescribing of cessation medications in England, or replaced prescriptions for NRT or bupropion. Consequently, this chapter describes a time series analysis using monthly data from THIN, which was carried out to investigate whether varenicline's introduction in December 2006, or the publication of NICE guidance related

to its use in July 2007, had an impact on recent trends in prescribing of smoking cessation medications in England. This study has been published in Addiction.[225]

5.2 Methods

Data

The outcome measures were monthly rates of general practice prescribing for each of NRT, bupropion and varenicline and all smoking cessation medications combined. From the THIN database, the total number of NRT, bupropion and varenicline prescriptions in all patients written in England for each month between June 2000 and June 2009 was extracted, and rates of prescribing for each medication and all medications combined calculated using the procedure described in section 3.2.

Analysis

An interrupted time series analysis using ARIMA modelling was carried out to estimate the effect of the introduction of varenicline and the publication of the NICE guidance on rates of prescribing of NRT and bupropion and total prescribing for smoking cessation medications.[226] ARIMA modelling, as opposed to segmented regression, was used, because the trend in prescribing following the introduction of varenicline did not appear to be linear. A standard interrupted time series ARIMA modelling approach as described in section 4.3.2 was used.[226] The three time series included in the analysis (NRT, bupropion and total prescribing) had outlying values at the beginning of the study period, reflecting the period soon after the medications became available on NHS prescription. Therefore, all the data points before July 2001 were omitted from the analysis. The series were log transformed to stabilise the variance, and differenced and seasonally differenced to remove trends. The

autocorrelation and partial autocorrelation functions were examined to determine the order of moving average (MA) and autoregressive (AR) terms and seasonal MA and AR terms needed to model the autocorrelation in the stationary series.

To look at the effect of each intervention on the series, the appropriate model for the period before each intervention was identified, and then fitted to the complete dataset, augmenting the model with a dummy variable, coded 0 for the period before the intervention and 1 thereafter. Since the introduction of smokefree legislation in England in July 2007 may have influenced prescribing during the study period, a variable was fitted to adjust for its effect. Based on initial descriptive analyses, the smokefree law appeared to increase prescribing in July 2007; therefore, this variable was coded 0 in every month except July 2007, which was coded 1, to model an immediate and abrupt (pulse) effect.

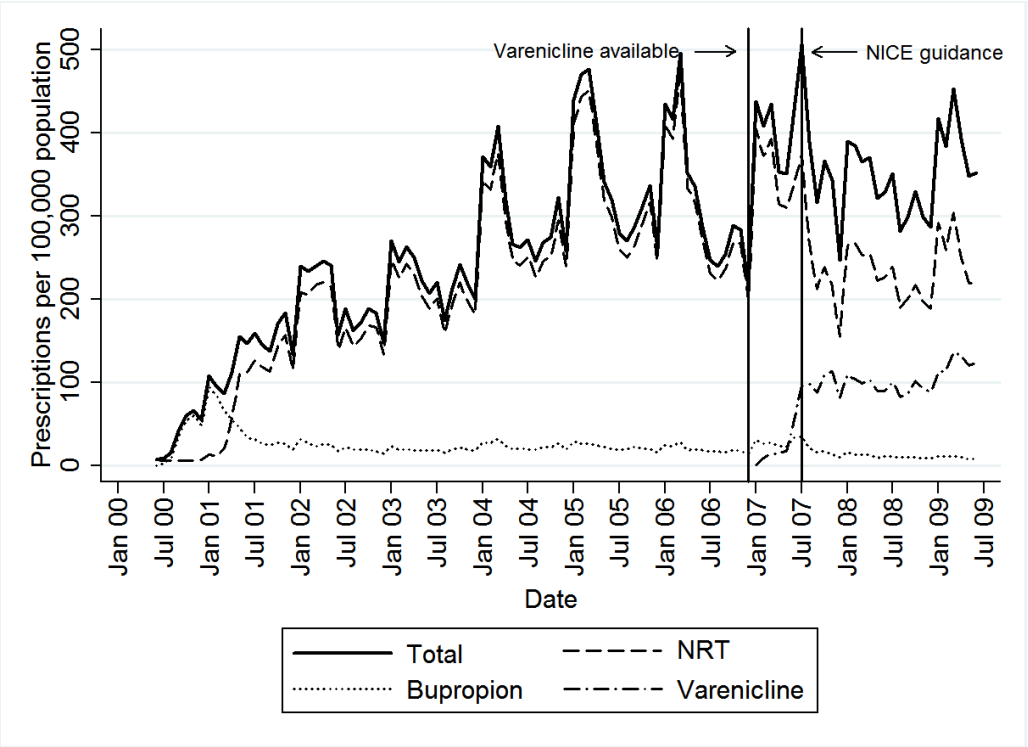
As the time series had been log transformed, the ARIMA model coefficients provided estimates of the percentage change in the monthly rate of prescribing after the introduction of varenicline and publication of the NICE guidance.

The analysis of THIN data for this study was approved by the Derbyshire Ethics Committee.

5.3 Results

Figure 5-1 shows the prescribing of smoking cessation medication per 100,000 patients in England each month between June 2000 and June 2009 by type of medication, and indicates the introduction of varenicline in December 2006 and the publication of the NICE guidance in July 2007.

Figure 5-1. Rates of prescribing of smoking cessation medication, England, based on THIN, June 2000-June 2009



Typically, as in the two years of NRT and bupropion prescribing data used in Chapter 3, there was a peak in prescribing in the first three months of each year, coinciding with New Year and national No Smoking Day in March. Legislation banning smoking in public places in England, which was introduced in July 2007, appears to have temporarily increased prescribing rates - there were peaks in prescribing of NRT and bupropion that month.

For most of the study period, NRT was clearly the most commonly prescribed stop smoking medication. Bupropion was never very frequently prescribed and lagged well behind NRT for most of the study period.

Prescribing of varenicline increased rapidly after it became available on the NHS, and became the second most commonly prescribed stop smoking drug in England after NRT. Prescribing of varenicline increased

most markedly in July 2007, growing to around 100 prescriptions per 100,000 population, and remained around this higher rate for the rest of the study period.

NRT prescribing increased steadily in the period before the introduction of varenicline (Figure 5-1). On inspection of Figure 5-1, aside from a brief peak when smokefree legislation was introduced, NRT prescribing rates appear to have been lower since varenicline was introduced, although, as shown in Table 5-1, the time series analysis found no statistically significant change in NRT prescribing either immediately after the introduction of varenicline ($p=0.828$), or after the publication of the NICE guidance ($p=0.159$).

Bupropion prescribing has declined since reaching a peak in 2001. However, there was no statistically significant effect of the introduction of varenicline ($p=0.401$), or of the NICE guidance ($p=0.108$), on prescribing for bupropion.

Despite the rapid growth in prescribing for varenicline, and the lack of significant fall in prescribing of existing medications, there was no step change in overall prescribing of smoking cessation medication after the introduction of varenicline ($p=0.760$) or after the publication of the guidance ($p=0.134$).

Table 5-1. Results of ARIMA time series analysis of the impact of varenicline on prescribing of smoking cessation medication

	Introduction of varenicline			**NICE guidance on varenicline**		
Outcome	**Change in prescribing (%)**	**95% CI**	**p-value**	**Change in prescribing (%)**	**95% CI**	**p-value**
All	-0.42	-3.10 – 2.27	0.760	-1.72	-3.96 – 0.53	0.134
NRT	-0.31	-3.11 – 2.49	0.828	-1.78	-4.26 – 0.69	0.159
Bupropion	-1.17	-3.90 – 1.56	0.401	-2.80	-6.22 - 0.61	0.108

5.4 Discussion

The results of this study suggest that the prescribing of varenicline has developed rapidly but, during the study period, did not lead to a statistically significant increase in overall prescribing for smoking cessation medications. The major strength of this study is that it uses validated large-scale data.[192] Approximately 6% of the population of England are currently registered with a practice that contributes data to THIN.[227] Furthermore, because the vast majority of prescriptions for smoking cessation medication in England are written in primary care, these general practice data ought to be a strong indicator of the medication that NHS patients receive to support a quit attempt, although cessation medication is provided via other sources.[228]

For example, within the NHS there is a mechanism, called Patient Group Directions (PGDs), whereby health professionals may supply certain medications to patients without prescriptions. Some NHS Stop Smoking Services use PGDs to issue NRT, and occasionally, bupropion or varenicline. Medication that is provided via PGD may not always be recorded in THIN and, therefore, the THIN data may underestimate the supply of stop smoking medication provided by health professionals. However, as there have been PGDs for smoking cessation medication throughout the study period, it is unlikely that PGDs have influenced trends in prescribing in a way that could have had an impact on the results of this study.

The study also does not include NRT purchased over-the-counter (OTC). This is not a major limitation, as the study deals with the impact of

a prescription-only medication, and it seems likely that this would have little influence on sales of an OTC cessation aid. However, it is possible that sales of OTC NRT increased as a result of varenicline becoming available, with more smokers motivated to quit as a result of the promotion of varenicline, but choosing not to obtain medication from a health care professional. On the other hand, the availability of varenicline may have reduced OTC NRT use due to smokers perceiving it as less effective than the new medication.

During the study period there was a decrease in smoking prevalence of approximately 1% per year, which may in turn have resulted in a smaller pool of smokers trying to make quit attempts; this may be reflected in the trends in prescribing.[51] However, these small annual decreases in prevalence translate to even smaller monthly changes in prevalence. Consequently, decreases in smoking prevalence are likely to have had a negligible effect on the monthly rates of prescribing estimated in this study, and are thus unlikely to have biased the results.

Another limitation of this study is that it was not possible to obtain estimates of the amount of medication supplied on prescription and hence how long these might last patients; instead the total numbers of prescriptions were used. If prescriptions for varenicline lasted patients longer on average than for those for NRT and bupropion, the effect of its introduction on overall prescribing for smoking cessation medication may have been underestimated. Previous evidence suggests that the average length of a prescription for bupropion or NRT is two weeks.[164] Varenicline is available in two week starter packs and in two and four week continuation packs. As GPs are likely to prescribe smoking cessation treatments similarly, it seems reasonable to assume that the average varenicline

prescription is similar in length to that for bupropion and NRT, but it remains possible that these could be longer. In a sensitivity analysis to establish whether this may have affected the study conclusions, the analyses were re-run with doubled rates of varenicline prescribing (hence assuming that varenicline prescriptions lasted for twice as long as those for bupropion and NRT). In these analyses, as in the original analyses, the introduction of varenicline did not have a significant effect on overall prescribing. Therefore, any variation in average length of prescriptions is unlikely to have affected the conclusions of this study. The results of this sensitivity analysis are presented in Appendix 9.6.

A major strength of this study is that it used ARIMA modelling, which, as described in section 4.3.2, adjusts for the confounding effect of secular trends in the outcome before the intervention of interest. However, as also previously described, a limitation of time series analysis is that it cannot easily control for events that may confound the effects of the intervention. This study included a period when the underlying pattern of prescribing may have been affected by the introduction of smokefree legislation, which may have been expected to increase prescribing. The effect of this legislation was controlled for by modelling it as an abrupt and immediate effect in July 2007. In spite of this, there may be residual confounding as a result of changes in prescribing associated with the legislation which preceded or followed its implementation, which could not be incorporated in the model. However, the lack of significant increase in prescribing despite the introduction of smokefree gives weight to the main finding of the analysis that the introduction of varenicline did not increase prescribing of smoking cessation medication.

The lack of increase in overall prescribing at the same time as a rapid rise in prescribing for varenicline, suggests that varenicline replaced some prescribing for NRT and/or bupropion during the same period. However, the time series model did not detect significant decreases in prescribing for either medication. A further sensitivity analysis was carried out to better explain this apparent 'disconnect' in the results. ARIMA models for the prescribing of NRT and bupropion were run, omitting, one at a time, the final months of the time series, where there appeared, based on Figure 5.1, to be an increase in prescribing of both medications. The sensitivity analysis showed that following the publication of the NICE guidance (but not the introduction of varenicline), there was a statistically significant decrease in prescribing of both NRT and bupropion, from August 2007 to November 2008 and October 2007 to November 2008 respectively. However, when subsequent months were included, the decrease was generally no longer statistically significant. This indicates that there is sufficient power to detect a decrease in prescribing, but that the ARIMA model is sensitive to the slight increase in prescribing of NRT and bupropion later in the study period, resulting in a statistically insignificant finding for the overall study period. The results of this sensitivity analysis are also presented in Appendix 9.6

These results suggest that varenicline has been readily accepted as a standard therapy by English GPs. It has rapidly become the second most commonly prescribed drug for smoking cessation. However, during the study period neither the availability of varenicline, nor the publication of guidance for its use had an additive effect on overall prescribing for smoking cessation medications. As a result, the introduction of varenicline may not have led to a greater proportion of smokers being prescribed

smoking cessation medication. This contrasts with previous research which suggested that introducing a new stop smoking medication increased overall rates of use.[164] The earlier study, based on data from 1999 to 2002, differed from the current study in that it examined dispensed medications as opposed to prescriptions issued, and looked at the introduction of a new form of NRT as opposed to a completely new medication and both these factors could explain the contrasting results.

Since this study was accepted for publication, other studies have investigated the impact of varenicline on quitting behaviour, both in England and in other countries. One study, by Kotz et al., used data from the Smoking Toolkit Study (STS) to assess whether varenicline substituted for, or added to, the use of NRT and bupropion, and whether it had an impact on quit attempts.[229] Contrary to the current study, they found that NRT use increased after the introduction of varenicline, and that varenicline did not substitute for the use of other medication, although this was in people making quit attempts rather than the general population. They also found that the rate of quit attempts decreased after the introduction of varenicline. However, the STS data covered a short time-period and may be prone to recall bias and significant sampling error due to small sample sizes. In contrast, the study in this chapter used objective, validated data with a monthly sample size of approximately 2.5 million over a much longer time-period. Furthermore, the study by Kotz et al. used monthly survey data but combined data to create only three time points which were used in the analysis and began only six months prior to the introduction of varenicline and was therefore not able to take account of underlying trends; the decrease in quit attempts observed may reflect a return to previous rates following an increase in quit attempts around the

introduction of smokefree legislation. Furthermore, the study used monthly survey data on self-reported quit attempts in the past three months, which may have introduced some misclassification. The differences between the two studies have been discussed in Letters to the Editor of Addiction.[230, 231]

A further study, based on the ITC Four Country Survey, found that in quit attempters in the US, UK, Canada, and Australia, the introduction of varenicline led to an increase in the number of smokers who reported the use of evidence-based treatment during their quit attempts, rather than simply gaining market share at the expense of other medications.[232] A key limitation of this study is that it uses only three years of survey data, and the underlying trends in medication use could therefore not be taken into account. In addition, the ITC study used self-report of stop smoking medications usage among quit attempters as an outcome, whereas in the current study, a more objective measure, medical records of prescriptions issued to all patients are considered. Furthermore, the ITC data include OTC NRT in addition to prescriptions. The inclusion of OTC medications may have accounted for the increase in stop smoking medications overall in the UK. This increase may partly be due to the introduction of smokefree legislation, as such legislation has been shown to increase OTC smoking cessation medication sales in other countries, and may therefore act as a confounder in the ITC study.[233, 234] For example, in all countries, self-reported NRT use remained the same across the study period, but this may reflect increased use of OTC NRT following smokefree combined with a decrease in prescribed NRT following the introduction of varenicline.

The lack of increase in the rates of prescribing identified in this study suggests that introducing a new, possibly more effective pharmacotherapy for smoking cessation medication has not encouraged a

higher proportion of smokers to use pharmacotherapy to support quit attempts. The results of this study have implications, not only for the UK and in relation to varenicline, but in any setting where new and innovative smoking cessation aids have been, or may in future be approved. Introducing a new smoking cessation aid may not add to the use of smoking cessation aids overall, and may even partially replace prescribing of existing, highly effective, aids. The lack of increase in smoking cessation medications raises questions as to why prescribing has failed to increase, and, consequently, what measures need to be taken in order ensure that the availability of a new medication increases smoking cessation medication use. This depends largely on who drives the decision to prescribe smoking cessation medication – physicians or patients - and there is little available data in this regard. A study conducted prior to the introduction of varenicline showed that a significant minority of GPs do not prescribe NRT and bupropion even when it is requested by patients, demonstrating that physician decisions are an important part of the process.[235] If it is physicians who drive the decision to prescribe, then measures may need to be taken to increase confidence in the effectiveness and safety of the medication, and to encourage them to prescribe varenicline to smokers who have previously tried to quit using NRT or bupropion and failed. If it is patients, raising awareness of varenicline, particularly in previously unsuccessful quit attempters, may be more important.[236] Research into these processes is needed to ensure that the introduction of new cessation aids is used to offer smokers a wider choice of treatment and endeavour to draw more smokers into the quitting process.

5.5 Conclusions

Prescribing for varenicline has developed rapidly in English general practice. However, it does not appear to have increased overall rates of prescribing for smoking cessation medication. The introduction of varenicline may not have led to a greater proportion of smokers being prescribed medication to help them stop smoking.

CHAPTER 6: THE IMPACT OF THE BROADENING OF INDICATIONS FOR NRT ON PRESCRIBING TO ADOLESCENTS AND PATIENTS WITH CARDIOVASCULAR DISEASE

6.1 Introduction

The importance of smoking cessation for adolescents, CVD patients and pregnant women has been described in Chapter 1. The benefits of using NRT in quit attempts have also been described. When NRT became available on prescription from the NHS in April 2001, however, there were initially safety concerns regarding the use of NRT by adolescents, CVD patients and pregnant smokers. For example, there were fears that it could cause cardiovascular events in at-risk individuals as a result of blood vessel constriction by nicotine – one of the mechanisms by which smoking itself causes acute cardiac events.[237] These fears were reported internationally: an article in the Wall Street Journal linked NRT with cardiovascular risk, and a range of case reports also suggested that NRT can cause cardiovascular events.[238, 239] As a result, until the end of 2005 there were inconsistencies and warnings in the product information for NRT regarding its use by these patient groups.[240]

All NRT patient information leaflets initially contained cautionary statements about their use by patients with CVD. Most Summaries of Product Characteristics (SPCs) recommended that NRT not be used by under 18 year olds or had contraindications for children, but others indicated that use by adolescents was allowed with advice from a doctor. Furthermore, the advice given in SPCs and Patient Information Leaflets sometimes differed for the same products. Similarly, there were inconsistencies in the advice regarding NRT use by pregnant women.[240] These inconsistencies and warnings may have created a barrier to the use of NRT for people in these groups, and may therefore have reduced their chances of making a successful quit attempt.

In November 2005, the Medicines and Healthcare Regulatory Authority (MHRA) published a report of the safety and efficacy of NRT. [237] The report offered reassurance that NRT is safe, or at least, safer than smoking in these patient groups. As a result, the licensing rules for NRT were changed such that it could be used by patients with CVD and adolescent smokers, as well as pregnant smokers.

Based on a small number of studies providing evidence of the efficacy and safety of NRT in adolescents, and given rates of smoking in teenagers and the absence of evidence of abuse of NRT by this group, the licensing arrangements were changed such that all forms of NRT can now be used by smokers aged 12 to 17 years, with the exception of Nicotinell lozenges which are licensed for children under 18 years only when recommended by a doctor.[241-244]

The report also concluded that, although there was limited evidence as to the safety of NRT in people with unstable CVD, there was considerable evidence that in smokers with stable CVD, the benefits of using NRT to quit smoking outweigh the risk.[245-251] The licensing regulations were therefore changed such that all forms of NRT could be used by patients with CVD, with the caveat that people with unstable CVD should try to quit with non-pharmacological aids first and only initiate NRT use under medical supervision.

The report also stated that while there were limited trial data on the efficacy of NRT in pregnant women, the risks of NRT use in pregnancy (and by breastfeeding women) to both mother and child are substantially lower than those posed by continued smoking.[252, 253] Thus the licensing regulations were changed such that, although pregnant smokers should try

to stop smoking without NRT, they can use NRT if a pharmacologically aided quit attempt is more likely to be successful.

Licensing rules for the prescribing of NRT to CVD patients remain inconsistent internationally. For example, the US Food and Drug Agency advises adolescent smokers, pregnant smokers and those with heart disease to talk to a health professional before using NRT.[254] In the Netherlands, the regulations are similar to those in the UK. The use of NRT is contraindicated for patients with acute CVD, and adolescents and patients with stable CVD are advised to seek the advice of a health professional before using NRT.[255] With regard to pregnant women, the Dutch guidance states that NRT should only be considered if pharmacologically unaided quitting is not possible and that they should seek the advice of a health profession before using it. The French guidance on smoking cessation treatment states that NRT does not cause cardiovascular events and poses no risks to adolescents. It does, however, say that NRT should only be used by adolescents with proven nicotine dependence and high motivation to quit and NRT is only licensed for over-15 year olds.[256] Like the Dutch guidance, the French guidance states that NRT use by pregnant women should only be considered if pharmacologically unaided quitting is not possible.

The broadening of indications may have stimulated interest in the use of NRT in adolescents, CVD patients and pregnant smokers, or may have caused general practitioners to be more willing to offer NRT to smokers in patient groups previously perceived as high risk. This may have resulted in an increase in prescribing of NRT to people in these groups. In particular, because varenicline is not licensed for adolescents, its introduction will not have substituted for the use of NRT in recent years,

and therefore a greater increase in prescribing of NRT to young people may have occurred. In this chapter, the impact of the change in indications on prescribing of NRT to both adolescents (Section 6.2) and CVD patients (Section 6.3) is investigated.

All analyses in this chapter were carried out in R version 2.12.0 and all graphs were drawn in Stata Version 11.0.[257] These studies were approved by the Derbyshire Research Ethics Committee.

6.2 The impact of the licensing changes on prescribing of NRT to adolescents

Data from THIN were used to explore patterns in prescribing of NRT to 12 to 17 year olds in England between January 2002 and June 2009 and to establish whether the broadening of the indications led to an increase in prescribing of NRT to adolescents. This study has been published in Addiction.[258]

6.2.1 Methods

Data

THIN contains the primary care records of approximately 400,000 patients aged 12-17. Up to 200,000 of these adolescent patients are currently registered with a practice and can be followed prospectively.

The outcome measures were rates of prescribing of all NRT products per 100,000 adolescents registered with a THIN practice per month. From the THIN database all patients who were aged 12 to 17 and contributing data each month between January 2002 and June 2009 were identified. The total number of NRT prescriptions each month recorded in the medical records of these patients was also identified. All the extracted data were stratified by age and sex.

The procedure described in section 3.2 was used to derive the rate of prescribing per 100,000 adolescents per month. The rates of prescribing of NRT for each month for all adolescents combined, for three smaller age groups (12-13, 14-15 and 16-17 year olds), and for males and females aged 12-17 were calculated.

Analysis

The trend in prescribing following the licensing change appeared to be linear, and a segmented regression analysis using GAMMs was therefore carried out to estimate the effect of the broadening of the indications on rates of prescribing of NRT to adolescents. The models estimated the changes in the level and changes in the trend of the series following the broadening of the indications on rates of prescribing of NRT in each age group and in adolescent males and females, using the procedure outlined in section 4.3.1. A GAMM was built for each time series, including, as appropriate, terms to describe the trend in NRT prescribing in the pre-intervention period, any immediate step change in the level of prescribing when the indications were broadened, and any change in the trend of prescribing in the post-intervention compared to pre-intervention data.[210] Stepwise elimination of non-statistically significant terms was used to build a parsimonious model. The models were checked for autocorrelation and seasonal autocorrelation using ACFs and PACFs. Where necessary, the model also contained a smooth term to model any regular seasonal pattern in prescribing repeated from year to year, and an autocorrelated error term to account for non-independence of model residuals.

6.2.2 Results

Figure 6-1 shows the rate of prescribing of NRT for patients aged 12-13, 14-15 and 16-17 between January 2002 and June 2009.

Throughout the study period, prescribing of NRT was highest in 16-17 year olds and extremely low in 12-13 year olds, generally under 10 prescriptions per 100,000 adolescents per month.

