The University of Nottingham

Can primary care data be used to evaluate the effectiveness of tobacco control policies?

Data quality, method development and assessment of the impact of smokefree legislation using data from The Health Improvement Network

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ABSTRACT

Background Smokefree legislation is just one of a number of tobacco control policies introduced in the UK in the last decade in an attempt to curb the harm caused by smoking. Whilst such legislation is known to have reduced non-smokers' exposure to environmental tobacco smoke, less is known about whether the introduction of a smoking ban encourages existing smokers to attempt to quit and to seek support to do so from appropriate sources such as their general practitioner. High quality data are needed to evaluate the effectiveness of legislation in prompting smokers to change their smoking behaviour, and data collected routinely in primary care may provide such an opportunity. However, there is little contemporary evidence about the quality of the smoking data recorded in primary care, nor how best to analyse these data, which must be addressed before the resource can be used to evaluate the effectiveness of tobacco control policies.

Methods Initially, a systematic review was undertaken to assess the impact of national comprehensive smokefree legislation on population smoking prevalence, cigarette consumption and quitting behaviour. Then, the quality of smoking status and cessation intervention recording in The Health Improvement Network (THIN) database, a large database of UK primary care records, was investigated using indirect standardisation to compare rates of recording with external data sources. Having identified Autoregressive Integrated Moving Average (ARIMA) interrupted time series analysis as an appropriate method to assess the impact of smokefree legislation on measures of smoking-related clinical activity recorded in THIN data, several sensitivity analyses were untaken to assess the impact of decisions that must be taken during the data analysis process. In the light of this knowledge, ARIMA models were used to investigate changes in the rate of recording of patients' smoking status, delivery of cessation advice, referral of smokers to

specialist cessation services and prescribing of smoking cessation medications in the months leading up to, and after, the introduction of smokefree legislation.

Results The findings of the systematic review provide some evidence that in populations where well-enforced, comprehensive smokefree policies have been implemented quitting activity increased in the run up to, and/or following, the introduction of the legislation. Assessment of the quality of the smoking information recorded in THIN showed that the data have improved in recent years, such that the recorded prevalence of smoking is now similar to that reported in national surveys. Some uncertainty does, however, remain about the quality of recording of the delivery of cessation advice or referral of smokers to cessation services. ARIMA modelling highlighted a 6.2% increase in Nicotine Replacement Therapy (NRT) prescribing in the six months before smokefree legislation was introduced in England, and a 13.2% increase in bupropion prescribing in the three months pre-ban. A 5.5% decline in NRT prescribing and a 13.7% decline in bupropion prescribing were seen in the nine months post-legislation, declines which were offset to an extent, but not completely, by prescribing of varenicline which was first available on prescription in December 2006. Similar, though non-statistically significant, patterns were seen in Scotland, Wales and Northern Ireland, where the smaller number of practices in THIN in these countries reduced the power to detect small changes in prescribing. In England, the patterns of change in prescribing did not differ with patient sex, age group, medical history or social class.

Conclusions The improved quality of the smoking data recorded in the THIN dataset suggests that primary care data may be a valuable resource with which to evaluate the effectiveness of tobacco control policies such as smokefree legislation. The significant increases in prescribing of NRT and bupropion in the run-up to the introduction of smokefree legislation in the UK suggest that smokers

looking to quit may seek support to do so from primary care, though the decline in rates of prescribing post-legislation suggests that this positive change may not be sustained. This may represent a missed opportunity to maximise the impact of smoking bans by ensuring that smokers are aware of, and indeed access, cessation support available through primary care both before and after legislation is enacted, and should be noted by policy makers planning the introduction of smokefree legislation elsewhere. Ensuring that smokers are aware of, and indeed access, the effective support that is available through primary care to help them quit may be one way to maximise the positive impacts of smokefree legislation and reduce the health and economic burdens of continued tobacco use.

PEER-REVIED PUBLICATIONS AND PRESENTATIONS ARISING FROM THIS THESIS

Szatkowski L, Lewis S, McNeill A, Coleman T. Is smoking status routinely recorded when patients register with a new GP? *Family Practice*. 2010. 27:673-75.

Szatkowski L, Lewis S, McNeill A, Coleman T. Can data from primary care medical records be used to monitor national smoking prevalence?
Submitted and currently under review.

Szatkowski L, McNeill A, Lewis S, Coleman T. A comparison of patient recall of smoking cessation advice with advice recorded in electronic medical records.
Submitted and currently under review.

Szatkowski L, Lewis S, McNeill A, Coleman T. The impact of the introduction of smokefree legislation on prescribing of stop-smoking medications in England.
Submitted and currently under review.

Szatkowski L, Coleman T, Lewis S, McNeill A. Can national smoking prevalence be monitored using primary care medical records data? *Society for Academic Primary Care 38th Annual Scientific Meeting*, St Andrews, 8-10th July 2009 (Oral presentation)

Szatkowski L, Lewis S, McNeill A, Coleman T. Can national smoking prevalence be monitored using primary care medical records data? *Society for Social Medicine Annual Scientific Meeting*, Newcastle, 9-11th September 2009 (Oral presentation)

Szatkowski L. How useful are large datasets of primary care medical records in evaluating the impacts of smokefree legislation on current smokers' behaviour? *Society of Research on Nicotine and Tobacco – Annual meeting of SRNT Europe*, Bath, 6-9th September 2010 (Oral symposium presentation)

Szatkowski L, Lewis S, McNeill A, Coleman T. The impact of the introduction of smokefree legislation on prescribing of stop-smoking medications in England. *European Conference on Tobacco or Health*, Amsterdam, 27-30th March 2011 (Oral presentation)

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LIST OF ABBREVIATIONS

95% CI	95% Confidence Interval
ACF	Autocorrelation Function
AHD	Additional Health Data
ARIMA	Autoregressive Integrated Moving Average
ASH	Action on Smoking and Health
BMA	British Medical Association
CHD	Coronary Heart Disease
CHS	Continuous Household Survey
COPD	Chronic Obstructive Pulmonary Disease
EPIC	Epidemiology and Pharmacology Information Core
FCTC	Framework Convention on Tobacco Control
GHS	General Household Survey
GLF	General Lifestyle Survey
GP	General Practitioner
GPRD	General Practice Research Database
HCP	Health Care Professional
HEA	Health Education Authority
InPS	In Practice Systems
MLE	Maximum Likelihood Estimation
NHS	National Health Service
NICE	National Institute of Health and Clinical Excellence
NRT	Nicotine Replacement Therapy
ONS	Office for National Statistics
OTC	Over-the-counter
OXMIS	Oxford Medical Information Systems
PACF	Partial Autocorrelation Function
PCT	Primary Care Trust
QOF	Quality and Outcomes Framework
RCT	Randomised Controlled Trial
TAC	Tobacco Advisory Council
THIN	The Health Improvement Network
TIA	Transient Ischemic Attack
UK	United Kingdom
VAMP	Value Added Medical Products
VAT	Value Added Tax
WHO	World Health Organisation

1. INTRODUCTION

1.1. THE BURDEN OF SMOKING

Smoking is arguably the most preventable threat to public health worldwide[1], responsible for the deaths of some 100 million people globally in the twentieth century, and with the potential to kill one billion before the end of this century[2]. In 2009 an estimated 81,400 adults aged over 35 in England died from smoking-related illness; 23% of all deaths amongst men and 14% of deaths amongst women can be attributed to the effects of smoking[3]. These deaths included 37,500 from cancer, 22,000 from respiratory disease and 20,600 from diseases of the circulatory system[3]. At least half of all smokers, and possibly as many as two-