Figure 6-1. Rates of prescribing of NRT, 12-13, 14-15 and 16-17 year olds, England, based on THIN, January 2002-June 2009

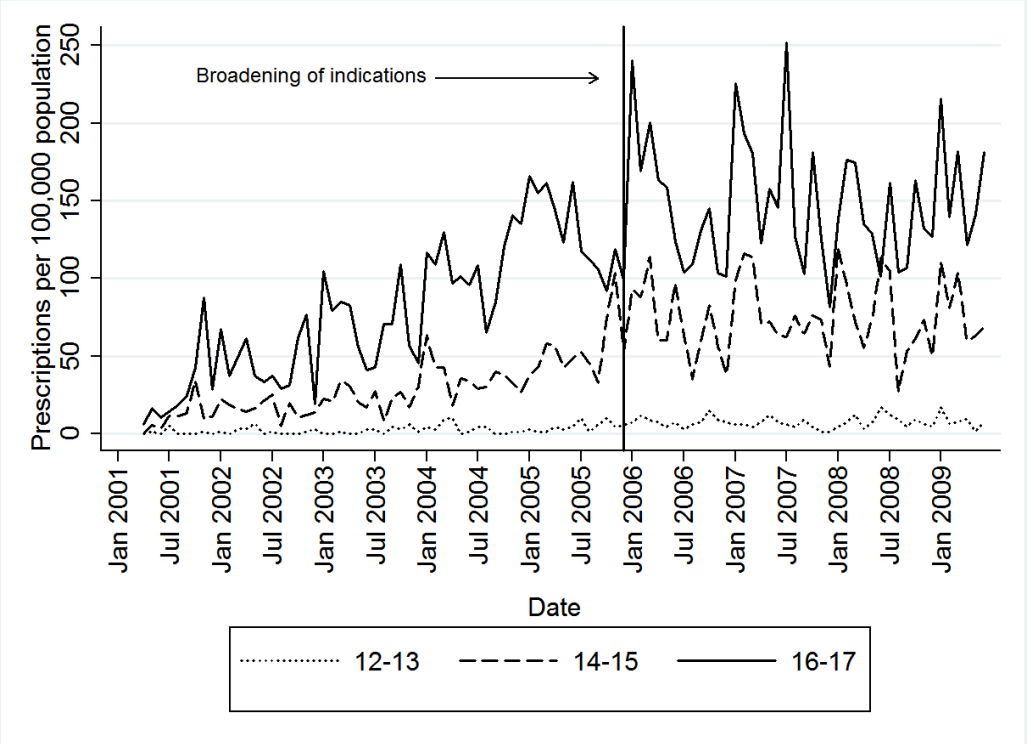
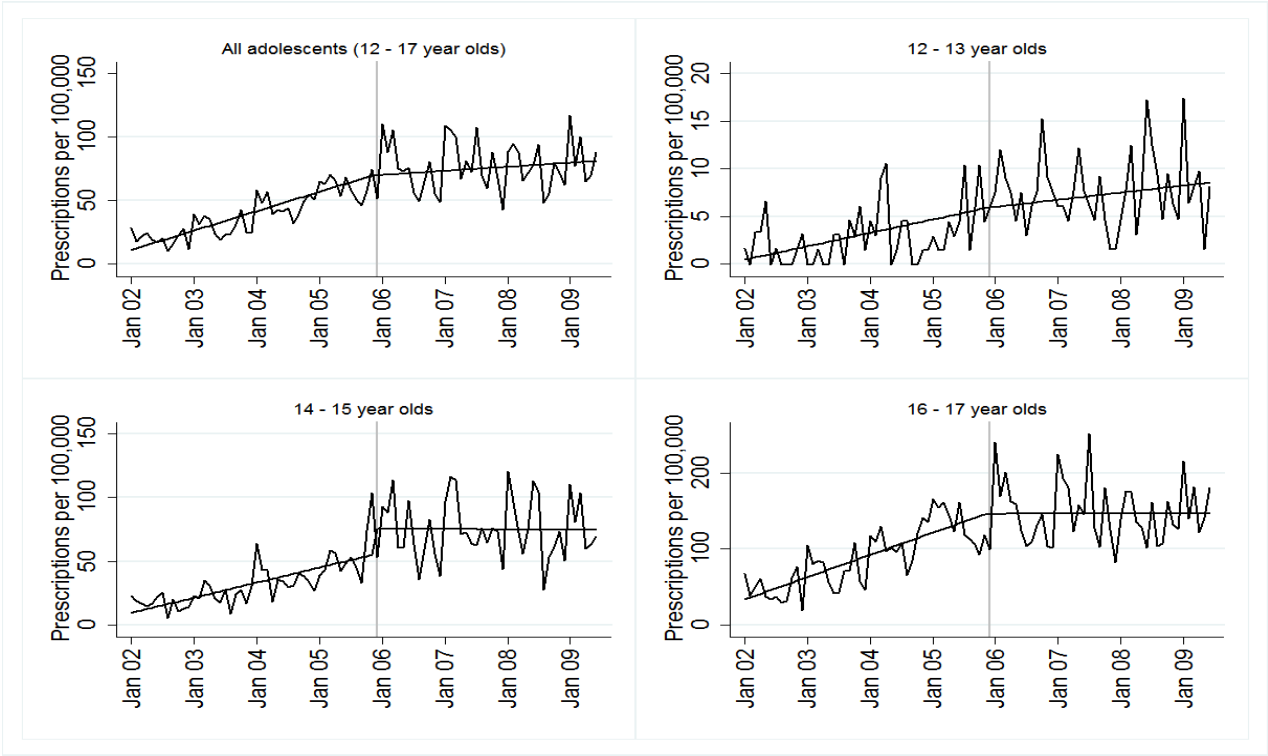


Figure 6-2 shows the rates of prescribing for each age group and all adolescents combined during the study period, and fitted trends from the segmented regression model showing trends in prescribing before and after the broadening of indications and any step change in the level of prescribing. Table 6-1 contains the results of the segmented regression analysis for each age group and by sex. It shows the baseline trend in prescribing (the monthly change in number of prescription per 100,000 adolescents before the licensing change), the step change in the monthly level of prescribing immediately after the broadening of indications and the change in the trend in the monthly numbers of prescriptions per 100,000 adolescents following the broadening of indications, compared with the baseline trend.

Figure 6-2. Rates of prescribing of NRT and fitted trends for 12-17, 12-13, 14-15 and 16-17 year olds before and after the NRT licensing change, England, based on THIN, January 2002-December 2008



Note: graphs have different y-axis scales.

Table 6-1. Results of segmented regression analysis of the impact of the broadening of the indications for NRT on prescribing of NRT to adolescents

	β_1 - Baseline trend	**95% CI**	**p-value**	**β_2 - Step level change**	**95% CI**	**p-value**	**β_3 - Change in trend**	**95% CI**	**p-value**
All	1.36	1.16-1.55	<0.001	-	-	-	-1.16	-1.52 - -0.79	<0.001
12-13	0.09	0.07-0.12	<0.001	-	-	-	-	-	-
14-15	1.08	0.82-1.34	<0.001	19.29	9.02-29.59	<0.001	-1.13	-1.51- -0.74	<0.001
16-17	2.62	2.16-3.08	<0.001	-	-	-	-2.73	-3.59- -1.88	<0.001
Females	1.66	1.42-1.91	<0.001	-	-	-	-1.65	-2.10 - -1.20	<0.001
Males	0.87	0.59-1.16	<0.001	13.37	2.21-24.52	0.02	-0.76	-1.19 - -0.33	<0.001

Note: only parameters significant in parsimonious model included

β_1: monthly change in number of prescription per 100,000 adolescents before licensing change

β_2: step change in the monthly level of prescribing immediately after licensing change

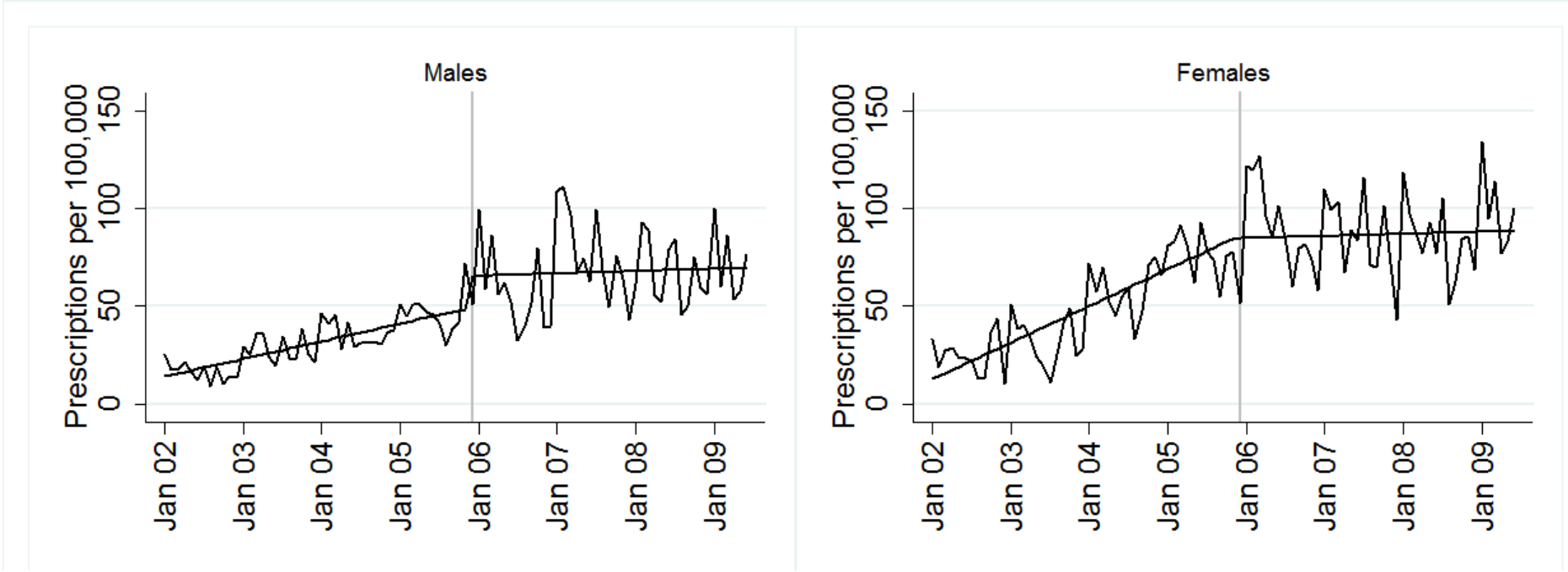
β_3: absolute change in trend in monthly numbers of prescriptions per 100,000 adolescents after licensing change, compared with baseline trend

In 12-17 year olds, prescribing increased by 1.36 prescriptions per 100,000 adolescents per month before the broadening of indications (95% CI 1.16-1.55, $p<0.001$). There was no immediate step change in the level of prescribing following the licensing change, but there was a significant change in trend ($p<0.001$) such that there was still an increase but at a lower rate.

In 12-13 year olds, prescribing increased by 0.09 prescriptions per 100,000 adolescents per month throughout the study period (95% CI 0.07-0.12, $p<0.001$); there was no step level or trend change following the broadening of indications. Prescribing of NRT to 14-15 year olds increased by 1.08 prescriptions per month per 100,000 adolescents prior to the licensing change (95% CI 0.82-1.34, $p<0.001$). In the same age group, prescribing increased by 19 prescriptions per 100,000 in the first month following the broadening of indications, before levelling off, as shown in Figure 6-2. In the oldest age group, prescribing followed an increasing trend until December 2005. There was no step change in the level of prescribing following the change in indications, and prescribing subsequently levelled off.

Figure 6.3 shows the rates of prescribing for males and females during the study period, and fitted values showing the trends in prescribing before and after the broadening of indications. During the study period girls tended to be prescribed NRT more frequently than boys, though rates of prescribing were fairly similar from early 2007.

Figure 6-3. Rates of prescribing of NRT and fitted values for 12-17 year olds by sex before and after the NRT licensing change, England, based on THIN, January 2002-June 2009



As shown in Table 6-1, in both males and females, prescribing followed an increasing trend before the licensing change ($p<0.001$), before levelling off, as also shown in Figure 6-3.

In females, there was no step change in the level of prescribing, whereas in males the rate of prescribing increased by 13 prescriptions per 100,000 adolescents in the month immediately following the change in indications (95% CI 2.21-24.52, $p=0.02$).

6.2.3 Discussion

To my knowledge this is the first study into the effect of the NRT licensing change on prescribing of this medication to adolescents. This study found no evidence of an increase. The major strengths of this study are the use of validated, large-scale data and the use of segmented regression analysis to estimate changes in the level and trend of NRT prescribing following the change.

A limitation of this study is that it used rates of prescribing of NRT to all adolescents as opposed to those recorded as smokers. However, as explained in section 2.4.4, research has suggested that the recording of smoking in THIN was incomplete until at least 2006, therefore including only recorded smokers is likely to have introduced bias.[259] It was also not possible to control for adolescent smoking prevalence, as no validated monthly measure is available. However, national smoking prevalence survey data suggest that during the study period there were year-on-year changes in prevalence of no more than 3 percentage points in 11-15 year olds and 4 percentage points in 16-19 year olds, with much smaller changes in most years.[52, 149] Any monthly changes in prevalence are therefore likely to have been very small. Consequently, changes in

smoking prevalence are likely to have had a negligible effect on the monthly rates of prescribing estimated in this study, and are thus unlikely to have biased the results.

A further limitation of this study is that, as highlighted in the other studies in this thesis, the THIN data include only prescriptions written in general practice and will therefore, to some extent, underestimate the rate of NRT prescribing. The majority of prescriptions for NRT are, however, written in primary care, therefore these data ought to be a good indicator of the medication that adolescents receive from medical professionals to support a quit attempt.[228]

Throughout the study period, prescribing increased with age, which reflects the fact that, in adolescents, the prevalence of smoking increases with age. In 2010 3% of 13 year olds were regular smokers (smoked at least once a week), whereas in 15 year olds the prevalence of regular smoking was 12%.[52] The rate of prescribing was higher in adolescent females than males. This contrasts with research from the USA which suggests that NRT use is more frequent in teenage boys than girls.[260] The higher rate of prescribing to girls in this study reflects a higher smoking prevalence in teenage girls than boys, but may also be due to the fact that, in England, teenage girls are more likely to visit their GP than teenage boys.[261] In 2008, girls aged 15-19 had an average of 4.5 GP consultations per year, whereas boys had an average of two.[261]

The primary aim of this study was to investigate whether the licensing change influenced GP prescribing. Changing the indications for NRT use to include adolescents might have been expected to lead to an increase in prescribing to this age group. However, this study found little

evidence that this occurred. This is particularly surprising given that the models were not able to take account of the introduction of the smoking ban, which may also have been expected to increase prescribing. In 12-17 year olds (all adolescents), there was no step change in the level of prescribing, and the monthly increase in prescribing of NRT was 1.16 prescriptions per 100,000 adolescents lower after the indications were broadened. In young adolescents, the gradual increasing trend in rates of NRT prescribing observed before the licensing change remained unchanged, and in older adolescents the increase in prescribing of NRT disappeared. There was also no step change in the level of prescribing to females. Small immediate increases in the prescribing of NRT were observed in 14-15 year olds and in adolescent males in the month following the broadening of indications, but here too prescribing rates subsequently levelled off.

These increases are likely to have had a minimal public health impact; in the context of national estimates of smoking prevalence in this age group it is evident that, despite the change in indications for NRT use to include this age group, the rate of prescribing to adolescent smokers remains low. In 2008 there was an average of 92 NRT prescriptions per 100,000 15 year olds per month. At most (bearing in mind that multiple prescriptions could have been given to the same individual), this equates to 0.09% of 15 year olds obtaining a prescription for NRT per month, despite a smoking prevalence within this age group of 12%.[52] This low rate of prescribing suggests that measures to increase adolescent access to cessation support in primary care are needed. One study has suggested that when adolescents receive smoking cessation counselling in primary care, a significant proportion of them agree to make a quit attempt.[262] This

suggests that general practice may indeed be an appropriate setting for adolescent smoking cessation, thus it is desirable to establish and overcome the factors which limit the prescribing of NRT to adolescents.

Despite the lack of increase in prescribing, it seems likely that there were benefits of the licensing change that could not be observed in this study. One benefit of the licensing change is that GPs can prescribe NRT to adolescent smokers without concern that their prescribing is considered to be unusual, dangerous or against the consensus of good clinical practice because it contradicts the labelling. Similarly, non-prescribers can now educate adolescents about the safety of medications without their advice being inconsistent with the labelling. Furthermore, the licensing change may have led to people prescribing via PGD to prescribe more NRT to adolescents, as they are only permitted to prescribe according to the product license.

There are both demand and supply side factors that provide possible explanations for the limited effect of the broadening of indications on prescribing in this age group. Teenagers make fewer visits to their GP than adults and may be less likely than adults to ask for NRT, therefore, despite the licensing change, general practice may not be an effective setting for the distribution of NRT to people within this age group.[261] In particular, it may be that young people who are most likely to be nicotine dependent and may therefore benefit from NRT are less likely to visit their GP. Previous international research suggests that the majority of adolescent smokers would consider using NRT, but also indicates that some young people would find using NRT embarrassing, unpleasant or expensive, which may also discourage its use in this age group.[263, 264]

There may also have been a lack of awareness of the licensing change among GPs or ongoing concerns among health care professionals as to the safety of NRT for teenagers. Furthermore, adolescent smokers smoke less heavily than adults; regular 11-15 year old smokers smoke 5.4 cigarettes per day on average, whereas adult smokers smoke an average of 13 cigarettes per day.[51, 265] It may therefore be perceived as unnecessary to treat teenage smokers with NRT. A further possible factor is the limited evidence as to the effectiveness of NRT for smoking cessation in this age group. Three studies indicate that the nicotine patch may be effective in adolescents, but a further study found no effect, as did a study looking at the effectiveness of nicotine nasal spray in adolescents.[241-243,266,267] On the other hand, the lack of change may simply be due to GPs' limited contact with addicted adolescents, particularly as they may be less likely to visit their GP than non-smokers.[262] Alternatively, it is possible that the licensing change did not result in GPs who had never previously prescribed NRT to teenagers starting to do so and that those GPs who were already prescribing NRT to young people did not start offering prescriptions more frequently.

Using NRT is likely to be less harmful than continued smoking as adolescent smokers who use NRT are not exposed to the toxic products of tobacco combustion.[240] Research is therefore required to understand why there is a low rate of prescribing of NRT to adolescents in the UK despite the licensing change, and how access to NRT might be improved for young dependent smokers in the future.

6.2.4 Conclusions

Reducing the prevalence of adolescent smoking is important as a means of alleviating the burden of smoking-related morbidity and mortality

in the future. The lack of increase in prescribing following the change in indications for NRT, however, suggests that there are barriers to increasing adolescent smoking cessation through general practice settings. Limited access to smoking cessation support may hinder a reduction in adolescent smoking prevalence now, which may have significant public health implications in the future.

6.3 The impact of the licensing changes on prescribing of NRT to CVD patients

Data from THIN were used to explore patterns in prescribing of NRT to patients with CVD in England between January 2002 and June 2009 and to establish whether the broadening of the indications led to an increase in prescribing of NRT to patients with coronary heart disease (CHD) and stroke, which are the main types of CVD in the UK, accounting for 46% and 23% of CVD deaths respectively.[268] This study has been accepted for publication in Addiction.

6.3.1 Methods

Data

This study used THIN data on prescribing of smoking cessation medication to patients in England who were aged 16 and over with CHD or stroke. The main outcome measures were the number of patients per 100,000 with CHD and stroke that received a prescription for NRT each month. From the THIN database all adult (16+) CHD and stroke patients contributing data each month between January 2002 and June 2009 were identified using Read Codes based on the definitions of these diseases from the QOF.[188] As described in section 1.6.9, the QOF sets out requirements for the management of smoking in patients with certain chronic diseases, and these include CVD. The CHD and stroke patients with a prescription for

NRT in each month during the study period were also identified. The rates of prescribing per 100,000 CHD and stroke patients were calculated using the procedure described in section 3.2.

It is possible that varenicline may have substituted for some of the use of NRT in CVD patients after it was introduced in December 2006. Therefore, in order to examine trends in total prescribing of all licensed smoking cessation medications to this patient group (i.e. NRT, varenicline and bupropion), data on prescribing of these to CHD and stroke patients were also extracted. Rates of prescribing were calculated as described above.

Data on prescribing to adults with recorded hypertension (a major risk factor for CVD), asthma and chronic obstructive pulmonary disease (COPD), as well as prescribing to the rest of the adult population were also extracted, in order to compare prescribing to CVD patients with that to groups for which the licensing for NRT did not change in November 2005.[269] Due to incompleteness in the recording of smoking status in THIN until 2006, we were unable to look at prescribing in smokers only for the whole time course of the study.[184] However, we used data from 2007 and 2008 (when the majority of patients in THIN had their smoking status recorded) to calculate average rates of prescribing per month in smokers with CHD and stroke and compare this with rates of prescribing in other disease groups, and in the rest of the population, in 2007 and 2008.[184] The data on patients with hypertension, asthma and COPD were also identified using Read Codes based on the definitions of these diseases from the QOF.

Analysis

The trend in prescribing following the licensing change appeared to be linear, and a segmented regression analysis was therefore carried out using GAMMs to estimate the effect of the broadening of the indications on rates of prescribing of NRT to patients with CHD and stroke, using the procedure described in section 4.3.1 and applied in section 6.2. GAMMs were also built for total prescribing (NRT, varenicline and bupropion) to explore overall trends in prescribing for smoking cessation medication during the study period.

6.3.2 Results

Data were available on up to 88,000 CHD patients and 39,000 stroke patients each month. Figure 6-4 shows the rates of prescribing of NRT to CHD and stroke patients during the study period. As in the general population (shown in Chapters 3 and 5), in most years there was a peak in prescribing in January and March, coinciding with the New Year and No Smoking Day, and the time series plot suggests an increase in prescribing of NRT up to 2006 with a reduction in subsequent years. Figure 6-4 also shows the fitted trends from the segmented regression modelling for prescribing of NRT, the results of which are also presented in Table 6-2. There was no statistically significant immediate step change in the level of prescribing following the licensing change; therefore, this term was omitted from the model. Table 6-2 shows the baseline trend in prescribing (the monthly change in the number of people receiving prescriptions per 100,000 before the licensing change) and the change in the trend in the monthly number of CHD and stroke patients receiving prescriptions per 100,000 following the broadening of indications, compared with the baseline trend.

Figure 6-4. Rates of prescribing of NRT and fitted trends in CHD and stroke patients before and after the NRT licensing change, England, based on THIN, January 2002-June 2009

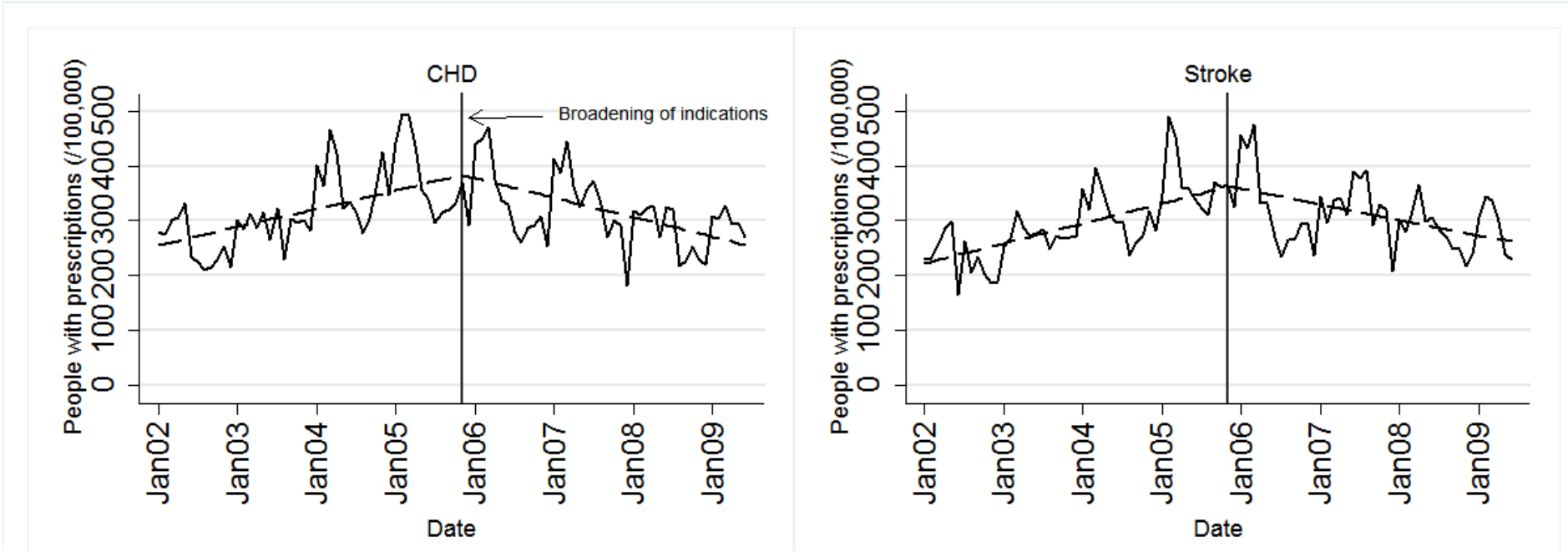


Table 6-2. Results of segmented regression analysis of the impact of the broadening of the indications for NRT on prescribing of NRT to CVD patients

		β_1 - Baseline trend	**95% CI**	**p-value**	**β_2 - Step level change**	**95% CI**	**p-value**	**β_3 - Change in trend**	**95% CI**	**p-value**
NRT prescribing	*CHD*	3.18	2.15-4.21	<0.0001	-	-	-	-6.45	-8.36- -4.53	<0.0001
	Stroke	3.37	2.31-4.43	<0.0001	-	-	-	-5.99	-7.96 - -4.01	<0.0001
All prescribing	*CHD*	2.73	1.23-4.25	<0.001	-	-	-	-3.0670	-5.87 - -0.26	0.035
	Stroke	3.29	1.81-4.76	<0.0001	-	-	-	-3.76	-6.49 - -1.0175	0.009

Note: only parameters significant in parsimonious model included
β_1: monthly change in number of prescription per 100,000 patients before licensing change
β_2: step change in the monthly level of prescribing immediately after licensing change
β_3: absolute change in trend in monthly numbers of prescriptions per 100,000 patients after licensing change, compared with baseline trend ($\beta_1 + \beta_3$ = post-intervention trend)

In CHD patients, the number of people receiving prescriptions for NRT was increasing at the rate of 3.18 per 100,000 patients per month between January 2002 and the broadening of indications in 2005 (95% CI 2.15-4.21, $p<0.0001$) (Table 6-2). There was no immediate step change in the level of prescribing following the licensing change, but after 2005 there was a significant change in trend ($p<0.0001$) representing a decrease in the rate of prescribing.

A similar trend was observed in stroke patients. In this group, the number of people receiving NRT prescriptions was increasing by 3.37 per 100,000 patients per month before the broadening of the indications (95% CI 2.31-4.43, $p<0.0001$) (Table 6-2 and Figure 6-4). There was no immediate step change in the level of prescribing following the licensing change, but there was a significant change in trend ($p<0.0001$) such that there was a decreasing trend in prescribing.

Figure 6-5 shows the rates of prescribing of all smoking cessation medications combined (NRT, varenicline and bupropion) in CHD and stroke patients during the study period, and the results of the segmented regression modelling are also presented in Table 6-2. Figure 6-5 shows that overall prescribing of this group of medications to both CHD and stroke patients increased until 2005 and remained fairly stable in the latter part of the study period. The rate of prescribing for bupropion decreased during the study period and was extremely low in the final years of the study; generally, only between five and ten patients per 100,000 received a prescription for bupropion each month in the period following the

introduction of varenicline (not shown). The majority of prescriptions were therefore for NRT and, after December 2006, NRT and varenicline.

Figure 6-5. Rates of prescribing of all smoking cessation medications (NRT, varenicline and bupropion) and fitted trends in CHD and stroke patients before and after the licensing change, England, based on THIN, January 2002-June 2009

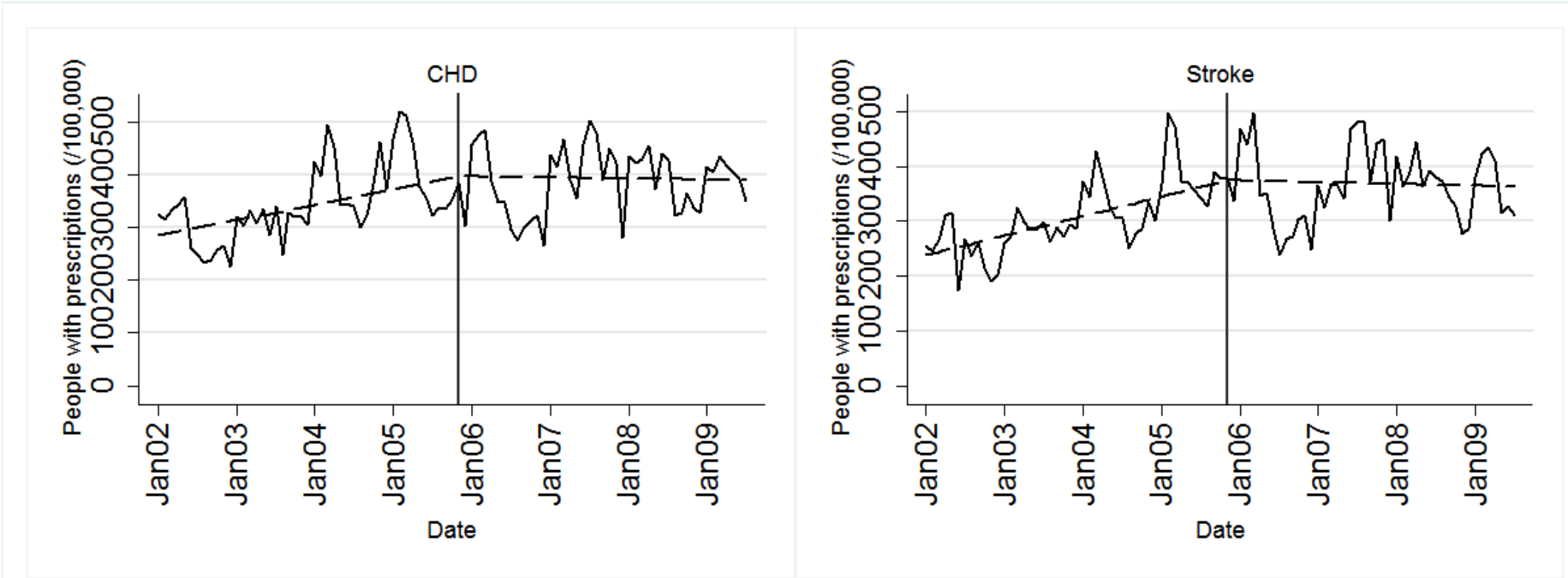
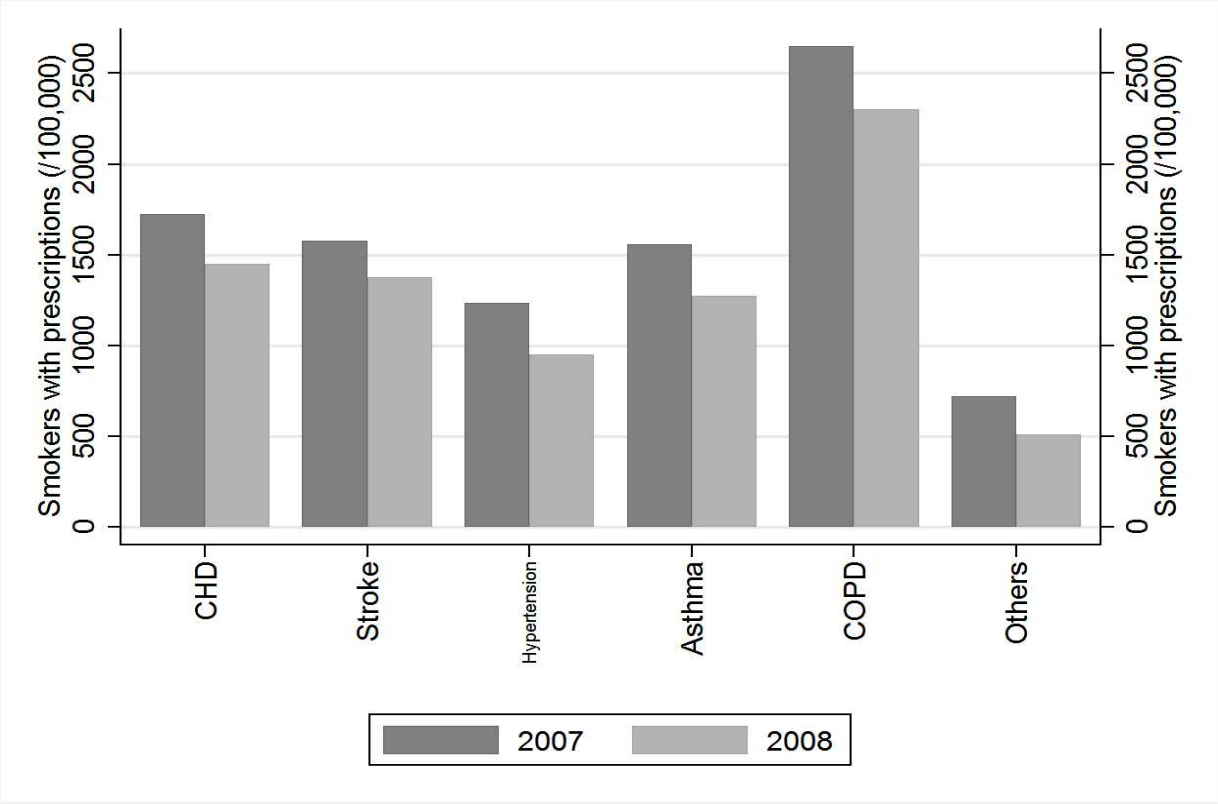


Figure 6.6 shows the average rate of prescribing of NRT to smokers with CHD, stroke, hypertension, asthma, COPD and without one of these diseases per month in 2007 and 2008. Prescribing was highest to smokers with COPD, at around 2500 per 100,000 smokers per month, and very similar in those with CHD, stroke and asthma, at around 1500 per 100,000 smokers per month. Prescribing of NRT to the rest of the population was about a third of that to smokers with CHD and stroke.

Figure 6-6. Number of smokers with NRT prescriptions per month by disease group, England, based on THIN, 2007 and 2008



6.3.3 Discussion

To my knowledge this is the first study into rates of prescribing of NRT to individuals with cardiovascular disease. Like the previous study in this chapter, the major strengths of this study are the use of validated, large-scale data, and the use of segmented regression analysis to estimate changes in the level and trend of NRT prescribing following the licensing change.

This study found that prescribing of NRT to CHD and stroke patients increased until the end of 2005 and subsequently decreased, with no immediate change following the MHRA licensing change. In 2007 and 2008 rates of prescribing of NRT to smokers with CVD were similar to that to smokers with asthma, and about three times as high as in the general population.

This study has several limitations which may explain part of the observed trends, but are unlikely to have affected the results. As in the other studies in this thesis, it was not possible to restrict the analysis of trends over time to smokers only, due to the incompleteness of smoking status data in THIN prior to 2006.[184] However, as explained in section 5.4, the small annual decreases in adult smoking prevalence during the study period are likely to have made a negligible contribution to the monthly changes in rates of prescribing observed in this study.

Similarly, as explained in earlier parts of this thesis, THIN smoking cessation medication prescribing data may underestimate the supply of stop smoking medication provided by health professionals, though it is unlikely that this has influenced trends in prescribing in a way that could have had an impact on the results of this study.

Like the other policy evaluation studies presented so far in this thesis, this study also does not include NRT purchased over-the-counter (OTC). However, it is unlikely that a sudden switch to OTC NRT has contributed to changes in prescribing of NRT during the study period, as NRT has been available OTC since 1999. In addition to this, smokers with CVD may be less likely to use OTC NRT, and more likely to seek medical advice before using NRT and therefore receive NRT on prescription. To my knowledge, there was no media publicity about the licensing change which is likely to have reassured patients with CVD that they could start buying NRT OTC rather than seeking the advice of a health professional.

The results of this study suggest that only a small proportion of smokers with CVD are receiving smoking cessation support in primary care, despite overwhelming reasons for them to stop smoking. The study found that 1500 per 100,000 smokers (1.5%) with CVD receive a prescription for NRT per month. This suggests that a maximum of 18% of smokers with CVD are obtaining a prescription for NRT each year; as quitting episodes may last longer than a month, it is likely that the actual percentage is even lower. The rate of prescribing of NRT in CVD patients therefore seems low. It is not known what proportion of smokers with CVD attempt to quit each year, but in the general population in England 36% of adults reported having made a quit attempt in the past year in 2010.[270] Given the immediate health risks, it seems likely that the rate is much higher in CVD patients, and the rate of prescribing to these patients therefore seems low as a proportion of CVD patients who try to quit as well as overall. This study therefore suggests that opportunities to help these smokers quit are being missed.

Removing the barriers to health professionals prescribing NRT to patients with CVD may have been expected to increase prescribing of this medication to this group, either as a result of GPs being more willing to prescribe to a group perceived as high risk, or as a result of these patients being more willing to use it. We found no immediate increase in prescribing following the change in indications, and that in the period following the licensing change, prescribing in this disease group declined. As in the previous study in this thesis, this seems particularly surprising given the introduction of the smoking ban in this period, which may also have been expected to increase prescribing. This apparent decline seems unlikely to be due to the broadening of indications for NRT on the basis of evidence that it is safe in this group. Furthermore, the decreasing trend in prescribing for NRT is similar to that observed in the general population in the study in Chapter 5. It therefore seems likely that factors other than the licensing change, which are common to the majority of patients to whom NRT is prescribed, have led to a widespread decrease in prescribing for NRT from 2006 onwards.

One possible explanation for the decrease in prescribing of NRT may be substitution by varenicline, which became available on NHS prescription a year following the licensing change and which, as shown in Chapter 5, rapidly became the second most popular smoking cessation medication. It is possible that varenicline, which had not yet been tested in CVD patients when it became available but seemed likely to have no cardiovascular effects, may have substituted for some of the use of NRT in CVD patients.[271] Our results showed that, despite the decrease in prescribing for NRT in the period following the licensing change, overall prescribing for smoking cessation medication remained fairly stable, indicating that the

decrease in NRT prescribing was at least partly offset by prescribing for varenicline. It is not known whether varenicline halted an overall decline in prescribing of smoking cessation medication in this patient group, or whether it substituted for some prescribing of NRT. Either way, however, it appears that, overall, prescribing for smoking cessation medication to CVD patients has not reduced in recent years.

Despite the lack of increase in prescribing of NRT to CVD patients, it is likely, as was highlighted in the previous study, that there were benefits of the licensing change that could not be observed in this study in terms of reassuring GPs who prescribe NRT to CVD patients, and non-prescribers who provide advice about its use.

6.3.4 Conclusions

Smoking cessation has been shown to slow CVD progression and reduce the risk of premature death by 50%, and it is therefore important that CVD patients are supported in making quit attempts. Prescribing of NRT to CVD patients who smoke is comparable to that in other patient groups, but remains low. MHRA recommendations approving the use of NRT by CVD patients have not increased prescribing – NRT prescribing to this group of patients has declined since 2005, although the reduction may have been offset by a rapid increase in prescribing for varenicline. As such, it appears that opportunities for smoking cessation intervention in primary care patients with CVD are being missed.

6.4 Chapter conclusions

The results of the studies presented in this chapter are largely consistent with each other. Prescribing of NRT decreased in CVD patients following the licensing change, whereas in adolescents it levelled off; this

most likely reflects that varenicline replaced some NRT prescribing to CVD patients, whereas this was not the case for adolescents, for whom varenicline is not licensed in England. However, both studies found that, contrary to what may have been anticipated, the licensing change seems likely to have had an extremely limited impact on public health, in that it did not result in marked increases in prescribing of NRT. Both the study on prescribing of NRT to adolescents and the CVD patient study found that some GPs were already prescribing NRT to these groups before the licensing change, but that those that were resistant prior to the change remained so following it.

In both groups, prescribing of smoking cessation medication appears to be low relative to the prevalence of smoking despite the change in licensing. Thus the overarching conclusion in both studies is that opportunities for smoking cessation intervention in primary care are being missed. To our knowledge, similar studies have not be conducted in other countries. If these results are replicated outside of the UK, it is possible that adolescent smokers and those with CVD around the world are not receiving adequate support to quit smoking. Further research is needed to identify the barriers to prescribing smoking cessation in these groups so that they can be adequately supported in future quit attempts.

CHAPTER 7: THE IMPACT OF MASS MEDIA CAMPAIGNS ON SMOKING CESSATION ACTIVITY

7.1 Introduction

The role of mass media campaigns in tobacco control has been introduced in Chapter 1. As explained in section 1.6.2, international evidence suggests that tobacco control mass media campaigns can increase the chances of quitting and reduce smoking prevalence; however the evidence is not conclusive. Furthermore, very few academic studies have looked at the effectiveness of mass media campaigns in the UK, none of which have been published in the past decade.[173, 272-274] Many government or charity-funded campaigns undergo some evaluation of their immediate impact, but this is usually on the basis of small scale quantitative or qualitative surveys conducted over very short periods of time just before and after the campaign, without formal inferential statistical analysis; as such there is a dearth of UK-specific evidence.

In addition, evidence from the US suggests that advertising for NRT may also influence quitting, but no peer-reviewed studies have been undertaken of its effect on quitting behaviour in the UK or elsewhere.[89, 90]

As a result of the recent cuts in funding for tobacco control mass media campaigns, there is an urgent need to evaluate the effectiveness of both types of campaign in the UK. Investigating the effect of tobacco control campaigns is important to establish whether the cuts to government funding are justified, and what their implications may be for public health. These cuts also seem likely to place greater reliance on corporate-funded campaigns for NRT to encourage quitting, and it is therefore important to consider the effect of these campaigns as well as tobacco control campaigns.

During the course of my PhD research, I therefore obtained funding to conduct analyses of the impact of both types of mass media campaigns. ASH UK provided two months funding to carry out a preliminary descriptive analysis of the potential impact of both types of campaigns on a wide range on indicators of quitting behaviour. The report of this work is attached in Appendix 9.10. The report hinted at effects of both types of campaigns, but underlined the need for formal statistical analysis using high quality data to confirm and quantify the magnitude of those effects. I subsequently led on a project grant obtained from the Cancer Research UK Tobacco Advisory Group to conduct such an analysis. The results of this study are presented in this chapter.

The aims of the study were to assess the association between tobacco control advertising and advertising for NRT purchased by the pharmaceutical industry, and a range of sensitive indicators of quitting behaviour which seemed likely to respond to changes in advertising: calls to the free NHS smoking helpline, and rates of prescribing and over-the-counter (OTC) sales of NRT.

7.2 Methods

7.2.1 Exposure Data

This study used time series data on television ratings points (TVRs), a standard broadcasting industry measure of the audience which views a television programme or advert, as its measure of exposure to anti-tobacco mass media advertising and smoking cessation medication advertising. A TVR is defined as the percentage of a particular audience that has seen a commercial break. The measures of exposure to advertising in this study were:

- TVRs purchased for tobacco control campaigns by the Central Office of Information (COI, on behalf of the government), Cancer Research UK and the British Heart Foundation (the three main purchasers of such advertising during the time period) each month from January 2002 to May 2010, and

- TVRs purchased by pharmaceutical companies to advertise NRT each month from January 2005 to December 2009.

The tobacco control TVR data used in this study include all mass media campaigns related to smoking, including those targeting young people and related to smokefree legislation, as all of these campaigns may have influenced quitting behaviour. The TVR data nominally cover the whole of the UK, but due to devolved responsibilities for health promotion media campaigns in the UK, the COI TVR data primarily cover England only, with some overlap into other home nations through advertising in the press. The TVRs overlapping into Scotland and Wales have therefore been removed. Some of the outcome data cover England only, but due to the makeup of the UK's TV regions, TVRs for Wales could not be separated from those for England.

The pharmaceutical company TVR data are available for the whole of the UK but, to allow better comparison with the government-funded campaign data, only data on England and Wales have been used in this study.

The TVRs for England and Wales were calculated by summing population-weighted values of TVRs for each television region in England and Wales.

Advertising spend data are also available. For this study, however, TVR data were selected over spend data, as these ought to provide a more accurate representation of exposure to campaigns (as the cost of advertising is likely to vary over time) and were available for a longer time period. However, spend data were compared with TVR data to ensure that there would be no significant differences in the results depending on the exposure used. Appendix 9.9 shows that the trends in these two advertising exposures are extremely similar.

7.2.2 Outcome data

This study used time series data on three outcome measures which were available on a monthly basis for a long time period and seemed likely to be most responsive to changes in advertising exposure: calls to the NHS stop smoking helpline, prescribing of NRT, and OTC sales of NRT. The preliminary report for ASH also included quit attempts based on the STS and brief stop smoking advice data from THIN, but as explained in Chapter 2, these seem likely to be of limited quality on a monthly basis and were therefore not included in this study. The helpline calls data are available only for England. The NRT prescribing and OTC sales data cover England and Wales.

As explained in section 2.4.3, there is evidence that quitlines can help smokers to give up smoking, and numbers of quitline calls are therefore a useful measure of quitting behaviour. Many of the tobacco control mass media campaigns have included the NHS helpline number, and are therefore likely to have influenced calls to the helpline. This study uses the number of calls to the NHS helpline per month from November 2004 to June 2010.

Sales of OTC NRT have been used as an indicator of quitting activity in previous studies and are anticipated to respond to NRT advertising, although tobacco control campaigns might also influence OTC NRT sales.[135, 164, 165] NRT has been shown to be effective in aiding smoking cessation, and increases in sales may therefore lead to an increase in the number of people quitting.[126] The OTC sales data used in this study are the Electronic Point of Sales scanner data obtained from IRI described in section 2.4.1.[166] These data are supplied as 4-weekly summaries. To convert these to monthly equivalents, it was assumed that 1/28th of sales occur on each day in each 4-week period. The monthly population denominators for these data were calculated using the ONS mid-year population estimates for England and Wales for each year; year-on-year increases were apportioned uniformly by month.[19] The unit sales each month were divided by the monthly population denominators to obtain the rate of sales per 100,000 population per month from November 2003 to September 2008.

Prescribing of NRT may also be influenced by NRT advertising and tobacco control campaigns if these encourage smokers to seek smoking cessation medication or more general support with stopping smoking respectively, from their GP. Data on prescribing of NRT from THIN were used. The denominator for each month was the total number of live individuals contributing data to the THIN database throughout each month. It was assumed that those contributing data within each month provided one person-month of follow-up, and the numbers of prescriptions divided by the total person months to derive the rate of prescribing per month from January 2002 to June 2009.

7.2.3 Analysis

Multiple time series analysis was used to investigate the impact of advertising on the quitting behaviour outcomes. To determine which type of MTSA should be used, Granger Causality tests were carried out on pairs of stationarised time series as described in section 4.4. It was found that the weak exogeneity assumption was violated. In the case of mass media campaigns, the effect of campaigns may occur the day or week following exposure to a campaign; therefore, the use of monthly data seems likely to create contemporaneous correlation, suggesting instantaneous causality. This is likely to explain the lack of weak exogeneity. Therefore, in this study, SVAR analysis was used. As explained in section 4.4, this method allows assumptions to be made about the direction of causality in order to unpick the temporal relationships between variables – the impact of an intervention within the current time period as well as any lagged effects in subsequent time periods.

SVAR modelling requires stationary data, so the time series were transformed and differenced to ensure stationarity. Due to zero observations in the data, an inverse hyperbolic sine transformation, rather than a logarithmic transformation, was used to stabilise variance in both the input and the output series.[217, 222] Differencing the transformed time series rendered them stationary.

Short-run SVAR models of the effect of tobacco control advertising and NRT advertising on quitline calls, OTC NRT sales and prescribing for NRT were run. The SVAR was estimated using the procedure outlined in section 4.4.[223] First, matrices containing the constraints were specified such that the direction of causality was assumed to be from campaigns to quitting behaviour and not vice versa. Information criteria were used to

identify the optimal number of lags to use. Once optimised, the model was run and diagnostic testing undertaken to establish that the model was properly specified.[223] Modelling the transformed-differenced data provides the percentage change of each series; therefore the results can be interpreted directly as elasticities i.e. the percentage change in the outcome variable following a one percent change in the explanatory variable. IRFs which show the percentage change in the output variable (the quitting behaviour outcomes) in response to a 1% change in the input variable in the same month and in the subsequent 12 months, were obtained.[275] Cumulative IRFs which show the overall effect of campaigns up to a twelve month lag were also obtained.

Since many of the time series displayed seasonal effects, the effect of adjusting for different seasonal indicator variables (quarterly, monthly etc.) as exogenous factors was examined and information criteria used to select the best fitting model as described in section 4.4.2. For each pair of variables, information criteria showed that the model which allowed a separate effect for each month provided the best fit. Nevertheless, adjusting for seasonality assumes that any seasonal effect in outcomes is independent of increased advertising at certain times of the year (it is well-documented that quit attempts increase at the beginning of the year due to the New Year and No Smoking Day [79, 276, 277]), whereas some of the seasonal increase in quitting may be *due* to increased advertising; it is not possible to separate the two effects. It is therefore possible that adjusting for seasonality causes the true effect of campaigns to be underestimated, and therefore the results of the seasonally unadjusted and adjusted models are presented for comparison.

The results are presented as a table of the contemporaneous (i.e. within-month) effects of all the models, and graphs of the IRFs for each month up to 12 months lag. Also presented are a table of the cumulative effects of campaigns at the 12 month lag, and CIRFs which show the overall effect of mass media campaigns each month up to 12 months following the campaigns. All analyses were conducted in Stata Version 11.0.

7.3 Results

Figure 7-1 shows tobacco control TVRs from January 2002 to December 2009 and pharmaceutical company TVRs from February 2005 to December 2009. There was no discernible long-term trend in tobacco control TVRs during the study period, with much fluctuation from one month to the next. TVRs tended to peak in January, and were highest in January 2005 and 2010. There were few months with no advertising. Pharmaceutical company TVRs were characterised by peaks and troughs throughout the period studied. Most peaks in NRT TVRs were in January. The largest peaks were in January 2005 and July 2007, when smokefree legislation was implemented in England.

Figure 7-1. Tobacco control TVRs, England and Wales, January 2002 to December 2009, and pharmaceutical company TVRs, England and Wales, February 2005 to December 2009

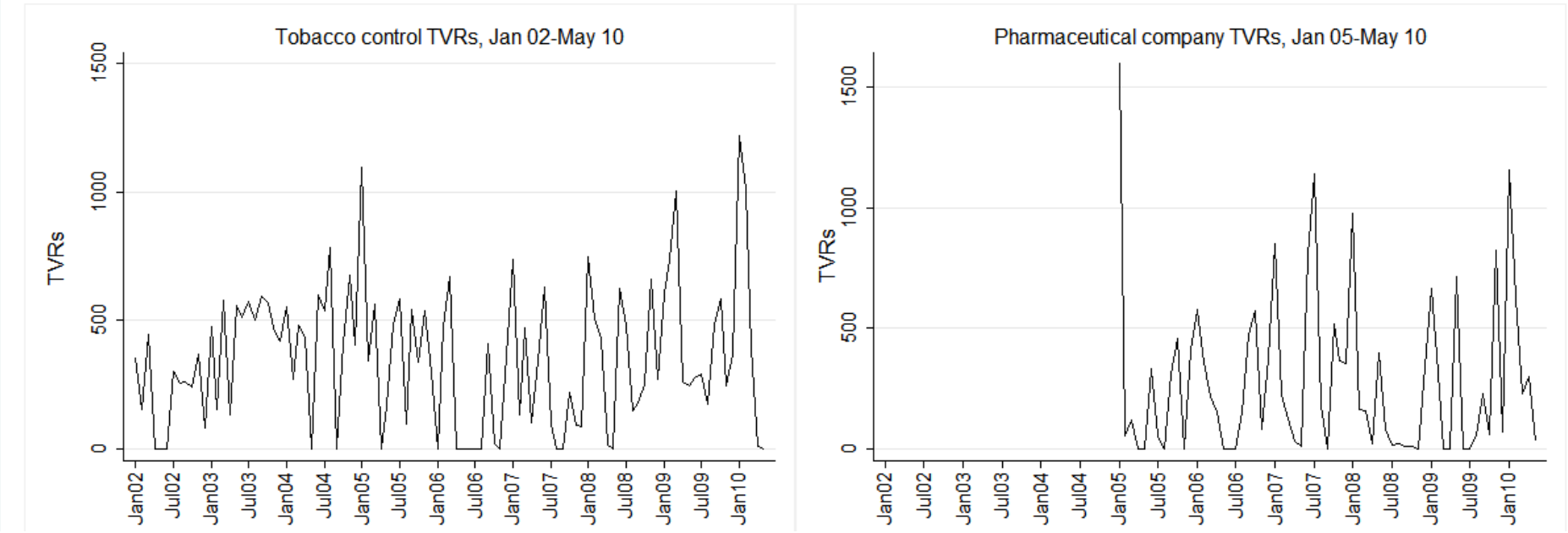


Figure 7-2 shows plots of each outcome measure for the study period. There was a very large peak in quitline calls in January and February 2005, with around 70,000 calls. The number of calls then levelled off at between 10 and 30,000 for the rest of the period. Seasonal peaks generally occurred in January to March each year. As shown in previous chapters, NRT prescribing increased until 2005, and appears to have decreased since 2007. In most years there was a clear peak in prescribing in the first three months of the year and a much smaller peak in October. The level of OTC NRT sales increased gradually during the study period, with seasonal peaks of a similar magnitude in January to March each year. Sales in January tended to be approximately 50% higher than in the summer months. In July 2007, however, when smokefree legislation was introduced in England, sales were higher than in any other month during the study period.

Figure 7-2. Quitline calls, England, November 2004-December 2009; Rates of NRT prescribing, England and Wales, January 2002-June 2009 and OTC NRT unit sales, England and Wales, November 2003-September 2009

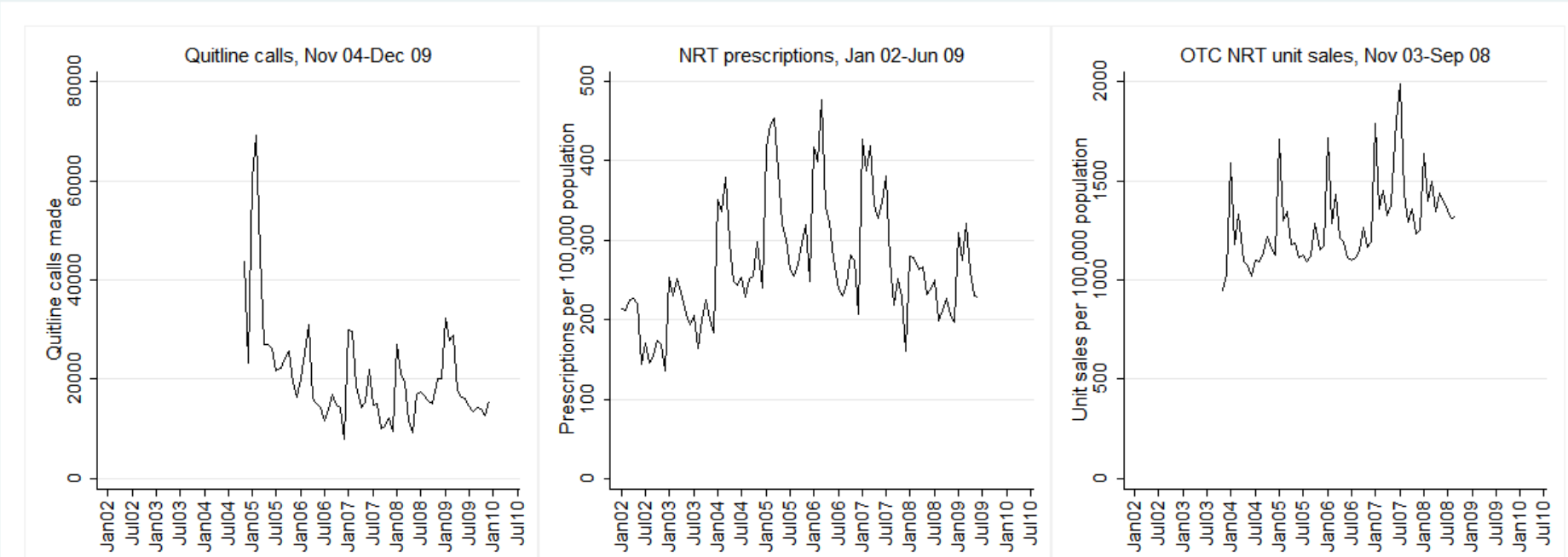


Table 7-1 shows the contemporaneous (that is, within-month) results of the SVAR models. All of the elasticities were positive. In the seasonally unadjusted model, tobacco control campaigns had a statistically significant effect on quitline calls in the same month, with a 1% increase in tobacco control TVRs leading to a 0.129% increase in quitline calls. This effect was still statistically significant, but reduced, in the seasonally adjusted model. Tobacco control TVRs did not have a statistically significant within-month effect on OTC NRT sales or NRT prescribing.

Pharmaceutical company TVRs had a small statistically significant effect on OTC NRT sales in the seasonally unadjusted model – a 0.05% increase in sales per 1% increase in advertising. However, the increase was not statistically significant in the seasonally adjusted model. Pharmaceutical company TVRs did not have a statistically significant effect within-month effect on quitline calls (although the effect in the unadjusted model was borderline non-significant) or NRT prescribing.

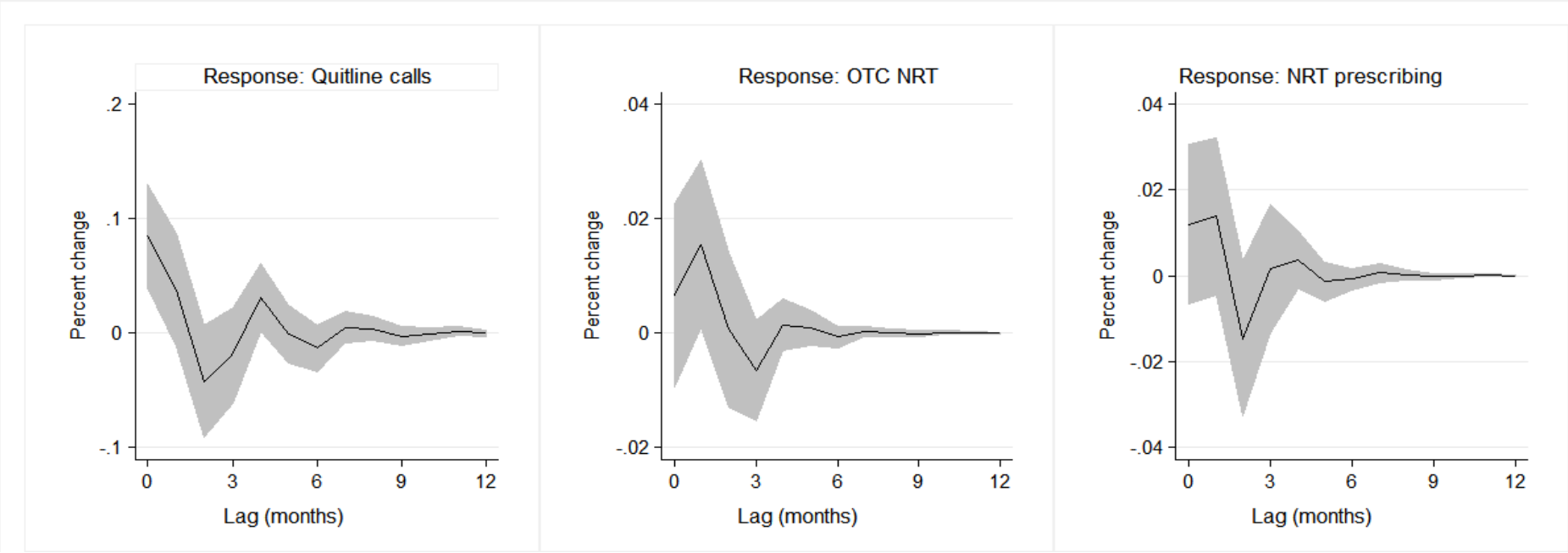
Table 7-1. Results of SVAR models of the impact of anti-tobacco mass media campaigns on quitting behaviour – Contemporaneous effects

Exposure	Outcome	Unadjusted SVAR			Seasonally adjusted SVAR		
		IRF	95% CI	p-value	IRF	95% CI	p-value
Tobacco control TVRs	*Quitline calls*	0.129*	0.053 - 0.205	0.002	0.085*	0.040 - 0.129	0.007
	OTC NRT	0.0198	-0.018 - 0.058	0.313	0.007	-0.009 - 0.023	0.430
	NRT prescribing	0.034	-0.008 - 0.077	0.121	0.012	-0.007 - 0.031	0.220
Pharmaceutical company TVRs	*Quitline calls*	0.084	0.003 - 0.165	0.049	0.040	-0.012 - 0.091	0.141
	OTC NRT	0.051*	0.014 - 0.088	0.011	0.012	-0.007 - 0.032	0.213
	NRT prescribing	0.028	-0.023 - 0.080	0.285	0.020	-0.004 - 0.044	0.121

*Significant at 5% significance level

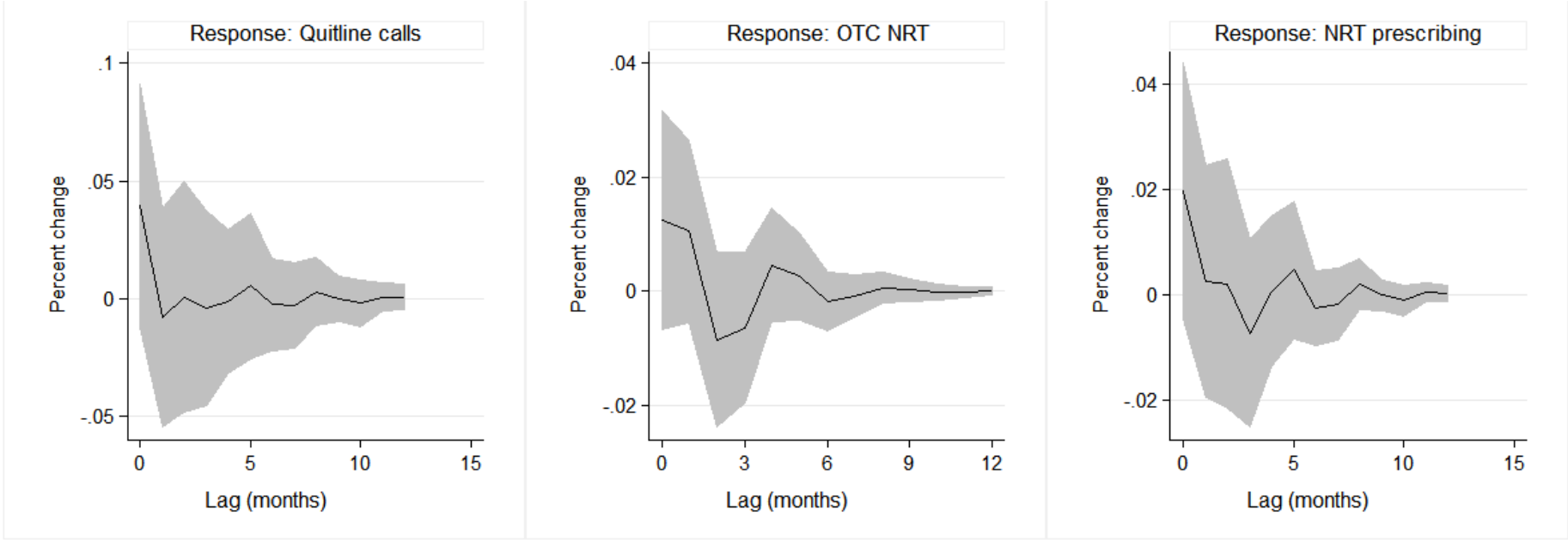
The IRFs for the seasonally adjusted models are presented in Figure 7-3 and Figure 7-4. They suggest that there are no significant lagged effects of tobacco control or NRT advertising, except a very small and marginally significant effect of tobacco control TVRs on OTC NRT sales one month after the campaigns, and a small non-significant effect of tobacco control TVRs on NRT prescribing in the same period.

Figure 7-3. Impulse Response Functions: Impact of tobacco control TVRs on quitline calls, OTC NRT and NRT prescribing (seasonally adjusted model)



Note: IRFs have different y-axis scales.

Figure 7-4. Impulse Response Functions: Impact of pharmaceutical company TVRs on quitline calls, OTC NRT and NRT prescribing (seasonally adjusted model)



Note: IRFs have different y-axis scales.

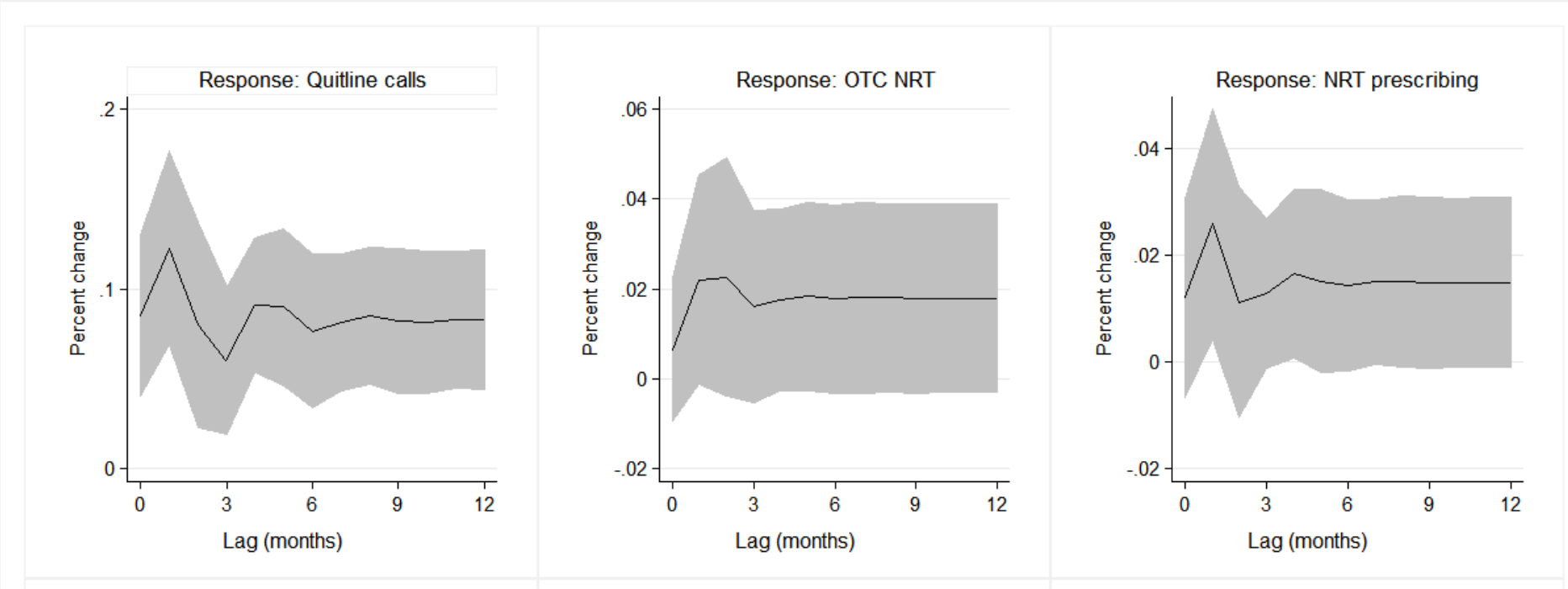
Table 7.2 shows the cumulative effects of advertising at 12 months. In all models the point estimate was positive (and statistically significant for the effect of tobacco control advertising on quitline calls) at 12 months. Due to the lack of lagged effects, the estimates at one year were similar to the contemporaneous (within-month) estimates. The CIRFs are shown in Figure 7.5 and Figure 7.6.

Table 7-2. Results of SVAR models of the impact of anti-tobacco mass media campaigns on quitting behaviour – Cumulative effects at 12 months

Exposure	Outcome	Unadjusted SVAR			Seasonally adjusted SVAR		
		COIRF	95% CI	p-value	COIRF	95% CI	p-value
Tobacco control TVRs	*Quitline calls*	0.110*	0.038- 0.181	0.005	0.083*	0.044- 0.122	<0.001
	OTC NRT	0.021	-0.014- 0.055	0.246	0.018	-0.003- 0.039	0.104
	NRT prescribing	0.037	-0.005- 0.079	0.093	0.015	-0.001- 0.031	0.076
Pharmaceutical company TVRs	*Quitline calls*	0.095*	0.017 - 0.172	0.022	0.031	-0.012- 0.091	0.165
	OTC NRT	0.0367*	0.004- 0.069	0.033	0.013	-0.007 - 0.073	0.220
	NRT prescribing	0.046	0.017- 0.172	0.071	0.020	-0.002- 0.042	0.081

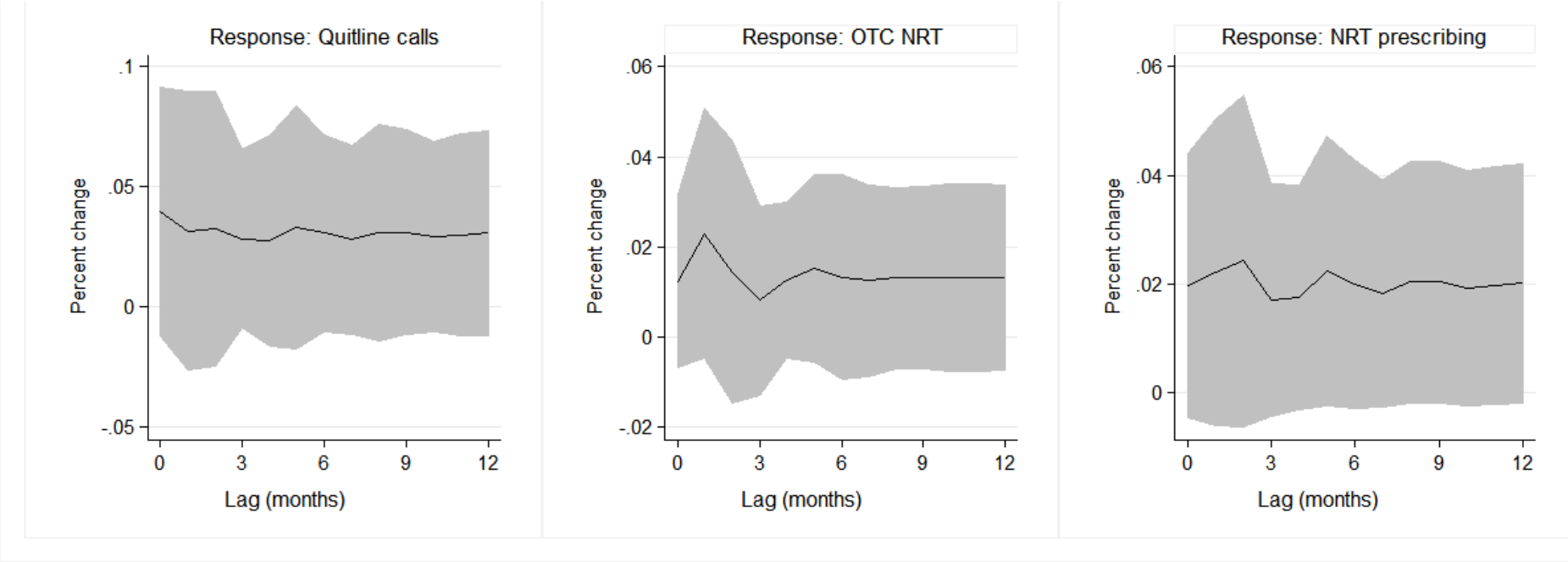
*Significant at 5% significance level

Figure 7-5. Cumulative Impulse Response Functions: Impact of tobacco control campaigns on quitline calls, OTC NRT and NRT prescribing



Note: CIRFs have different y-axis scales.

Figure 7-6. Cumulative Impulse Response Functions: Impact of pharmaceutical company campaigns for NRT on quitline calls, OTC NRT and NRT prescribing



Note: CIRFs have different y-axis scales.

7.4 Discussion

This is the first study in over 10 years to provide evidence on the effect of tobacco control advertising on quitting behaviour in England and Wales. To my knowledge, it is also the first study to explore the impact of pharmaceutical company-funded advertising on quitting behaviour in the UK, and to examine the impact of both types of campaign on NRT prescribing. Tobacco control advertising was significantly associated with an increase in calls to the NHS helpline in the same month. A significant increase in calls was not observed beyond one month of the advertising. Pharmaceutical company advertising had a positive within-month effect on NRT sales, but this effect was markedly smaller than that seen for tobacco control TVRs on quitline calls, and not significant after controlling for seasonal effects of quitting behaviour. During the freeze on public health mass media campaigns between April 2010 and October 2011, no tobacco control campaigns were run, and the new tobacco control campaign has lower funding than that prior to the freeze. Based on these results, this is likely to have a detrimental effect on quitting behaviour.

The major strengths of this study are the long time period studied and the use of monthly data, which enabled close matching of the timing and magnitude of campaigns to relevant outcomes. Whilst the outcome measures are indirect measures of quitting, the strength of these measures is that they are objective. This contrasts to campaign evaluations which use survey data, which is prone to recall bias, especially if not carried out immediately following the campaigns. Also, the measures used in this study are outcomes which are likely to have a significant influence on quitting; quitlines can help people to quit smoking, while NRT is an effective pharmacological cessation aid. Furthermore, this study uses

statistical methods which are able to take account of the many complexities of time series data, including simultaneity, seasonality, lags in effect and autocorrelation. To my knowledge, SVAR modelling had not been employed in a public health context prior to its application in this study. Since this study was conducted, however, my colleagues and I have also used SVAR modelling in a study investigating the impact of tobacco price and affordability on smoking prevalence in the UK. This study has been submitted for publication, and a conference abstract based on it is included in Appendix 9.9.

A limitation of this study is that it may be underpowered to detect very small effects. The pharmaceutical company advertising models have fewer data points than the tobacco control advertising model, and lack of power may explain the lack of statistical significance in this model. The tobacco control TVRs and calls model was re-run over the same timeframe as the data available on sales to explore how this affected the results. This model yielded an effect of similar size and statistical significance as that modelled over the whole time series, and still over twice as big as the effect of NRT advertising on any outcome. This suggests that the differential effects reported here are not due to the different timeframes of available data. It was also not possible to separate the effect of seasonal advertising from independent seasonal quitting behaviours and therefore both the seasonally adjusted and unadjusted data are presented. If seasonal effects are a combination of advertising and factors independent of advertising, then the true effect of advertising most likely lies somewhere between the seasonally-adjusted and unadjusted estimates. Additionally, it was not possible to adjust for potential confounding by other interventions such as smokefree legislation, which was implemented

in England and Wales in 2007. Doing so would present the same problem as the adjustments for seasonality - a lot of the smokefree effect will have been due to the increased advertising, so it would not be possible to separate out the effects.

Finally, it is important to note that, because this study looked at campaigns overall, as opposed to individual campaigns, these results may obscure the larger or more long-term impact of particularly good campaigns – both tobacco control and pharmaceutical company-funded campaigns. The small magnitude of effect probably reflects the importance of content - in that less effective campaigns reduce the overall effect – and perhaps reflects different effects in different population groups.

The associations explored in this study have, until now, only been explored in a small group of countries. Further research should investigate whether the results of the study can be replicated elsewhere. In particular, the impact of pharmaceutical company campaigns for NRT and the impact of campaigns on prescribing of smoking cessation medication are under-researched. The results of the current study are consistent with existing studies conducted in the US, New Zealand and Australia. Several studies have demonstrated an association between tobacco control advertising and calls to quitlines.[173, 278-281] A limited number of studies in the US and Australia has shown that pharmaceutical company advertising can have a positive effect on NRT sales, although advertising has been shown not to increase demand for all products studied.[82, 89, 90] The results of this study, which are based on aggregated data for all NRT products and find a small, non-significant positive effect of NRT advertising, may, as described above, also reflect that some pharmaceutical company-funded campaigns are more effective than others. To my knowledge, this is the first study to look

at the impact of tobacco control mass media campaigns on prescribing of smoking cessation medication. The limited effect identified in this study points to missed opportunities: tobacco control advertising may benefit from a greater focus on encouraging supported quit attempts (such as using a medication shown to increase quit success), while pharmaceutical companies should perhaps consider the advantages of using their advertising space to encourage smokers to seek advice and medication from their GP.

This study found that the effect of campaigns was generally restricted to the month during which they were run. This short-term effect is consistent with existing studies and suggests that prolonged campaigns are needed to maximise their impact.[82, 282, 283] The short-term effect may, however, be perceived to indicate that mass media campaigns bring forward quitting behaviour as opposed to increasing quitting overall, as previous studies suggest occurred when smokefree legislation was implemented in England in 2007.[79, 80, 284] If this were the case with mass media campaigns, one would expect to see an increase in quitting behaviour followed by a decrease in subsequent months and no change overall. However, the CIRFs showed that in all models the point estimate was positive (and statistically significant for the effect of tobacco control advertising on quitline calls) at 12 months. This suggests that mass media campaigns do not simply redistribute quitting behaviour but have an additional impact.

This study is important in that it provides evidence that tobacco control campaigns in England and Wales *are* effective in encouraging quitting behaviour. Further extensive UK-specific research is required to build on this study and should explore the impact of campaign type and

content; it is highly likely that some campaigns will have had a much greater effect than that estimated from the generic measure of campaign exposure used in this study. For example, campaigns that contain a quitline number may have a greater impact on calls, and campaign effectiveness may also vary with funding sources (for example government versus charity-funded campaigns). Further research is needed to explore effects of campaigns on a more comprehensive set of indicators of smoking behaviour and the cost-effectiveness of campaigns, as well as to explore the effect of campaigns in different sociodemographic groups to establish whether they influence behaviour in the groups with the highest rates of smoking.

7.5 Conclusions

This study has used robust methods previously not used in public health research to investigate the impact of mass media campaigns on quitting behaviour. The results suggest that tobacco control campaigns may be more effective at triggering quitting behaviour than pharmaceutical company NRT campaigns. The implication is that relying on corporate-funded advertising to influence smoking cessation would be misguided, and there are likely to be implications for other areas of health behaviour such as alcohol control. In addition, the results of this study suggest that the recent freeze on publicly-funded spend on tobacco control mass media campaigns may have significantly reduced quitting behaviour. Furthermore, the short-term nature of the advertising effects that are observed suggests that any advertising needs to be sustained, which would have implications for reducing funding of such campaigns in the future.

CHAPTER 8: SUMMARY CONCLUSIONS AND FUTURE DIRECTIONS FOR RESEARCH

8.1 Introduction

The overall aims of this thesis were to investigate the suitability of a range of data sources for evaluating the impact of tobacco control policies on quitting behaviour in England, and to use validated measures to evaluate the impact of recent tobacco control initiatives in England using time series analysis.

This concluding chapter summarises the key lessons learned from the research in this thesis, and highlights avenues for future research for the four broad areas studied: the use of existing data for evaluating tobacco control policy, the use of time series methods for evaluating tobacco control policy, and the impact of two types of tobacco control policy – increasing access to smoking cessation medication, and anti-tobacco mass media campaigns.

8.2 Existing data for evaluating the impact of tobacco control policy on quitting behaviour in England

8.2.1 Summary of findings

Chapter 1 of this thesis identified important indicators of quitting behaviour and highlighted that robust evaluation of individual tobacco control policies generally requires long time series data with short time intervals to enable long-term trends to be taken into account.

Chapter 2 provided a comprehensive overview of the data sources containing information on quitting behaviour in England, and explored which sources provide data that lend themselves to tobacco control policy evaluation. It found that some of the survey data on quitting behaviour in England are good for monitoring behaviour, because they are conducted in large, representative samples, but are generally not suitable for the evaluation of individual policies using time series. This is because they are

usually annual, or have small sample sizes on a monthly basis, resulting in short time series which are insufficiently sensitive for identifying the impact of individual policies.

In contrast, routinely collected data are often available in large samples over long time periods and on a monthly basis, making them appropriate for evaluating tobacco control policies, although they often do not measure key outcomes of interest.

Existing evidence and the new validation study in Chapter 3 showed that, in particular, primary care data from THIN are a valuable source of time series data on smoking prevalence and prescribing of smoking cessation medication, although the smoking prevalence data are only valid from 2006. In addition, data on smoking cessation advice giving and referrals to smoking cessation services in primary care have previously been shown to be of limited quality.

8.2.2 How can data on quitting behaviour in England be improved?

None of the data sources described in Chapter 2 are without limitations. The THIN data have the potential to be more useful if GPs can be encouraged to consistently deliver and record cessation advice and referrals, and future research should explore how this could be achieved. Further to this, the prevalence data ought to be re-validated in the future to confirm the validity that has been shown at a national and regional level in recent years.

A significant gap in the existing data is the lack of a valid, frequent measure of quit attempts. This would be an extremely important sensitive outcome for measuring the impact of tobacco control policies on quitting behaviour. The IHS provides a frequent, large and representative sample

of the population, and therefore including a question on quit attempts (for example, in the last month) in the survey seems likely to be a good way of obtaining good data on quit attempts. This, coupled with a monthly measure of smoking prevalence (for example, from the IHS or from THIN), would provide valuable data on the short-term and longer-term effects of policy on quitting. Both the IHS and THIN contain extensive sociodemographic data and would therefore allow investigation of differential policy effects in different population groups and, in particular, the effect of policies on health inequalities.

It is important to combine subjective measures (such as self-reported quit attempts and smoking status) with objective measures such as prescribing of cessation medication, use of cessation services and quitline calls. Indeed, objectivity is a major strength of the measures of quitting behaviour used in the evaluation studies in this thesis. When combined with such data, high quality data on quit attempts and prevalence would help to provide comprehensive evidence on the impact of policy on quitting behaviour.

The more comprehensive a set of indicators is available for policy evaluation, the stronger the evidence on the effectiveness of policies will be. It would therefore be particularly useful if these indicators could be supported by evidence from other sources, such as the Smoking Toolkit Study (STS) and the ITC Project. The STS contains data on a range of indicators of quitting behaviour, such as quit attempts and cessation support used, but its use in policy evaluation studies is currently limited by the small monthly sample size and brevity of the time series. It could, however, become invaluable in policy evaluations if sustained over time. For example, survey waves could be combined to ensure adequate sample

sizes for time series analysis, and pre-policy trends could be taken into account. The key strength of the ITC Project data is that they include comparative data from a wide range of countries. To maximise the value of the ITC data, however, the surveys need to be conducted on a regular basis, and questions related to newly proposed policies added as rapidly as possible, to ensure that the necessary data are available. Evidence as to *how* policy affects behaviours, in addition to evidence as to whether it does so, would help us to understand how policy could be improved, which would guide policy development both in England and internationally. The ITC dataset contains proximal and distal indicators which can be used to obtain this type of evidence. The cost of running both the STS and the ITC Project are clearly, however, a potential barrier in their continuation and expansion.

8.2.3 Avenues for future research

In addition to the research related to primary care data proposed above, there are two key avenues of future research related to data for policy evaluations.

The first is to conduct similar analyses of data sources in international settings. England probably has, despite the limitations of the data, more comprehensive and regular data on quitting behaviour than most other countries. For example, previous research has shown that the measurement and monitoring of trends in smoking prevalence in many EU countries is inconsistent and infrequent.[285] It would therefore be useful to identify the gaps and limitations of data on quitting behaviour in other countries. In particular, the lessons learned in this thesis may facilitate setting up high quality data collection for future evaluations; the number of indicators need not be large, but ought to be relevant and collected in

large, representative samples and at frequent time intervals, to maximise the quality of evaluations.

The second important line of research is to investigate data sources in other health policy areas, particularly in those that are less well developed than tobacco control. One example is alcohol policy. Alcohol consumption has been rising in the UK since the 1950s, with detrimental consequences for public health and public order.[286] Policies and initiatives to address issues of alcohol misuse to date have been significantly less comprehensive than those to reduce tobacco-related harm, but policies on pricing, marketing and health messages are emerging or under consideration in UK countries. Monitoring changes in drinking habits over time, and in different population groups, and applying appropriate inferential statistical methods to these data, is key to evaluating the impact of these policies and to guiding future policy. In my future research I therefore propose to carry out work towards establishing a database of UK data relating to drinking behaviour, which will facilitate future research evaluating the impact of national alcohol policy. I will follow a similar approach to that which was used to develop the NTCD and in Chapter 2 of this thesis to identify key indicators of alcohol behaviour and misuse from existing datasets, describe any evidence for their validity (or how this might obtained), identify any gaps in the available data, and identify the policies, initiatives or public health interventions which might be evaluated using the existing data.

8.3 Using time series analysis for the evaluation of public health policies

8.3.1 Summary of methods

Chapter 1 identified time series analysis as a robust statistical method for evaluating the impact of tobacco control policy. Chapter 4 built on previous work on the application of time series methods to public health policy evaluations by describing a broader range of time series methods: ARIMA modelling and segmented regression analysis using GAMs/GAMMs (for interrupted time series analysis, used when a policy has been introduced at a specific point in time) and dynamic regression analysis and vector autoregression analysis (for multiple time series designs, needed to investigate the impact of a continuous policy exposure on a continuous outcome). All of these methods are currently infrequently used in public health policy evaluation, and in particular, to my knowledge, VAR and SVAR modelling have not been used in this context before.

8.3.2 Interrupted time series analysis: Lessons learned and avenues for future research

Segmented regression analysis is an interrupted time series method which can, depending on the complexity of the autocorrelation, be used with a relatively short time series. However, due to its added flexibility in modelling policy effects (such as being able to model temporary as well as permanent effects, as well as being able to model non-linear trends), if sufficient data are available, ARIMA modelling is often preferable to segmented regression analysis.

Interrupted time series analysis is an extremely useful study design, because it takes account of existing trends and autocorrelation. Given that multiple tobacco control policies are often implemented at or around the same time, and the fact that it is difficult to disentangle the

effects of different policies, however, it is important to consider any potentially confounding policies and their likely effect when carrying out policy evaluation studies. Even when care has been taken to take account of confounding events, it may not be possible to conclude that there is a causal relationship between a policy intervention and a change in an outcome measure. High statistical significant and strength of effect may be key indicators of causality, but other, unobservable factors may still explain the results. For example, in Chapter 6 of this thesis a levelling off in prescribing of NRT to adolescents was observed immediately following the licensing change. However, it seems likely that other factors caused this levelling off; a lack of data on these factors means their impact cannot be estimated. Thus researchers conducting TSA should always try to be aware of possible alternative explanations for their results and it is also important to triangulate the results of interrupted time series studies with other types of policy evaluation if possible, so as to maximise the likelihood of identifying true policy effects.

Chapters 5 and 6 of this thesis demonstrated how each of these methods can be applied to evaluate policy effects. In Chapter 5 ARIMA modelling was used to evaluate the impact of the introduction of varenicline on prescribing for smoking cessation medication.

In Chapter 6 segmented regression was used to analyse the impact of the broadening of the indications for NRT on prescribing of the drug to adolescents and CVD patients.

To increase their value, further research is needed into the relative power of the two methods, which, as described in Chapter 4, remains unclear. When correctly used, however, these methods can provide strong

evidence of policy effects, and are therefore potentially useful tools not just in tobacco control, but in all areas of public health policy. Ensuring that these methods become more routinely applied in public health policy research should therefore be a priority for researchers.

8.3.3 Multiple time series analysis: Lessons learned and avenues for future research

Dynamic regression analysis and VAR modelling are both methods for estimating the impact of one time series on another. Chapter 4 of this thesis described these models and the methods involved in choosing between them. Chapter 7 demonstrated how these methods can be used to evaluate the impact of a continuous tobacco control policy exposure, using a variation of VAR analysis, SVAR modelling.

Multiple time series analysis also has some of the issues surrounding causality; if confounders (such as policy events which have an effect on the outcomes) have not been taken into account, statistical association may not reflect true causality. However, as the exposure is measured over time (unlike in an interrupted time series model), this may not be as problematic if confounder is not present throughout the time series. For example, smokefree legislation may have influenced quitting behaviour (over and above the effect of advertising related to smokefree) during some of the study period, but because the model is based on many months of data, its overall confounding effect is likely to be reduced. Most potential confounders can, if data are available, be fitted to these models, and thus the likelihood of a causal effect can be maximised.

These methods have rarely been used in a public health context, and future research should explore other areas in which they could be applied. Our research team has already gone on to use a SVAR model to

estimate the effect of tobacco price on smoking prevalence in the UK. An abstract based on this study is presented in Appendix 9.9. I also hope to apply these methods in a future study to investigate the impact of price on OTC NRT sales in the UK.

In addition to dynamic regression and VAR/SVAR, there are a range of other multiple time series models which it has been beyond the scope of this thesis to explore. The multiple time series literature is, unfortunately, extremely complex; because they have rarely been used in public health research, little attempt has until now been made to make these econometric methods accessible to public health researchers. This thesis has made a start, but future research should review other time series models to determine how these methods and their results differ from those described in this thesis, and whether and how they could be applied to maximise the strength of the evidence that can be obtained from them. In particular, research should look at the use of long-run time series models in public health. The methods described in this thesis have focussed on the short-run because it was anticipated that the continuous policy exposure investigated, mass media campaigns, would have a short-term impact on the outcomes of interest.

To that end, I am collaborating with ASH UK and Landman Economics to conduct a detailed study of the impact of tobacco price on consumption. This will use data from an existing study by HM Revenue and Customs as a starting point, and compare the results of different multiple time series methods, including short and long-run models.[287]

8.4 The impact of increasing access to smoking cessation medications in England

8.4.1 Summary of findings

Chapters 5 and 6 of this thesis explored the impact of recent changes in the availability of pharmacological smoking cessation aids in England using prescribing data from THIN. These studies, which used an objective measure of prescribing, suggest that neither the introduction of varenicline nor the broadening of the indications for NRT are likely to have had a significant impact on public health. Although prescribing for varenicline increased rapidly in English general practice following its introduction, overall rates of prescribing for smoking cessation medication do not appear to have increased. Similarly, prescribing of NRT did not increase in adolescents or CVD patients following the licensing changes which permitted these groups to receive the drug.

8.4.2 Implications of findings and avenues for future research

Increasing access to smoking cessation medication then, does not appear to have had the desired effect on quitting behaviour: the general practice data suggest that it has not increased supported quit attempts. Future research should explore whether and how rates of smoking cessation support in primary care could be increased.

There may, however, have been favourable effects of the changes that cannot be observed from the data used in this thesis. For example, varenicline may be more effective than NRT and bupropion, and therefore its use may have increased the success of quit attempts.[128] Furthermore, the NRT licensing change may have reassured medical professionals who were already prescribing the drug, or increased the provision of NRT in the relevant groups in other settings, such as smoking cessation services.

This underlines the aforementioned need for the triangulation of evaluation studies – comparing the results of studies which use different methods and different settings – in order to obtain a better understanding of the effects of policy changes. Thus a comprehensive perspective can be gained, which may be influential in driving future policy changes in both national and international settings.

8.5 The impact of anti-tobacco mass media campaigns in England and Wales

8.5.1 Summary of findings

Chapter 7 of this thesis was a much-needed study of the impact of anti-tobacco mass media campaigns in England and Wales. Recent cuts in government spending on tobacco control campaigns and the dearth of recent UK-specific evidence made this a particularly important and topical study. The study found that during the study period, on average, tobacco control advertising was significantly associated with an increase in calls to the NHS stop smoking helpline. NRT advertising had a positive effect on NRT sales, but this effect was markedly smaller than that seen for tobacco control TVRs on quitline calls.

8.5.2 Implications of findings and avenues for future research

The implications of these findings are that the recent cuts in advertising are likely to have reduced quitting behaviour. Further to this, it seems likely that it would be unwise to rely on corporate-funded advertising to influence quitting behaviour. This may also be the case for other areas of health behaviour where mass media campaigns are used.

This is an important finding, but in order to maximise the impact of future anti-tobacco campaigns, extensive research is required to identify the types and characteristics of the most effective and cost-effective

campaigns using a variety of indicators of quitting behaviour and identify those that are most successful in reaching target groups with the highest smoking rates.

I have been involved in developing a proposal for a project, which has received funding from the National Prevention Research Initiative, which will evaluate the impact of UK anti-tobacco mass media campaigns carried out since 2004 on a set of key indicators of adult smoking behaviours including smoking prevalence, cigarette consumption, quitting behaviour, smoking in the home, and smoking-related health outcomes using a combination of time series analysis and longitudinal data analysis approaches in existing national datasets. We aim to determine what types of campaign are most effective and cost-effective in terms of their immediate and longer term impacts, and their potential to reduce smoking-related health inequality. The campaigns will be classified in terms of the channel of delivery (TV, radio, press and billboard campaigns), duration, their aims and target audience, informational and emotional content and style.

Thus the proposed research will draw on many of the lessons learned through this PhD thesis to conduct a comprehensive evaluation of the impact of anti-tobacco mass media campaigns. It will use a range of study designs, data sources and outcome measures which, together, should provide comprehensive evidence as to the impact of mass media campaigns in the UK and the content of the most effective and cost-effective campaigns, and in doing so will help to guide future policy on a local, national and international level. It is possible that this comprehensive evaluation design could also be used in other areas of public health.

8.6 Overall conclusions

This thesis has provided an important illustration of the data and methods that are needed for robust tobacco control policy evaluation. It has highlighted time series analysis as a particularly good study design for policy evaluation, and has described a range of data from existing sources which provide information on smoking cessation behaviour in England. Although it has shown that there are significant gaps in the existing data available for tobacco control policy evaluation using time series analysis, there are some high quality time series data, which have been used to evaluate a group of tobacco control policies recently implemented in England. Overall, this thesis has highlighted the need for the regular collection of data on key indicators of quitting behaviour, and that the frequent use of time series analysis in policy evaluation can play a vital role in strengthening the evidence for the effectiveness of policies, both in tobacco control, and in other areas of public health.

CHAPTER 9: APPENDICES

9.1 Nottingham Tobacco Control Database variables and descriptions

	Variable	Description
GLF/GHS	Denominators	Total number of individuals that completed the survey
GLF/GHS	Current smokers	Number of individuals answering "yes" to the question: "Do you smoke at all nowadays?"
GLF/GHS	Want to quit	Number of individuals answering "yes" to the question: "Do you want to quit smoking?"
Omnibus	Current smokers	Number of individuals answering "yes" to the questions: "Do you smoke cigarettes at all nowadays?" (Module 130) "Do you smoke cigarettes?" (Module 210)
Omnibus	Denominators	Total number of individuals that completed the survey.
Omnibus	GP stop smoking advice in the last 5 years	Number of individuals answering "yes" to the question: "Has your GP given you advice about stopping smoking in the last 5 years"
Omnibus	Over the counter NRT purchases in the last year	Number of individuals reporting having paid for NRT in the last year (excluding chargeable prescriptions).
Omnibus	Prescribed smoking cessation medication in the past year	Number of individuals reporting having obtained a prescription for a smoking cessation product in the last year. Broken down by medication type, but not by formulation (not asked about).
Omnibus	Quit attempts in the last year	Number of individuals reporting having made at least one quit attempt (of unspecified duration) in the last year.
Omnibus	Want to quit	Number of individuals answering "yes" to the question: "Do you want to quit smoking?"
Health Survey for England	Denominators	Total number of individuals that completed the survey.

Health Survey for England	Current smokers	Number of individuals answering "yes" to the question: "Do you smoke at all nowadays?"
Health Survey for England	Want to quit	Number of individuals answering "yes" to the question: "Do you want to quit smoking?"
Smoking Toolkit	Denominators	Total number of smokers that completed the survey.
Smoking Toolkit	Quit attempts in the last month	Number of individuals reporting having made at least 1 quit attempt during the month immediately prior to the date on which they completed the survey.
Smoking Toolkit	Plan to quit	Number of individuals reporting having made a plan to quit smoking in the future.
Smoking Toolkit	Want to quit	Number of individuals indicating that they want to quit smoking.
Smoking Toolkit	Used smoking cessation clinic in last month	Number of individuals reporting having visited a smoking cessation clinic during any quit attempt in the last month.
Smoking Toolkit	Used smoking cessation medication in the past month	Number of individuals reporting having used a stop-smoking medication during any quit attempt in the last month. Broken down by medication.
Quitline	Quitline calls	Total number of calls to the NHS Stop Smoking Helpline
IRI	Sales of OTC NRT	Total number of NRT items sold at retail (over-the-counter and off-the-shelf), broken down by formulation. This reflects the actual number of packets sold, rather than the number of purchases.
ePACT	Dispensed smoking cessation medication	Total number of items dispensed. This reflects the number of items listed on the prescription form, rather than the actual number of packets issued (i.e. a prescription for 60 tablets counts as one item regardless of whether two packets of 30 were actually issued).
THIN	Denominators	Total number of currently-registered living individuals enrolled in THIN.

THIN	Brief stop smoking advice from GP	Number of individuals to whom brief advice is given.
THIN	GP-prescribed smoking cessation medication	Overall number of prescriptions issued in each class.
THIN	Current smokers	Number of currently-registered individuals enrolled in THIN with a last smoking status recording indicating any current smoking.

Adapted from ”NPRI Dataset v2.00 Data Format and Variable Descriptions” by Jack Gibson.

9.2 Can primary care data be used to monitor regional smoking prevalence? An analysis of The Health Improvement Network primary care data

This study formed part of a medical student project supervised by me and Sarah Lewis. I subsequently prepared the manuscript for publication. This study has been published in BMC Public Health.[288]

9.2.1 Background

Robust regional data on smoking prevalence are important for monitoring regional trends in smoking and evaluating the impact of national and regional tobacco control interventions. Currently, few large-scale high-quality regional data on smoking prevalence in the UK are available. The main source of regional prevalence data in the United Kingdom (UK) is national survey data. The General Lifestyle Survey (GLF), the current 'gold standard' for measuring smoking prevalence in Great Britain, has highlighted significant variation in smoking prevalence across the British regions.[50] However, survey data tend to be infrequently collected or have small sample sizes, particularly at the regional level, and there is often a significant time lag between the collection and the release of the data.[147, 184] Electronic primary care databases have the potential to provide a valuable source of regional data on smoking prevalence due to their size, availability of monthly data and continuity.

The Health Improvement Network (THIN) (http://www.epic-uk.org/thin.htm) is a database of UK electronic primary care records. The validity of THIN data has been demonstrated for major events.[178-183] More recently, THIN data on smoking status have been validated at the national level. From 2006 onwards there was, despite the very different methods of obtaining prevalence estimates between the two data sources, generally good agreement between the prevalence of current smoking recorded in

THIN and smoking rates based on national survey data from the GLF, suggesting that THIN may be an accurate means of monitoring smoking prevalence nationally.[184] However, the validity of THIN data on smoking prevalence at the regional level, which may be less precise as a result of smaller sample sizes and reduced representativeness, has yet to be demonstrated.

A validation study was therefore conducted comparing estimates of regional smoking prevalence from THIN with those from the GLF to assess whether THIN data can be used to monitor regional variation and trends in smoking prevalence.

9.2.2 Methods

The version of THIN used in this study contains the primary care records of approximately 8 million patients from 446 general practices in England, Scotland, Wales and Northern Ireland, of whom 3.2 million are currently registered with a practice and can be followed prospectively; retrospective data is available for the remaining patients who have since either died or transferred from THIN practices. Prospective medical records are recorded using the Vision general practice computer system software, and serve as the primary medical record for the practice. GPs are able to record diagnoses, demographic information, lifestyle characteristics (such as smoking status) and other medical information. The dataset represents approximately 6% of the UK population.[227]

Currently, the main source of statistics for monitoring smoking prevalence in Britain is a national, annual survey, the GLF,[51] formerly known as the General Household Survey (GHS). It collects information on a range of topics from around 16,000 adults aged 16+ living in private

households in England, Wales and Scotland each year. Topics include housing, employment, health, alcohol consumption and income as well as smoking, and data are available by age and sex. It uses a probability, stratified two-stage sample design and aims to interview all adults aged 16 or over at each sampled address.[158] In 2009 the response rate was 73%.[50] For this study, the GLF's measure of the prevalence of current cigarette smoking, which is obtained by asking respondents 'do you smoke cigarettes at all nowadays', was used. The data were weighted for non-response and also weighted to the population distribution of region, age group and sex.

The GLF covers England, Wales and Scotland only; therefore, the validation of the regional THIN prevalence data did not include data from Northern Ireland. The GLF surveys people aged 16 and over only, and therefore under 16s were also excluded from this study. GLF data from 2000 to 2008, stratified by government office region (GOR), were used in this study.

For each year from 2000 to 2009 all live patients who were over the age of 16 and registered with a practice on an index date of 1st July of that year were identified from the THIN dataset and stratified by region. THIN data are regionally stratified by Strategic Health Authority (SHA). SHAs are coterminous with GORs, except that the South East region is divided into two: South Central and South East Coast. The THIN data for these two SHA regions were therefore combined. Patients who registered with a practice within the previous three months were excluded from this analysis (the GP contract requires that the smoking status of newly-registering patients is recorded within three months for this recording to be financially rewarded). The prevalence of smoking each year was calculated from the data

recorded in medical records. All records of smoking status, identified by relevant Read Codes (a hierarchical dictionary of medical nomenclature [289]), entered into a patient's notes on or after their registration date were extracted. Patients were classified as current smokers at a given index date if their most recent smoking-related entry in their medical records prior to this index date identified them as such. The percentage of patients with no smoking status recorded decreased during the study period, from 36% in 2000 to 10% in 2009. A previous study has shown that the majority of patients with missing smoking records in THIN are ex or non-smokers, and therefore all patients with no smoking formation were assumed not to be current smokers at that point in time.[290]

The way in which estimates of smoking prevalence are obtained are clearly very different in THIN and the GLF; however, the previous validation of THIN smoking prevalence data also used the GLF as a comparator and found that the estimates were comparable from 2006, suggesting that it is appropriate to compare these two data sources.[184]

The sampling method of the GLF is designed to produce regionally representative estimates of smoking prevalence.[158] However, THIN comprises those GP practices in each region that have agreed to contribute their data to the database, and may not be regionally representative. Therefore the demographic structure of THIN at the regional level was initially compared with regional population estimates from the Office of National Statistics.[193] THIN was found to be highly representative in terms of age and sex structure at the regional level. Population pyramids showing the representativeness of THIN by age and sex on a regional basis are presented as supplementary online material (Additional file 1, available at http://www.biomedcentral.com/1471-2458/11/773/additional). Since both

GLF and THIN are regionally representative, the prevalence of smoking was compared between these two data sources directly, without standardisation for age or sex. To ensure that this assumption was appropriate, age and sex-standardised estimates were also calculated. These were calculated through indirect standardisation by applying age- and sex-specific smoking rates from the corresponding GLF data to the THIN population. These are extremely similar to the unstandardised estimates and are shown in additional file 2 (available at http://www.biomedcentral.com/1471-2458/11/773/additional).

Annual estimates of smoking prevalence in the different regions based on THIN were compared graphically with point estimates, and confidence intervals around those estimates, from the GLF, to assess whether regional estimates of prevalence in THIN are similar to those from the GLF. Confidence intervals were not drawn for THIN as its much larger sample size results in precise estimates and very narrow confidence intervals which are not easily graphically distinguishable from the point estimates. These confidence intervals are shown in additional file 3 (available at http://www.biomedcentral.com/1471-2458/11/773/additional).

The data used in this study form part of the recently-developed Nottingham Tobacco Control Database, a compilation of sources of smoking-related information at a national and regional level. All analysis was carried out in Stata Version 11.0 (Stata Corp, College Station, TX) and the analysis of THIN data for this study was approved by the Derbyshire Research Ethics Committee.

9.2.3 Results

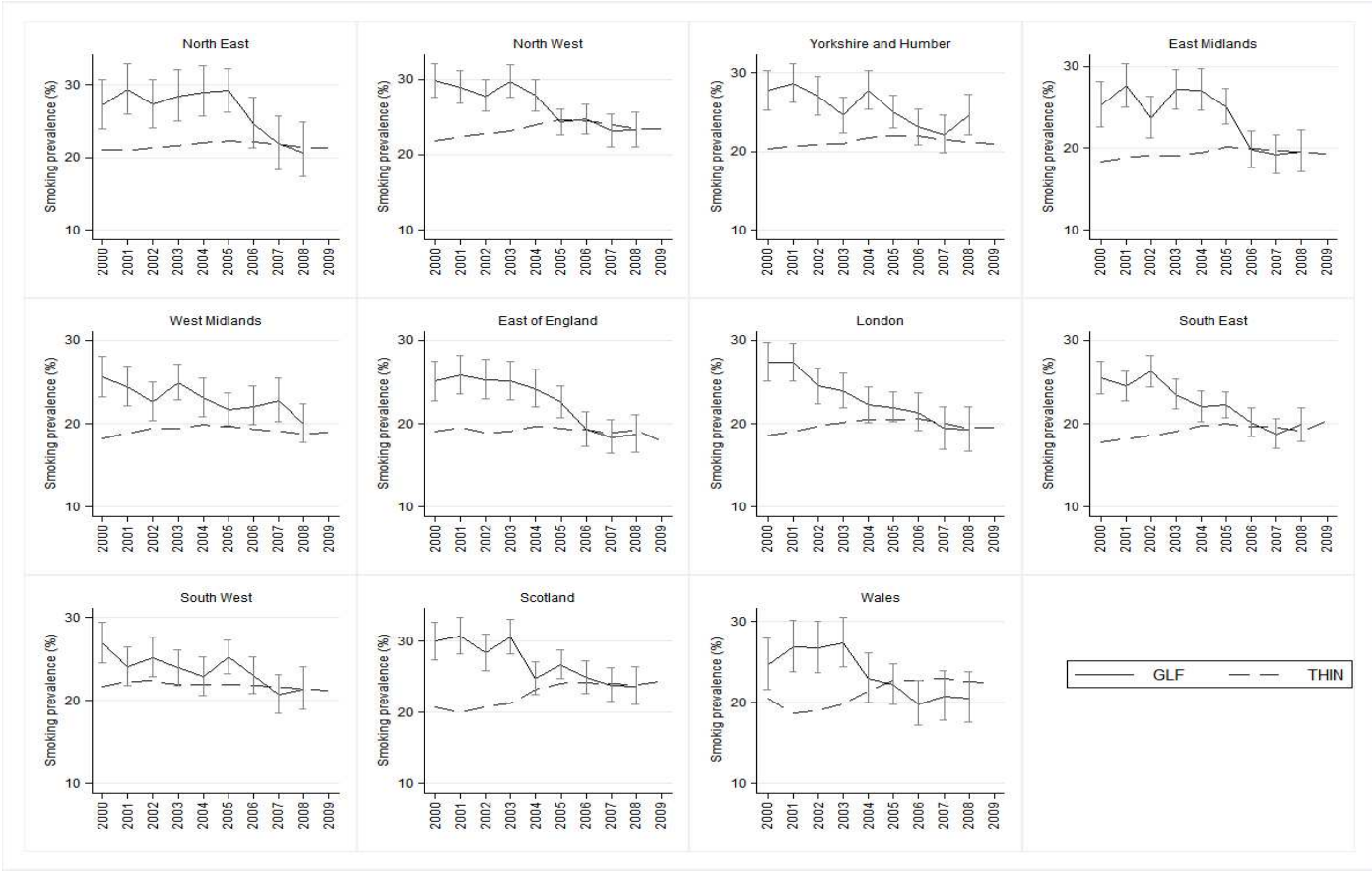
Table 9-1 below shows the sample sizes of the GLF and THIN by region in 2000 and 2008, demonstrating the much-reduced sample sizes in the regional data. The regional sample sizes in THIN remain extremely large, with over 100,000 people in each region in 2008. The regional GLF sample sizes are much smaller, ranging from 642 in the North East region to 2,082 in the South East in 2008.

Table 9-1. Sample sizes of General Lifestyle Survey and THIN, 2000 and 2008

	GLF 2000	THIN 2000	GLF 2008	THIN 2008
North East	686	99,054	642	109,322
North West	1,701	286,949	1,691	316,195
Yorkshire And	1,253	136,982	1,370	144,646
East Midlands	997	130,418	1,222	140,882
West Midlands	1,300	285,633	1,354	317,585
East Of England	1,348	222,265	1,497	243,355
London	1,504	293,421	1,207	338,859
South East	2,062	525,110	2,082	704,886
South West	1,303	290,763	1,420	350,742
Wales	724	141,372	830	210,585
Scotland	1,211	198,045	1,304	250,109
Total	14,089	2,703,864	14,619	3,245,031

Figure 9-1. Smoking prevalence by region from THIN and GLF (2000-2008) shows the comparison of THIN and GLF smoking prevalence data by region from 2000 to 2008. The GLF data show the general decreasing trend in smoking prevalence in recent years in all regions. In most regions, prevalence estimates from THIN converged with those from the GLF over the years of the study, with good agreement between the data sources, and THIN estimates falling within the confidence intervals of the GLF, from 2006 onwards.

Figure 9-1. Smoking prevalence by region from THIN and GLF (2000-2008)



In three regions this convergence is not observed. The data from the West Midlands did not converge during the study period, although the discrepancy between the two datasets fell, and the THIN estimate was within the confidence interval for the GLF estimate in the final year. The Yorkshire and Humber data converged during the study period, but the 2008 THIN estimate did not fall within the GLF confidence interval. The data from Wales converged from 2001 to 2005, at which point prevalence as measured by both data sources was approximately 22%. In subsequent years the values moved apart again; however, the THIN estimates were within the confidence interval for the GLF in the final two years of the study.

9.2.4 Discussion

To our knowledge, this is the first study to validate primary care smoking data at the regional level. These results show that estimates of regional smoking prevalence from THIN are highly comparable to the corresponding estimates from the current main source of such data. In most regions, smoking prevalence based on THIN data was similar to that found by the GLF from 2006 onwards. Primary care data could therefore be used to help target tobacco control initiatives at the areas with the highest smoking prevalence and to monitor prevalence across regions.

The main limitation of this study is that it was not possible to compare THIN data with the corresponding data for all of the UK's regions. The GLF covers Great Britain only, and therefore it was not possible to validate prevalence data for Northern Ireland. However, the results were

generally consistent across all regions that were included, and it is likely that THIN smoking prevalence estimates for Northern Ireland are similarly accurate. Further to this, it was not possible to explore the comparability of THIN and GLF prevalence estimates beyond 2008. Estimates from these two data sources were similar in the final three years of the study only; further research will be required in the future to ascertain whether this agreement is maintained in subsequent years.

A further limitation of this study is that the GLF and THIN may underestimate smoking prevalence, as both GLF respondents and general practice patients do not have their smoking status biochemically validated. However, the high costs associated with such validation mean that it is extremely difficult to obtain it for such large samples. In addition, because there is considerable variation in the completeness of recording between UK general practices, these results are not necessarily generalisable across all practices.

A final limitation of this study is that the significantly diminished sample sizes of the GLF at the regional level mean that there may be significant error in its estimates. However, during the study period the GLF was the largest survey providing regional prevalence data for Great Britain, and is therefore the most appropriate comparator.

Despite the diminished sample size of the THIN data at the regional level, the results of this study are broadly consistent with those of the previous validation study of these data carried out at the national level. As at the national level, prevalence estimates based on THIN from most regions were found to be similar to those based on the GLF from 2006.[184]

The convergence in prevalence estimates from THIN and the GLF is almost certainly a result of the voluntary, pay-for-performance general practice contract introduced in 2004.[291] The contract requires GPs to record their patients' smoking status at least every 27 months (every 15 months for patients with specified chronic diseases) and has been taken up by almost all GPs.[117]

Convergence between the two datasets by 2006 was not observed in all regions; there was greater discrepancy between the data sources for the West Midlands, Yorkshire and the Humber and Wales. Regional GLF data are based on small sample sizes, with resultant higher sampling error, as demonstrated by the wide confidence intervals, and any discrepancy between THIN and GLF estimates may reflect uncertainty associated with the GLF data rather than inadequacy of estimates from THIN. Further to this, while this study confirmed that THIN is representative regionally in terms of age and sex, it did not assess representativeness in terms of other factors such as social class. This may also account for some of the discrepancy in the three aforementioned regions. That even in these regions, the THIN estimates in two of the final three years (Yorkshire and Humber), the final year (West Midlands) and the final two years (Wales) of the study were within the confidence intervals of the GLF estimates demonstrates that estimates from GLF and THIN for these regions may indeed be comparable. The discrepancy in the final year of data for Yorkshire and Humber may be due to young adults being underrepresented in the THIN population of this region in the final year of the study (as shown in additional file 1).

There are several advantages to using THIN prevalence data compared with the national survey data. THIN data are routinely collected, are released 3-4 times per year, and have a lag of only 3-8 months before data become available.[184] A further advantage is its size; the standard error of THIN's smoking prevalence estimates is significantly smaller than those of the GLF at a national level.[184] At a regional level, GLF estimates are prone to more error due to much reduced sample sizes and confidence intervals are so wide, as demonstrated in Figure 9-1, that changes from year to year will be difficult to detect; therefore the large sample size in THIN is extremely valuable. Further to this, THIN provides monthly data, which is particularly useful in the evaluation of short term impacts of tobacco control initiatives.

Based on the THIN data, it was found that in 2008 Scotland (24%), the North West (23.5%), and Northern Ireland (23.5%) had the highest smoking prevalence in the UK. The East of England (19%), the West Midlands (19%) and South East England (19%) had the lowest prevalence. There remains substantial variation in smoking prevalence between the regions, with higher prevalence often being observed in regions with the lowest per capita disposable income.[292] Smoking is an important contributor to health inequalities.[53, 137] Therefore, reducing regional differences in smoking prevalence will contribute to alleviating health inequalities in the UK. This study indicates that THIN may be a useful source of data for monitoring these regional differences.

To our knowledge, the current study and that by Szatkowski et al. are the first to explore the possibility of using primary care data to monitor

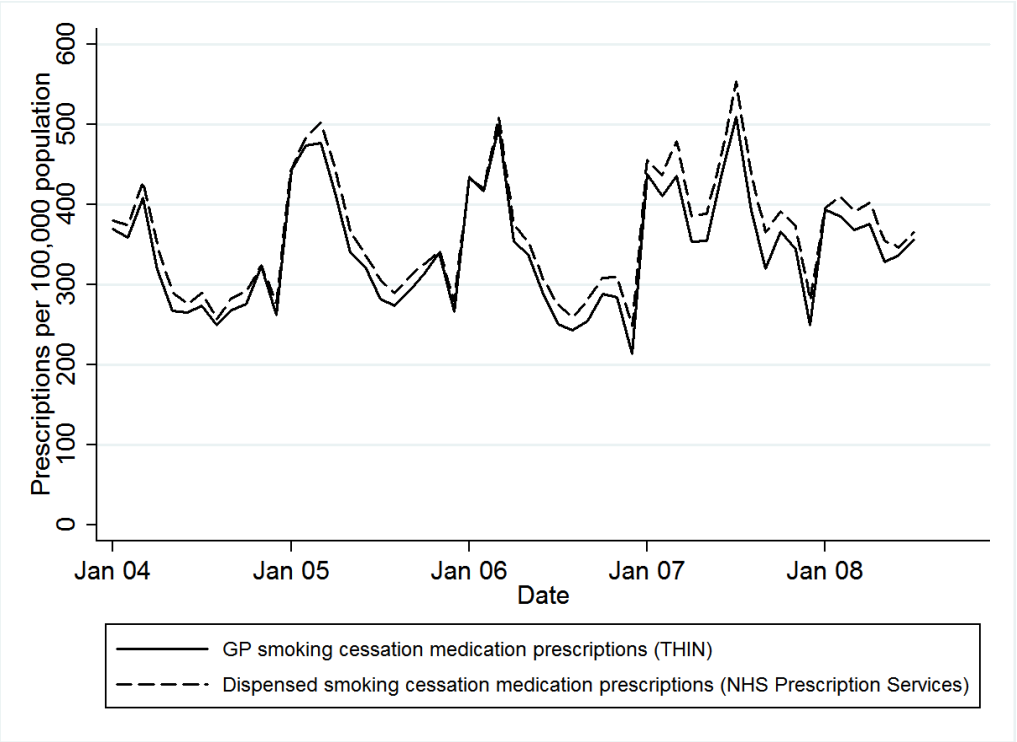
smoking prevalence; these results indicate that primary care data are a potentially valuable source of such information.[184] Previous research suggests that surveys which monitor smoking prevalence in EU Member States often have small sample sizes and are irregularly carried out.[285] This suggests that the way in which smoking prevalence is monitored internationally has similar limitations to the way it is currently monitored in Britain. Future research exploring the possibility of using primary care data to monitor smoking prevalence in countries other than Britain may therefore be warranted.

9.2.5 Conclusions

It is important to monitor regional patterns of smoking prevalence to ensure tobacco control measures in the UK are targeted at the areas most in need and help to reduce the health inequality caused by smoking. THIN data on smoking prevalence at the regional level are comparable with the main source of UK data on this measure, and could therefore be used to monitor longitudinal regional trends in smoking prevalence.

9.3 Validation of THIN smoking cessation medication prescribing data

Figure 9-2. Rates of prescribing of smoking cessation medication, England, based on THIN and ePACT, January 2004-July 2008



9.4 Stata commands for time series analysis

9.4.1 General time series commands

To declare data to be time series data:
tsset timevar

To draw a time plot of a series:
tsline series

To draw an autocorrelation function (ACF):
ac series

To draw a partial autocorrelation function (PACF):
pac series

To generate a new variable containing the first difference of a series:
gen dseries = D1.series

To generate a new variable containing the first seasonal difference of a series:
gen sdseries = S12.series

To generate a new variable containing the first differenced and seasonally differenced series:
gen dsdseries = D1.S12.series

To generate a new variable containing the natural logarithm of a series:
gen logseries = ln(series)

To generate a dummy variable indicating the presence of an intervention in a given month e.g. December 2006:
gen intervention = 0
recode intervention 0=1 if month==tm(2006-12)

9.4.2 Commands to fit a segmented regression model in Stata

To fit a simple linear regression:
regress series time level slope

To fit a Prais-Winsten regression:
prais series time level slope

9.4.3 Commands to fit an ARIMA model in Stata

To fit an ARIMA model to a pre-intervention series:
arima series if month<intervention_month, arima(p,d,q) sarima(P,D,Q,S)

To draw a histogram of the residuals from an ARIMA model:
predict residuals if timevar <= tm(2006,11), residuals

ac residuals if timevar <= tm(2006,11)
hist residuals, normal

To obtain the information criteria for a model:
estat ic

To estimate the impact of an intervention on a series:
arima D1.S12.series intervention, arima(p,0,q) sarima(P,0,Q,S)

N.B. If the series requires differencing (either first or seasonal) the prefix D1.S12, D1., or S12., must be placed before series variable on the left hand side of the command and d and D replaced by 0 on the right hand side. This is to ensure that the intervention variable is not itself differenced in the model estimation procedure.

9.4.4 Commands to fit a dynamic regression model in Stata

To check weak exogeneity assumption:
var output input, lags(numlist)
vargranger

If weak exogeneity confirmed, specify preliminary model:
arima output input l(numlist).input

N.B. Drop lags one at a time if non-significant.

9.4.5 Commands to fit a SVAR model in Stata

To specify the matrices:
matrix A = (1,0\.,1)
matrix B = (.,0\0,.)

N.B. The B matrix places restrictions on the error structure and usually takes the form above.

To run preliminary SVAR model:
svar input output, aeq(A) beq(B)

N.B. variables in SVAR command have to be in same order as in A-matrix

To work out lags required using information criteria:
varsoc

To include exogenous variables:
svar input output, aeq(A) beq(B) lags(1/2) exog(exogvar)

To check for autocorrelation in the model:
varlmar

N.B. Evidence of the presence of autocorrelation suggests a greater number of lags is needed.

To check stability (stationarity of the model):
varstable

To check whether model errors are normally distributed:
varnorm

To obtain tables and graphs of IRF and CIRF:
matrix sig_var=e(Sigma)
matrix list sig_var
matrix chol_var=cholesky(sig_var)
matrix list chol_var

irf set irf, replace
irf create name, step(12)
irf graph oirf, impulse(input) response(output)
irf table oirf, impulse(input) response(output)
irf table coirf, impulse(input) response(output)
irf graph coirf, impulse(input) response(output)

9.5 R code for segmented regression analysis

To read in data:

```
dat<- read.csv("/Volumes/data.csv")
dat[1:100,]
```

To draw time plot of data:

```
par(mfrow=c(1,1))
plot(dat$time, dat$series,type="l")
```

To fit linear model with predictors: time, level change, slope change:

```
mod1<- lm(series ~(time + level + slope),data=dat)
summary(mod1)
```

To plot model residuals:

```
hist(residuals(mod1), main="Model residuals")
resi<- residuals(mod1)
plot(dat$time,resi,type="b", main="Residuals over time")
abline(h=0)
```

To draw an autocorrelation function (ACF):

```
acf(resi, main="Residual ACF")
```

To draw a partial autocorrelation function (PACF):

```
pacf(resi, main="Residual PACF")
```

To model smooth seasonality with gam + time + level + slope:

```
library(mgcv)
mod2<- gamm(series~time+slope+s(month),data=dat)
summary(mod2$gam)
```

To model smooth seasonality with gam + time + level + slope + MA(2) errors:

```
library(mgcv)
mod2<- gamm(series
time+level+slope+s(month),data=dat,correlation=corARMA(c(0.5,
0.5),p=0,q=2))
summary(mod2$gam)
```

9.6 Results of sensitivity analyses for Chapter 5

Table 9-2. Results of ARIMA time series analysis of the impact of varenicline on prescribing of smoking cessation medication using doubled rates of prescribing of varenicline

	Change in prescribing	**95% CI**	**p-value**
Introduction of varenicline	0.06	-4.07-4.19	0.977
Publication of varenicline guidance	-2.14	-7.15-2.87	0.403

Table 9-3. Results of ARIMA time series analysis of the impact of varenicline on prescribing of smoking cessation medication omitting the final months of the time series

	NRT				**Bupropion**			
	Introduction of varenicline		**Publication of varenicline guidance**		**Introduction of varenicline**		**Publication of varenicline guidance**	
End of time series	**Change in prescribing (%)**	**p-value**	**Change in prescribing (%)**	**p-value**	**Change in prescribing (%)**	**p-value**	**Change in prescribing (%)**	**p-value**
Jul-07	**3.80**	**0.013**	**-**	**-**	**8.10**	**<0.001**	-	**-**
Aug-07	2.90	0.056	-28.16	1	**6.64**	**0.004**	-40.75	1
Sep-07	0.93	0.53	-29.17	0.805	3.55	0.097	-39.74	0.187
Oct-07	1.54	0.382	**-20.23**	**<0.001**	-0.17	0.948	**-27.61**	**<0.001**
Nov-07	-2.50	0.171	**-16.99**	**<0.001**	-1.96	0.477	**-23.66**	**<0.001**
Dec-07	-2.83	0.119	**-14.80**	**<0.001**	-2.76	0.316	**-20.20**	**<0.001**
Jan-08	**-3.81**	**0.033**	**-13.55**	**<0.001**	-3.88	0.155	**-19.13**	**<0.001**
Feb-08	-3.29	0.055	**-11.24**	**<0.001**	-4.18	0.123	**-17.59**	**<0.001**
Mar-08	**-3.57**	**0.034**	**-10.67**	**<0.001**	-4.19	0.117	**-16.05**	**<0.001**
Apr-08	-2.39	0.148	**-8.63**	**<0.001**	-3.00	0.236	**-13.29**	**<0.001**
May-08	-2.49	0.121	**-7.56**	**<0.001**	-3.93	0.090	**-13.34**	**<0.001**
Jun-08	-2.70	0.086	**-6.47**	**<0.001**	-3.86	0.089	**-12.99**	**<0.001**
Jul-08	-2.84	0.066	**-6.24**	**<0.001**	-3.97	0.071	**-12.86**	**<0.001**
Aug-08	-2.42	0.112	**-5.51**	**0.002**	-2.87	0.175	**-9.83**	**<0.001**

	NRT				Bupropion			
	Introduction of varenicline		Publication of varenicline guidance		Introduction of varenicline		Publication of varenicline guidance	
End of time series	**Change in prescribing (%)**	**p-value**	**Change in prescribing (%)**	**p-value**	**Change in prescribing (%)**	**p-value**	**Change in prescribing (%)**	**p-value**
Sep-08	-1.11	0.491	**-4.12**	**0.018**	-1.76	0.373	**-6.54**	**0.005**
Oct-08	-0.86	0.601	**-3.59**	**0.041**	-1.56	0.426	**-5.30**	**0.022**
Nov-08	-0. 75	0.644	**-3.62**	**0.036**	-1.74	0.361	**-5.06**	**0.028**
Dec-08	0.25	0.883	-2.34	0.104	-0.77	0.652	-3.29	0.102
Jan-09	0.15	0.927	-2.51	0.067	-1.30	0.403	-3.69	0.045
Feb-09	-0.27	0.864	**-2.82**	**0.028**	-1.09	0.474	-3.19	0.08
Mar-09	0.25	0.870	-2.34	0.059	-0.88	0.552	-2.76	0.13
Apr-09	-0.16	0.914	-2.26	0.066	-0.83	0.574	-2.55	0.163
May-09	-0.25	0.861	-2.20	0.071	-1.19	0.399	-2.90	0.093
Jun-09	-0.31	0.828	-1.78	0.159	-1.17	0.401	-2.80	0.108

Figures in bold: Significant at the 5% level

9.7 Impact of media campaigns on smoking cessation activity: descriptive analysis

This report was written for ASH UK, and informed the subsequent proposal for the study described in Chapter 7, which was funded by the Cancer Research UK Tobacco Advisory Group.

9.7.1 Background

International evidence has shown that anti-tobacco mass media campaigns can increase smoking cessation and reduce smoking prevalence.[82-87] However, the existing studies are heterogeneous, in terms of both the nature and intensity of the media campaigns and the populations studied, and the quality of the studies is variable.[293] Many studies have difficulty in distinguishing the impacts of media campaigns from those of other tobacco control policies that tend to occur concurrently, as well as other broad secular trends in smoking behaviour.[293] Furthermore, very few peer-reviewed academic studies have looked at the effectiveness of mass media campaigns in the UK; as such there is a dearth of UK-specific evidence.[173, 272-274] In the light of current public spending cuts, which threaten media spend on tobacco control, there is a need for evaluation of the effect of anti-tobacco advertising campaigns to be carried out in the UK.

The two main types of anti-tobacco advertising campaigns in the UK are government- or charity-funded anti-tobacco campaigns and pharmaceutical company-funded campaigns advertising smoking cessation medication. Government-funded anti-smoking mass media campaigns in the UK have conveyed the dangers of smoking and secondhand smoke, the implementation of smokefree legislation and smoking cessation services, with the aim of changing smoking behaviour. Some are targeted directly at

encouraging people to quit and try to help to enable quit attempts by advertising the services available to support people's quit attempts. Advertisements for nicotine replacement therapy (NRT) provide information on different types of NRT with the primary aim of increasing sales of NRT. However, by also conveying the health benefits of quitting, these adverts may also increase the number of people who want to quit smoking and influence quitting behaviour. Cuts in government funding seem likely to place greater reliance on pharmaceutical company-funded campaigns, and it is therefore important to consider the relative impact of both types of spend.

The aim of this study is to carry out a descriptive analysis, comparing monthly changes in advertising and a range of measures of quitting behaviour, to explore the possible association between these two types of anti-tobacco mass media campaigns and indicators of quitting behaviour, including calls to the NHS quitline, prescribing and over-the-counter (OTC) sales of nicotine replacement therapy (NRT), quit attempts and brief stop smoking advice given by GPs. This will guide and inform subsequent formal statistical work to model these associations by highlighting the measures of quitting behaviour most likely to be influenced by mass media campaigns. This work should not be considered to provide conclusive evidence of the effectiveness (or non-effectiveness) of anti-tobacco campaigns, but as a vital precursor to subsequent work

9.7.2 Aims and Objectives

The aim of this report is to explore whether changes in the level of anti-tobacco campaigns may influence changes in smoking cessation behaviour in England. The specific objectives of this work are

- to compare descriptively changes in measures of advertising reach of anti-tobacco campaigns funded by the Department of Health and changes in measures of quitting behaviour
- to compare descriptively changes in measures of advertising reach of anti-tobacco campaigns funded by pharmaceutical companies and changes in measures of quitting behaviour

9.7.3 Methods

Exposure Data

This study uses a standard broadcasting industry measure of the audience which views a television programme or advert, television ratings points (TVRs), as its measure of exposure to anti-tobacco mass media advertising and smoking cessation medication advertising. A TVR is defined as the percentage of a particular audience that has seen a commercial break. TVRs represent the total TVRs for a given area (such as the whole of the UK), and are calculated using population-weighted TVRs from each television region. They are therefore weighted for different levels of advertising in different regions. The measures of exposure to advertising are:

- TVRs purchased for tobacco control campaigns by the Central Office of Information (COI), Cancer Research UK and the British

Heart Foundation each month from January 2002 to May 2010, and

- TVRs purchased by pharmaceutical companies to advertise nicotine replacement therapy each month from January 2005 to December 2009.

The data from COI used in this study includes all mass media campaigns related to smoking, including those targeting young people and related to smokefree legislation.

Advertising spend data are also available. For this study, TVR data were selected over spend data, as these ought to provide a more accurate representation of exposure to campaigns. However, spend data were compared with TVR data to ensure that there would be no significant differences in the results depending on the exposure used.

Due to devolved responsibilities for health promotion media campaigns in the UK, the COI TVR data cover primarily cover England only, with some overlap into other home nations through advertising in the press. The data used in this study are for England and Wales only; the TVRs overlapping into Scotland and Northern Ireland have been removed, but those for Wales cannot be removed, due to overlapping television regions. The pharmaceutical company TVR data are available for the whole of the UK but, to allow better comparison with the government-funded campaign data, only data on England and Wales have been used in this study. The TVRs for England and Wales have been calculated by summing population-weighted values of TVRs for each television region in England and Wales.

Outcome data

This study uses five outcome measures which seem likely to be sensitive to changes in advertising exposure.

- Calls to the NHS quitline
- Prescribing of NRT, based on primary care data
- OTC sales of NRT
- Quit attempts, based on survey data
- Brief stop smoking advice given in primary care, based on primary care data

Calls to the helpline and NRT prescribing and OTC sales appear to be the measures most likely to be sensitive to changes in anti-tobacco advertising and smoking cessation medication advertising respectively. However, in order to better compare the impact of both types of media campaigns, we will explore, descriptively, the effect of both types of advertising on each of these outcomes, as well as their effect on brief advice and quit attempts.

The quitline calls and quit attempts data are available only for England. The primary care data are UK-wide, but, for consistency with the exposure variables, which cover England and Wales, we have identified and used prescribing data from within England and Wales. The OTC sales data cover England, Wales and Scotland; they are not available for Northern Ireland. They are broken down by region (although the sales in Wales cannot be separated from those in South West England), therefore we have used OTC NRT sales data on England and Wales for consistency with the exposure variables.

Quitline calls

Quitlines have been shown to be effective in helping smokers quit, and quitline calls are therefore an important measure of smoking cessation activity.[173-175] Many of the government funded mass media campaigns have included the NHS quitline number, and are therefore likely to have influenced calls to the quitline. This study uses the number of calls the NHS quitline per month from November 2004 to June 2010.

Prescribing of NRT and brief stop smoking advice

Both NRT and brief physician stop smoking advice have been shown to be effective in aiding smoking cessation.[126, 186] The Health Improvement Network (THIN) is a database of UK primary care records including all diagnoses and prescriptions recorded on all patients in nearly 500 practices throughout the UK, including 367 practices in England. It contains smoking-related data including prescribing of smoking cessation medication and brief stop smoking advice. These data have been extracted on a monthly aggregate basis in the Nottingham Tobacco Control Database, a compilation of sources of smoking-related information at a national level. The denominator for each month is the total number of live individuals contributing data to the THIN database throughout each month. We assumed that those contributing data within each month provided one person-month of follow-up, and divided the numbers of prescriptions by the total person months to derive the rate of prescribing and brief advice giving per 100,000 of the population per month from January 2002 to June 2009. THIN NRT prescription data have been validated in a previous study.[192]

NRT over-the-counter sales

OTC NRT has been used as an indicator of quitting activity and increases in sales may therefore increase the number of people quitting.[135, 164, 294] The OTC sales data used in this study are Electronic Point of Sales scanner data obtained from Information Resources Inc. (IRI, now Symphony IRI).[166] It includes data from all stores except Boots stores. IRI data are supplied as 4-weekly summaries. To convert these to monthly equivalents, it was assumed that 1/28th of sales occur on each day in each 4-week period. We graphically compared these data with confidential sales data from GSK to ensure validity. The monthly population denominators for these data were calculated using the Office for National Statistics mid-year population estimates for England and Wales for each year, increasing by one twelfth of the annual increase per month.[193] We divided the unit sales each month by the monthly population denominators to obtain the rate of sales per 100,000 population per month from November 2003 to September 2008.

Quit attempts

Quit attempts are evidently a vital measure of smoking cessation behaviour, and finding an effect of mass media campaigns on quit attempts would clearly be very valuable in arguing for the importance of such campaigns. This study uses monthly quit attempts data from The Smoking Toolkit, a monthly survey of around 500 smokers in England, which provides estimates of the proportion of smokers who have made a quit attempt in the past month each month since November 2006. This study uses data from November 2006 to December 2009.

Analysis

The monthly advertising exposure and monthly outcome measures were compared graphically to compare monthly changes and try to identify possible associations between anti-tobacco campaigns and smoking cessation behaviour. All analysis was carried out in Stata Version 11.0.

9.7.4 Results

Trends in exposures

Figure 9-3 shows government-purchased TVRs from January 2002 to December 2009 and pharmaceutical company TVRs from February 2005 to December 2009.

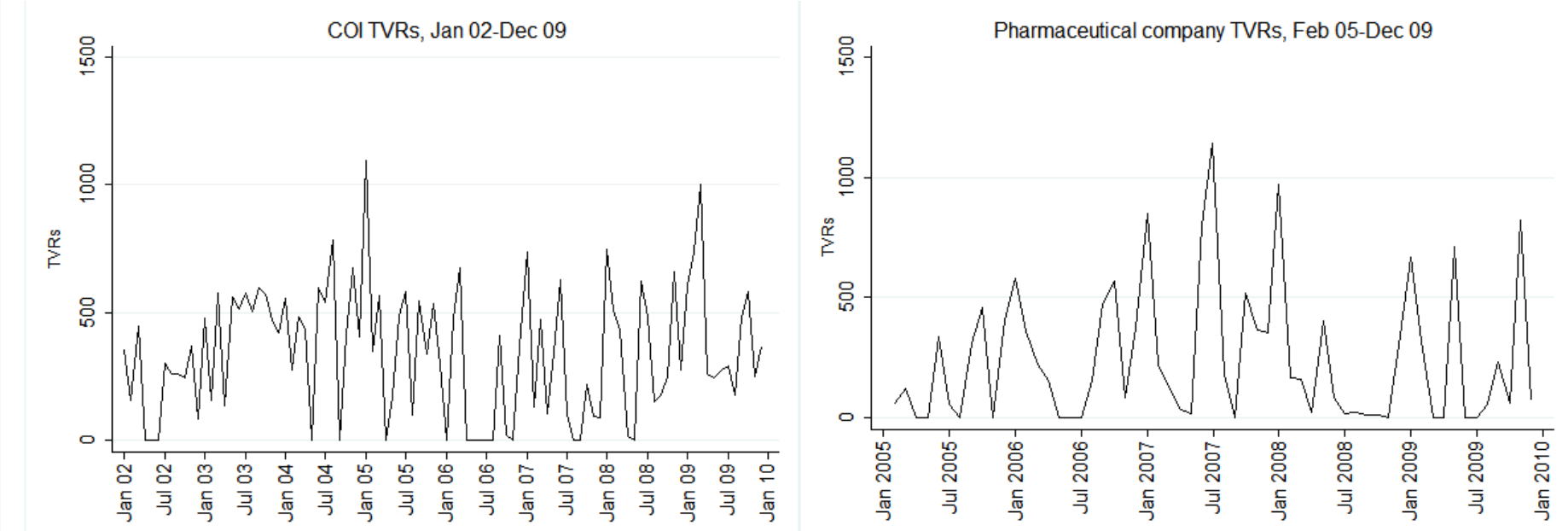
COI TVRs

There was no discernible trend in government-purchased TVRs during the study period, with much fluctuation from one month to the next. There were few months with no advertising. Campaigns appear to have been of longer duration until 2005, after which there was more fluctuation and months of zero spend until the latter part of 2008. TVRs were highest in January 2005 and 2010.

Pharmaceutical company GRPs and spend on NRT advertising

Pharmaceutical company TVRs for NRT advertising were characterised by peaks and troughs throughout the period. Most peaks in TVRs came in January. The largest peak was in July 2007, when smokefree legislation was implemented in England.

Figure 9-3. Advertising exposure variables, January 2002-December 2009



Trends in outcomes

Figure 9-4 shows plots of each outcome measure for the study period.

Quitline calls

There was a very large peak in quitline calls in January and February 2005, with around 70000 calls. The number of calls then levelled off at between 10 and 30 000 for the rest of the period. Seasonal peaks generally occurred in January to March each year.

NRT prescribing

NRT prescribing increased until 2005, and appears to have decreased in 2007. In most years there was a clear peak in prescribing in the first three months of the year and a much smaller peak in October.

NRT OTC sales

The level of OTC NRT sales changed little during the study period, with seasonal peaks of a similar magnitude in January to March each year. Sales in January tended to be approximately 50% higher than in the summer months. In July 2007, however, when smokefree legislation was introduced in England, sales were higher than in any other month during the study period.

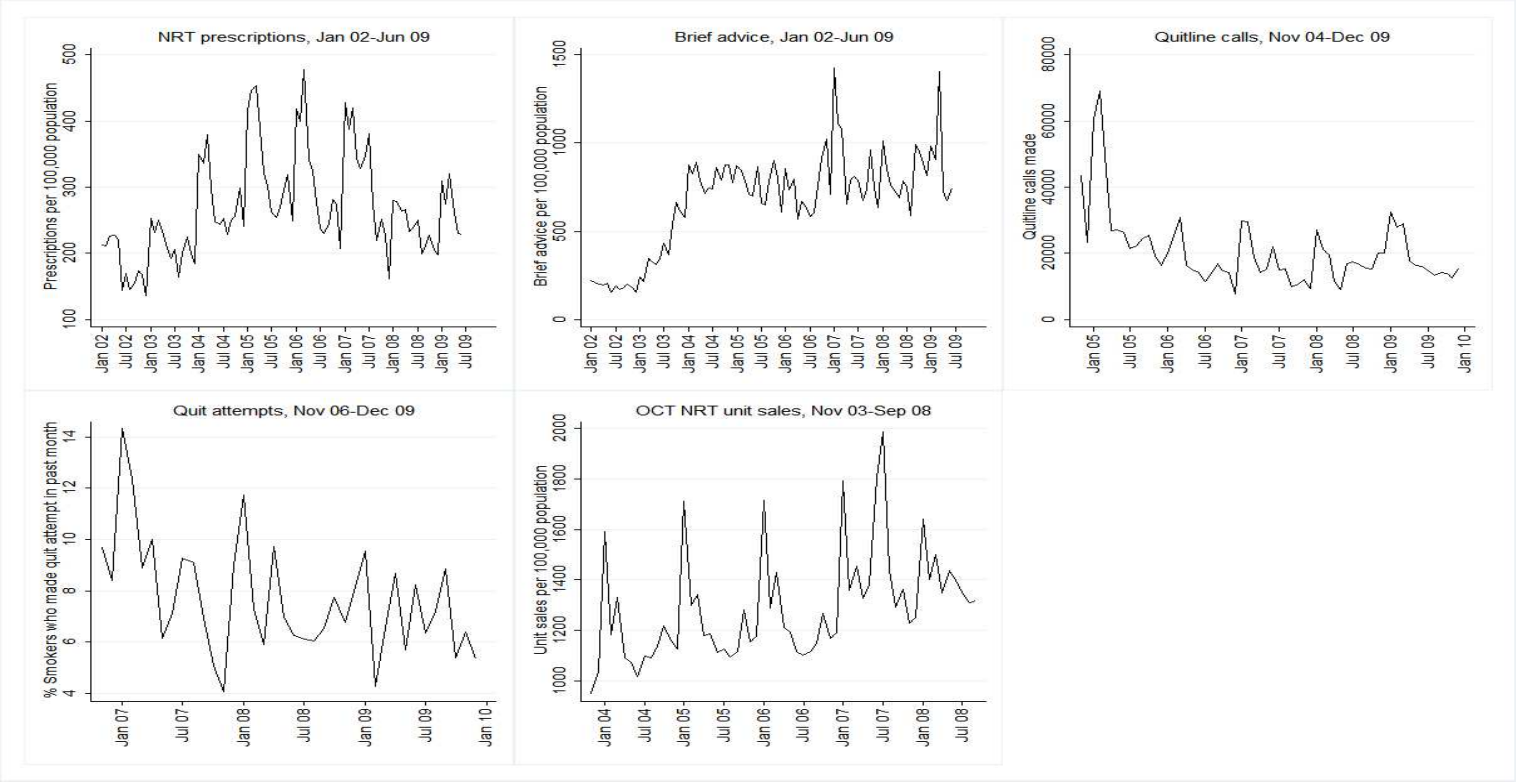
Quit attempts

In each year there was a peak in quit attempts in January, coinciding with the New Year. The largest peak in the proportion of smokers making quit attempts was in January 2007. There were also smaller peaks in April each year, following No Smoking Day in March.

GP stop smoking advice

Recorded brief stop smoking advice increased between January 2002 and the start of 2004, before levelling off. Subsequently, brief advice fluctuated between around 750 to 1000 per 100,000 per month, with small peaks in the autumn of each year and large peaks in early 2007 and in March 2009.

Figure 9-4. Quitting behaviour outcome variables, January 2002-January 2010



Descriptive comparisons

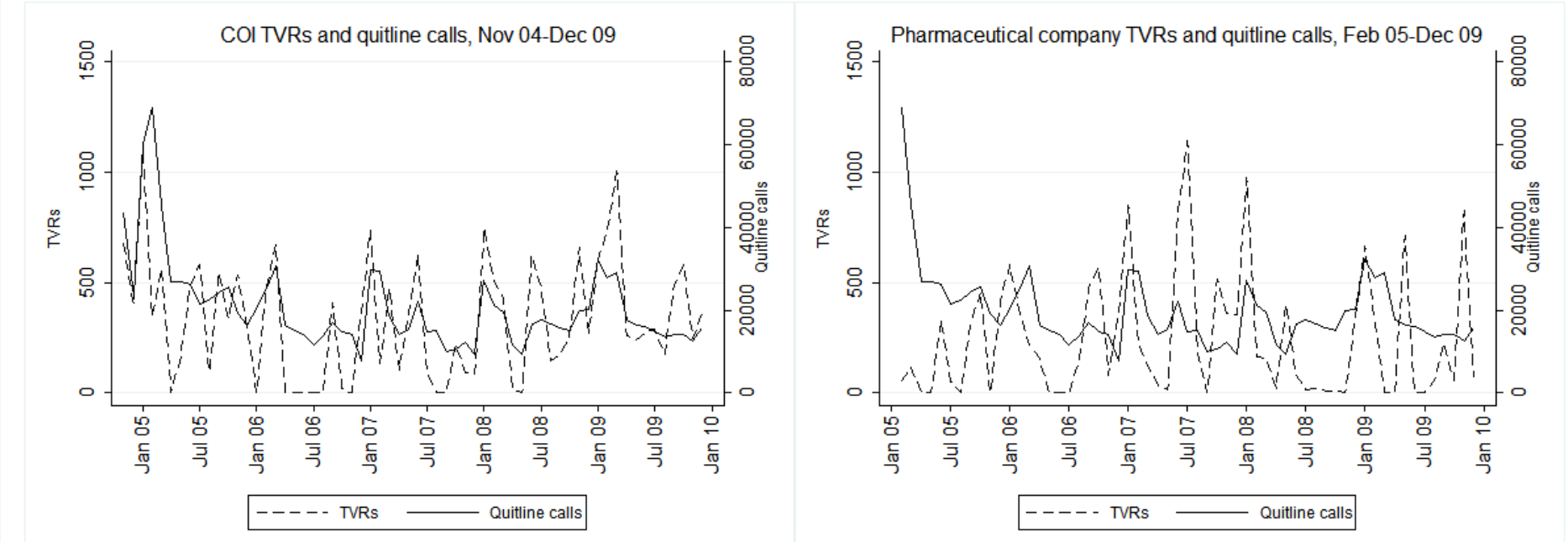
Advertising and quitline calls

Figure 9-5 below shows the number of government-purchased and pharmaceutical company TVRs purchased and quitline calls made in England each month from November 2004 to May 2010. During this period, there was no upward or downward trend in either of the series. In most years government-funded TVRs were high in the first three months of the year, especially in January, and similar seasonality is observed in the quitline calls. The time series seem to rise and fall, to a large extent, together. Furthermore, the number of calls appears to be particularly low when few or no TVRs are purchased.

Pharmaceutical company TVRs and quitline calls tended to show similar seasonal peaks in the early months of the year, but tended not to move together outside of the January to March period.

There was only a small peak in quitline calls in July 2007, when TVRs for both types of anti-tobacco campaign were high.

Figure 9-5. Comparison of trends: Anti-tobacco advertising and quitline calls, November 2004-December 2009

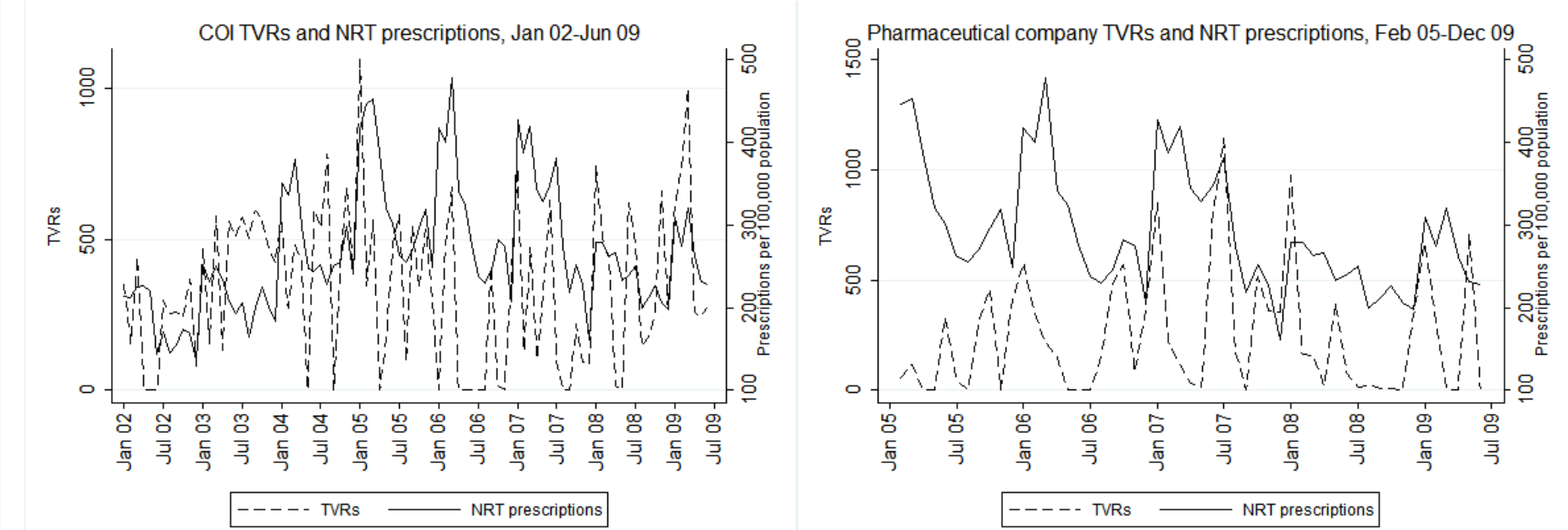


Advertising and NRT prescribing

Figure 9-6 below shows the number of government-funded and pharmaceutical company TVRs purchased and rates of NRT prescribing each month. It is more difficult to identify a potential association between government-funded TVRs and prescriptions than between government-funded TVRs and quitline calls (Figure 4). There is substantial movement together between the two time series; however, this is primarily seasonal variation and increased advertising and prescribing around the time of the introduction of smokefree legislation.

The same is true for pharmaceutical company TVRs for NRT: there does not appear to be an increase in prescribing in months where there is more advertising, except those months associated with increased quitting behaviour.

Figure 9-6. Comparison of trends: Anti-tobacco advertising and NRT prescribing, January 2002-December 2009

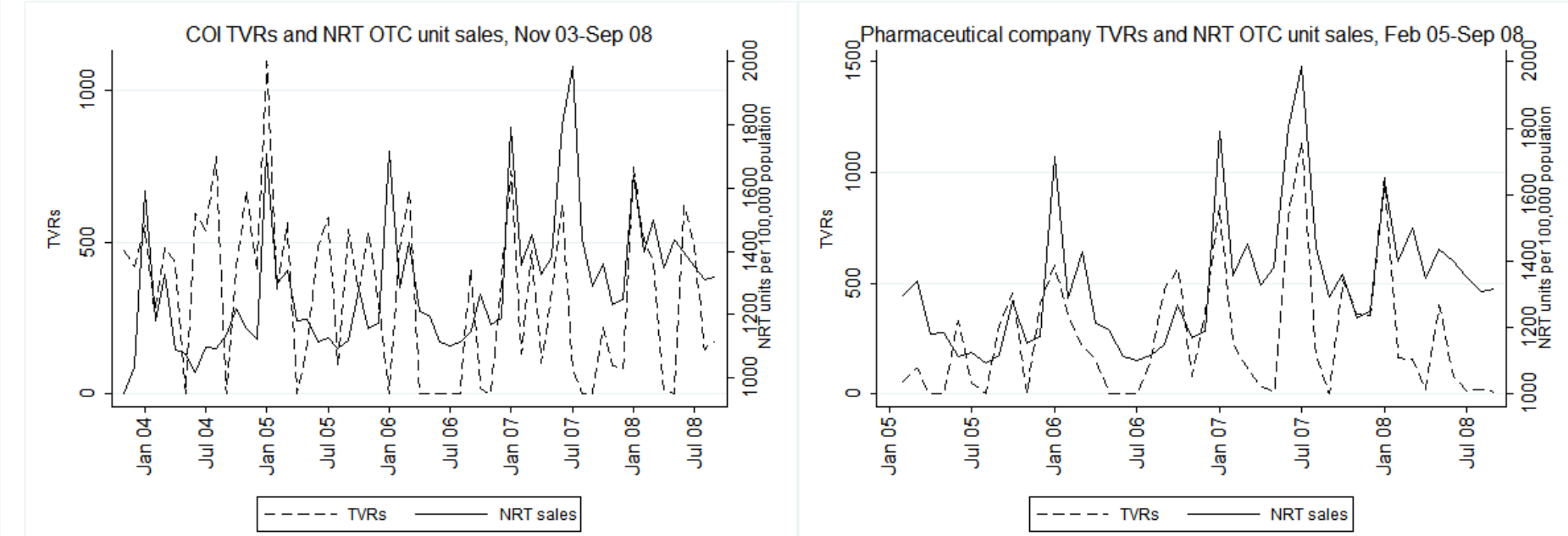


Advertising and NRT OTC sales

Figure 9-7 below shows the number of government-funded and pharmaceutical company TVRs purchased and monthly rates of OTC NRT sales. Government-funded TVRs and OCT NRT sales show similar seasonal trends, with peaks often in the early months of the year. In January 2006, there was no NRT advertising, yet a peak in sales comparable with those in other years. Aside from seasonal patterns and high TVRs and sales around the introduction of smokefree legislation, these variables tend not to rise and fall together.

Pharmaceutical company TVRs and OTC NRT generally rise and fall together. There are peak in both January and July 2007, with frequent smaller peaks in both time series in other months. Sales are lowest in months with little or no advertising.

Figure 9-7. Comparison of trends: Anti-tobacco advertising and OTC NRT sales, November 2003-September 2009

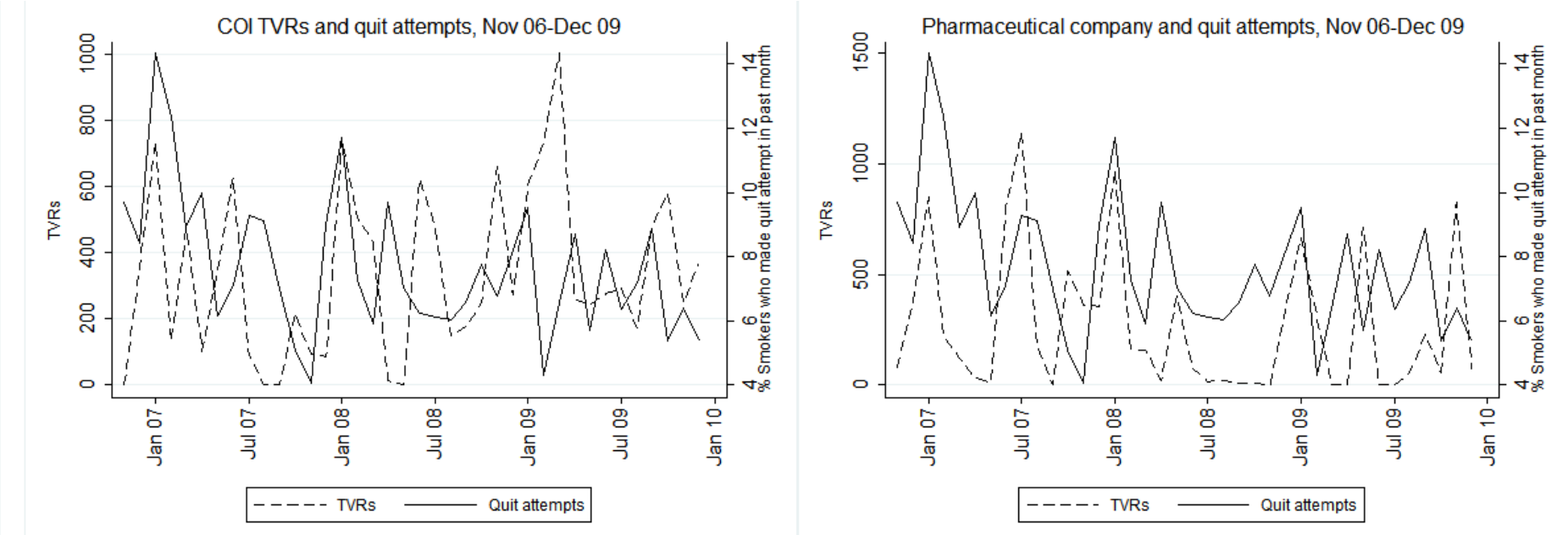


Advertising and quit attempts

Figure 9-8 below shows the number of government and pharmaceutical company-funded TVRs purchased and the proportion of smokers in England making quit attempts each month November 2006 to May 2010. Government-purchased TVRs and quit attempts both show seasonal peaks in January, and a peak around July 2007, when smokefree legislation was introduced. Over and above these similarities, these variables do not generally seem to move together.

The results are very similar for pharmaceutical company advertising and quit attempts.

Figure 9-8. Comparison of trends: Anti-tobacco advertising and quit attempts, November 2006-December 2009

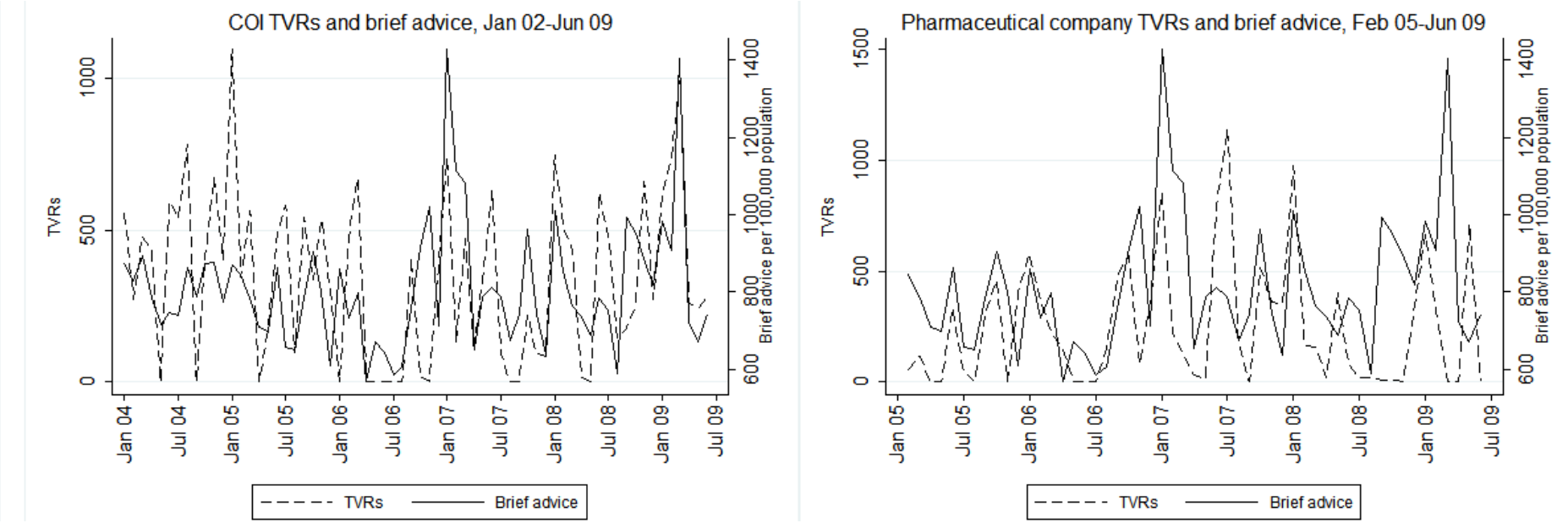


Advertising and brief advice

Figure 9-9 below shows the number of COI and pharmaceutical company TVRs purchased and the proportion of patients receiving brief stop smoking advice from their GP each month. There are similar fluctuations in the COI advertising and brief advice giving and low rates of advice giving in many of the months with little or no advertising spend. However, there was a low rate of brief advice in January 2005 despite a large peak in advertising, but in March 2009 there were large peaks in both advertising and brief advice.

Pharmaceutical company TVRs and brief advice moved very closely together throughout the early part of the study period, until early 2008. More recently, peaks in brief advice have not occurred in months with high levels of advertising. In March 2009 there was a large peak in brief advice and no pharmaceutical company-purchased advertising.

Figure 9-9. Comparison of trends: Anti-tobacco advertising and brief advice giving, January 2002-June 2009



9.7.5 Discussion

This report is the first step into important research exploring the effect of anti-tobacco mass media campaigns on smoking cessation behaviour. Mass media campaigns are an intervention which can reach whole populations at a low per capita cost, where small individual effects have the potential to have a substantial overall impact; therefore establishing their effects is important.[81, 272] It is 10 years since the last peer-reviewed study of the effect of mass media campaigns on smoking behaviour in the UK was published.[272] That study highlighted the sparsity of studies in this area, and yet there continues to be a dearth of UK-specific evidence, although the literature on these campaigns in the USA and Australia has increased. This descriptive study is the first step in a study which will begin to fill the gap in the evidence for anti-tobacco mass media campaigns in the UK.

Summary of results

This study found that it seems likely that government-funded and pharmaceutical company-funded antismoking advertising have an impact on some aspects of quitting behaviour. All the outcomes displayed some similarities in trends to the exposures. For the most part, both outcomes and exposures were similar in terms of seasonality; the exposures and outcomes had comparable peaks in the early months of each year, when quitting behaviour has been shown to be highest.[277] This may indicate an effect of advertising on quitting behaviour which is strongest in the early months of the year. However, it is possible that increased quitting behaviour in the early months of the year is independent of increased advertising. This means that where similarities in peaks and troughs of advertising and measures of quitting behaviour are only seasonal, there is

likely to be no true association between the aggregated measures of advertising used in this study and smoking cessation behaviour in England and Wales.

It seems most likely that government-funded anti-smoking advertising has an effect on quitline calls and, possibly, brief advice giving by GPs, and that pharmaceutical company-funded advertising for NRT influences OTC NRT sales and again, possibly, brief advice giving, as these appear to demonstrate similarities in monthly fluctuations over and above seasonal peaks.

Government anti-smoking advertising often contains the quitline number, and it is therefore unsurprising that quitline calls seems to be associated with advertising. Similarly, it is intuitive that NRT advertising should cause increases in OTC NRT sales and again, these are two time series that were similar. Perhaps more surprising, is the indication that brief advice may be influenced by advertising. If this is shown to be a true association, it perhaps indicates that some people obtain advice from their GP following advertising which has played a role in making them try to quit smoking.

Study limitations

This descriptive analysis is important, but has limitations which explain the need for detailed statistical analysis. The issues surrounding seasonality described above clearly highlight why descriptive analysis is not sufficient in exploring the effect of anti-tobacco advertising. It is not possible, using descriptive analysis, to adjust for seasonal effects (or confounders such as, for example, the introduction of smokefree legislation in July 2007, cigarette prices etc.), and it is therefore not possible to draw

conclusions as to the effect of mass media campaigns. It is therefore important to analyse these associations, particularly those which seem likely to be positive, using formal statistical analysis, which will enable us to adjust for these seasonal effects, as well as, to the extent that they can be accurately modelled, the effects of relevant confounders. Statistical analysis will also enable us to provide effect estimates, as well as exploring any lags in the effect of advertising on smoking cessation behaviour.

Furthermore, due to a lack of detailed information as to the content of the various campaigns, it was not possible to explore the effects of different types of mass media campaigns in this study. It is important to consider that different mass media campaigns, particularly government-funded ones, may differ substantially in their content. For example, they may aim to encourage smoking cessation or raise awareness of smokefree legislation or the dangers of passive smoking. These may have different effects on different measures of smoking cessation behaviour. The impact of such differences may be reflected in this analysis. For example, a peak in government-funded advertising did not coincide with a peak in brief advice in January 2005, but both were high in March 2009. The differential effects of different types of studies have been demonstrated in previous studies. For example, studies have shown that the number of quitline calls generated by advertising varied depending on the content of the adverts.[278, 279, 295, 296] Furthermore, there may be differential effects of campaigns in different sociodemographic groups, different types of media channels and of adverts shown on different channels and different times of day, as suggested by existing evidence.[278, 297] Both this study and the forthcoming statistical analyses of these data are likely to underestimate the effect of mass media campaigns in that they are unable to distinguish

between different types of campaigns, some of which may be more effective than others; if a positive effect of aggregated TVRs is found at this early stage, which seems likely, it will likely be obscuring a larger effect of particular campaigns.

A further analysis which should be carried out is a study which examines the effect of mass media campaigns on a regional basis. Advertising intensity varies across the country, partly due to variations in smoking behaviour (e.g. smoking prevalence). Analysis on a national level cannot pick up regional variation in the impact of anti-smoking campaigns, and may obscure the impact of mass media campaigns due to the inclusion of regions with little advertising and hence, little impact on cessation behaviour.

While this work, and subsequent statistical analyses of the data available, which will be carried out in 2011 in the context of the CRUK Tobacco Advisory Group-funded project, provide vital information, more detailed analysis exploring these differential effects in the future is crucial.

Selection of outcomes

An important public health outcome related to smoking and smoking cessation is smoking prevalence, and previous international evidence suggests that mass media campaigns can reduce this.[82] Ideally, therefore, this study would have used smoking prevalence as an outcome. However, the outcome measures use in this study were selected based on their availability on a monthly basis, likely or demonstrated validity, and likely sensitivity to changes in anti-tobacco mass media campaigns. Based on this, it is not possible, to include smoking prevalence as an outcome measure. Monthly prevalence data are available from THIN, but are likely

to be unreliable on a monthly basis and insufficiently sensitive to monthly changes in advertising exposure. Annual prevalence estimates are available from the General Household Survey (the most frequently cited source of UK prevalence estimates) and THIN (valid from 2006).[259] However, there are substantial limitations to using annual prevalence data to answer this research question. It restricts the number of data points (making statistical models less robust) and makes it more difficult to take account of the many other factors that may affect changes in prevalence over time, such as tobacco advertising bans, health warnings and smokefree legislation. Further to this, annual data may not be able to detect small or transient impacts on smoking prevalence which are the result of interventions being implemented at varying intensities during the year, thus leading to underestimated effects of campaigns.[82] This study and subsequent statistical analysis therefore have the disadvantage of not being able to study the impact of mass media campaigns on prevalence; however, by using other monthly outcomes, the impact of mass media campaigns can be more accurately explored, in terms of the lag time to impacts and the duration of impacts.

Given that it is not possible to use smoking prevalence as an outcome measure in this study, quit attempts are a potentially crucial outcome. Quit attempts ought to be related to smoking cessation, and may be more sensitive to changes in advertising than smoking prevalence. Unfortunately, few monthly data on quit attempts in the UK are available. This study uses data from the Smoking Toolkit, and the descriptive analysis suggests that it is unlikely that aggregated TVRs of either pharmaceutical company or government-funded advertising will be shown to have an effect on this measure of quit attempts. However, this may be

due the limitations of the outcome data. The monthly sample size is small (around 500), and as such the monthly estimates are prone to substantial error, thus making them less accurate on a monthly basis. Furthermore, these data start in November 2006, when the imminent implementation of smokefree legislation may have influenced quit attempts. Due to the brevity of the time series and lack of pre-smokefree legislation data, it is unlikely to be possible to adequately take account of its effect. Due to these limitations, it is not appropriate to rely on these quit attempts data in investigating the effect of anti-smoking advertising. Proxy markers of quitting behaviour used in this study, such as prescribing and OTC sales of NRT, which may be more sensitive to changes in anti-tobacco advertising, are therefore extremely important.

This is one of the reasons why this study included prescribing and OTC sales of NRT, brief stop smoking advice in primary care and quitline calls, as well as quit attempts, as outcome measures. Further to this, they are, as described in the methods section, important indicators of smoking cessation, and including multiple indicators can also help to elucidate pathways to quitting. The measures we have used come from large-scale data sources, and therefore confidence intervals around the monthly estimates ought to be narrow. The use of large-scale and population level data is particularly valuable for the evaluation of anti-tobacco mass media campaigns, as small effects may be expected at the individual level. Also, because these data are routinely collected, we have been able to obtain several years of monthly data. We therefore feel that we have selected measures which, though not ideal, are the best possible measures available for use in this type of study in the UK.

Comparison with previous research

The most likely potential associations appear to be between government advertising and quitline calls and between pharmaceutical advertising and OTC NRT sales. This is unsurprising, as these are the outcomes most directly linked with these exposures. This is also consistent with existing evidence. Several studies have demonstrated an association between anti-smoking campaigns and calls to quitlines.[173, 278-281, 296-302] Studies have shown that pharmaceutical company advertising for NRT can have a positive effect on OTC NRT sales, although advertising did not increase demand for all products studied.[82, 89] However, although studies have found increased sales of NRT, there is a moral hazard in NRT advertising which may counteract the benefits of increased NRT sales, and the effects of which may not be detected by looking at NRT sales alone. NRT advertising may lead people to the belief that quitting is easy, and may therefore encourage people to take up smoking, or encourage existing smokers to smoke more or delay quit attempts.[303] This is reflected in a study which looked at the effect of NRT advertising on youth smoking.[303] It found that although NRT advertising had no effect on the uptake of smoking (although this may have been due to both an increase in initiation of smoking and in cessation), it increased cigarette consumption in existing smokers, with an elasticity of 0.1. In the future it will be important to look at the differential effect of NRT advertising on different age groups, as its net effect on public health may be negative.

Study implications

The public health implications of this study then, are unclear; given the seasonal and policy factors influencing both exposures and outcomes, it is not possible to clearly gauge the effect of either government advertising campaigns or pharmaceutical company mass media campaigns

for NRT on any of the outcomes. It is highly likely, however, that there is an effect of government advertising on quitline calls and of pharmaceutical companies advertising on OTC NRT sales. It is therefore appropriate to focus on these as a next step, with a view to much more comprehensive analysis, taking into account all the issues mentioned above, in the future.

9.7.6 Conclusions

This descriptive analysis has demonstrated that it is highly likely that anti-smoking mass media campaigns have an effect on at least some indicators of smoking cessation behaviour. The statistical analysis funded by Cancer Research UK's TAG grant to be carried out from March this year will be helpful in using more robust statistical techniques to examine these relationships further. Together, these two pieces of work will be vital in increasing the evidence base for the effectiveness of anti-tobacco campaigns in the UK, and will, we hope, trigger further work in this complex and multi-faceted tobacco control policy area.

9.8 Validation of mass media TVR data against advertising spend data

Figure 9-10. Comparison of tobacco control TVR and spend data

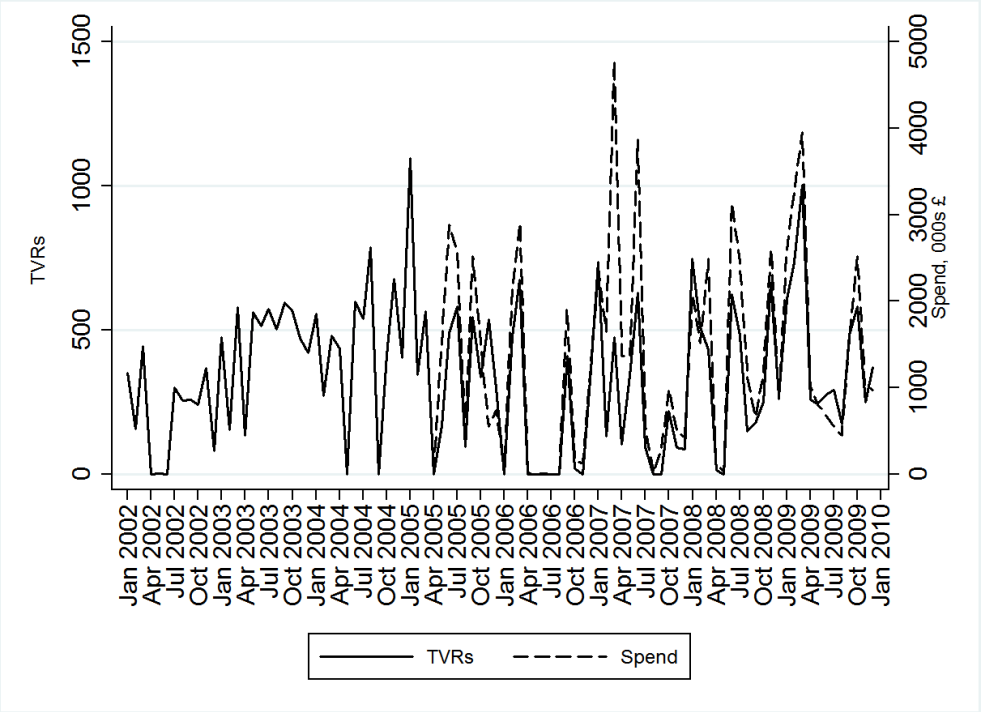
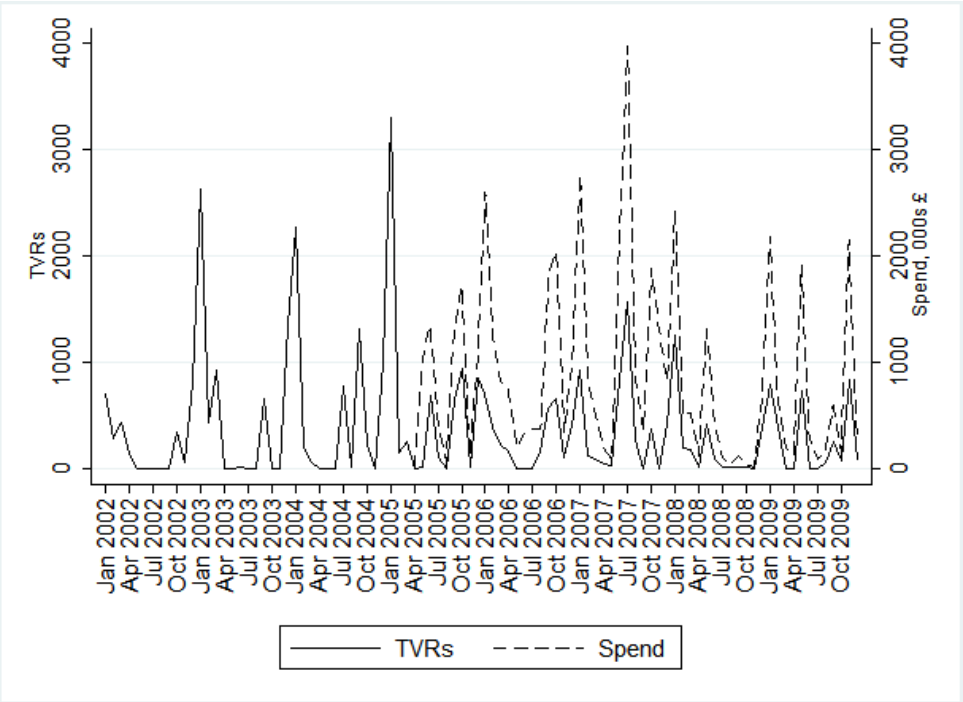


Figure 9-11. Comparison of pharmaceutical company TVR and spend data



9.9 Tobacco price, affordability and smoking prevalence in the UK

The analysis for this study was conducted by Dr Casey Quinn, based on the procedure for SVAR modelling I have used in Chapter 7. Casey Quinn wrote the first draft, and I prepared the final manuscript which has now been submitted for publication. The following abstract has been accepted for presentation at the World Conference on Tobacco or Health 2012.

Background

There is consistent evidence that increasing cigarette prices can reduce the prevalence of cigarette smoking. However, demand for tobacco products is only slightly responsive to price changes. The most recent peer-reviewed UK study examining the relationship between tobacco price and smoking found that men and women in lower socioeconomic groups were more responsive to changes in cigarette prices than higher socioeconomic groups. However, this study pre-dates significant tobacco pricing policies, notably the tobacco tax escalator that was implemented between 1993 and 2001. Given the recent re-introduction, in 2011, of above-inflation tobacco taxation in the UK, we re-examined the association between price and prevalence by sex and socioeconomic group before, during and after this policy was last in place.

Methods

We used Structural Vector Autoregressive (SVAR) modelling of time series data on adult smoking prevalence and different measures of tobacco affordability: a tobacco price index, a relative tobacco price index and a tobacco affordability index. We ran SVAR models for both sexes, manual

and non-manual groups, the three price and affordability indices and three time periods (1972-1992, 1993-2010 and 1972-2010).

Results

Our results from the 1972-1992 period are consistent with previously published studies. They show that tobacco prices are negatively associated with smoking prevalence, even though smoking overall is relatively inelastic with respect to price and income. Thus, while increases in price and decreases in affordability reduce prevalence, the effect is typically very small. The 1972-1992 period effects were not observed in the latter period; in most models, for the period 1993-2010, there was no statistically significant association between price and prevalence, indicating that elasticity has weakened further.

Likely explanations for this are that individuals adapted to increasing tobacco prices by using other forms of cheaper tobacco such as hand-rolled tobacco or forms of illicit tobacco such as smuggled or counterfeit, which increased in prevalence in the 1990s. A comprehensive strategy introduced to reduce tobacco smuggling introduced by the UK government in 2000 and strengthened at intervals since then has resulted in the market share for illicit cigarettes reducing; the proportion of smokers using hand-rolled tobacco has, however, continued to increase.

Conclusions

Smoking behaviours should be monitored closely and in a timely manner to establish the response of smokers to the price increases that will result from the recently re-introduced tobacco tax escalator. Measures to control smuggling and counterfeit cigarettes must also be maintained to ensure that the expected health benefits are realised.

9.10 Training

Epidemiology of Tobacco Use and the Tobacco Industry, 01-05/02/2010 (7.5 credits)

Tobacco Control Interventions, 07-11/06/2010 (7.5 credits of which 2.5 may contribute to postgraduate training programme)

Faculty Postgraduate Research Forum (Medicine and Health Sciences Faculty), 16/06/2010 (4 credits)

Creating and managing long documents in Microsoft Word, 25/10/2010 (2 credits)

Essential information skills for new researchers in Medicine and Health Sciences, 03/11/2010 (1 credit)

What do I want to get out of a conference – and how do I do it? 16/11/2010 (1 credit)

Using posters to communicate research, 25/11/2010 (1 credit)

Getting going on your thesis, 07/12/2010 (2 credits)

Finishing your thesis, 07/07/2011 (1 credit)

Preparing for the viva, 16/11/2011 (1 credit)

9.11 Grants

Langley T (Principal Investigator), Lewis S, McNeill A, Arnott D, Sims M. The impact of media campaigns on smoking cessation activity. Cancer Research UK Tobacco Advisory Group Project Grant. £15,428.33. March-August 2011.

9.12 Presentations

Invited presentations

Invited to give UK National Smoking Cessation Conference plenary presentation entitled 'Mass Media Campaigns', Birmingham, 18th-19th June 2012

Conference presentations

The use of primary care data to monitor smoking prevalence and supply of smoking cessation medication. Oral presentation, UK Society for Behavioural Medicine/National Prevention Research Initiative Annual Scientific Meeting, Southampton, 14th-15th December 2009.

Prescribing of smoking cessation medication since the introduction of varenicline. Oral presentation, UK National Smoking Cessation Conference, Glasgow, 14th-15th June 2010.

Prescribing of nicotine replacement therapy in adolescents in England. Oral presentation, Society for Academic Primary Care Annual Scientific Meeting, Norwich, 7th-9th July 2010.

Prescribing of smoking cessation medication in England since the introduction of varenicline. Poster presentation, Annual Meeting of the SRNT Europe, Bath, 6th-9th September 2010.

Prescribing of smoking cessation medication in England since the introduction of varenicline. Oral presentation, UK Society for Behavioural Medicine/National Prevention Research Initiative Annual Scientific Meeting, Leeds, 14th-15th December 2010.

Prescribing of nicotine replacement therapy in adolescents in England. Oral presentation, European Conference Tobacco or Health, Amsterdam, Netherlands, 28th-30th March 2011.

The impact of anti-tobacco mass media campaigns: feedback from a smokers' panel. Oral presentation, UK National Smoking Cessation Conference, London, 13th-14th June 2011.

Prescribing of nicotine replacement therapy to cardiovascular disease patients in England. Poster presentation, Annual Meeting of the SRNT Europe, Antalya, Turkey 8th-11th September 2011.

Regional smoking prevalence and quitting behaviour in the UK: Validation of The Health Improvement Network primary care data. Poster presentation, Annual Meeting of the SRNT Europe, Antalya, Turkey 8th-11th September 2011.

Tobacco control or pharmaceutical companies – Whose mass media campaigns have a bigger impact on quitting behaviour? Poster presentation, Annual Meeting of the SRNT Europe, Antalya, Turkey, 8th-11th September 2011.

A comprehensive evaluation of the impact of English tobacco control policy on smoking cessation activities: Results and lessons learned. Poster presentation at 7th Annual Scientific Meeting of the UK Society for Behavioural Medicine, Stirling, 13th-14th December 2011.

A comprehensive evaluation of the impact of English tobacco control policy on smoking cessation activities: Outcomes and lessons learned. Accepted for poster presentation at World Conference on Tobacco Or Health, Singapore, 20th-24th March 2012.

Tobacco control or pharmaceutical companies – Whose mass media campaigns have a bigger impact on quitting behaviour? Accepted for oral presentation at World Conference on Tobacco Or Health, Singapore, 20th-24th March 2012.

Tobacco price, affordability and smoking prevalence in the UK. Accepted for poster presentation at World Conference on Tobacco Or Health, Singapore, 20th-24th March 2012. (senior author and presenting author)

Using multiple time series analysis in public health research: An example using an evaluation of the impact of anti-tobacco mass media campaigns in

England and Wales. Accepted for oral presentation at Population Health – Methods and Challenges Conference, Birmingham 24th-26th April 2012.

Other presentations

A comprehensive evaluation of the impact of English tobacco control policy on smoking cessation activities: Background and early findings, Tobacco research group monthly meeting, 12th April 2010 .

A comprehensive evaluation of the impact of English tobacco control policy on smoking cessation activities: Background and early findings, UK Centre for Tobacco Control Studies postgraduate conference 2010, 20th April 2010.

Prescribing of nicotine replacement therapy to adolescents in England, UK Centre for Tobacco Control Studies postgraduate conference 2010, 21st April 2010 (poster presentation).

Evaluating the impact of English tobacco control policies on quitting behaviour, Epidemiology and Public Health Divisional Seminar, 14th February 2011.

Evaluating the impact of English tobacco control policies on quitting behaviour, Health Economics Research @ Nottingham (HER@N) seminar, 15th March 2011.

Impact of mass media campaigns on smoking cessation, UK Centre for Tobacco Control Studies Smokers' Panel, Bath, 16th March 2011

Evaluating the impact of English tobacco control policies on quitting behaviour, UK Centre for Tobacco Control Studies Postgraduate Student Conference, 21st-22nd November 2011.

9.13 Publications arising

Langley T, Szatkowski L, Gibson J, et al. Validation of The Health Improvement Network (THIN) primary care database for monitoring prescriptions for smoking cessation medications. Pharmacoepidemiology Drug Safe 2010;196(6):586-90.

Langley T, Huang Y, McNeill A, et al. Prescribing of smoking cessation medication in England since the introduction of varenicline. Addiction, 2011;106(7):1319–24.

Langley T, Huang Y, McNeill A, et al. Response to Kotz *et al*. (2011): Estimating the rate of usage of varenicline and other medication for smoking cessation. Addiction, 2001; 106(10):1869.

Langley T, Huang Y, McNeill, et al. Prescribing of nicotine replacement therapy in adolescents in England. Addiction, 2011;106(8):1513-1519.

Langley T, Szatkowski L, McNeill A, et al. Prescribing of nicotine replacement therapy to cardiovascular disease patients in England. Addiction (in print).

Langley T, McNeill A, Lewis S, et al. The impact of media campaigns on smoking cessation activity: a structural vector autoregression analysis. (submitted)

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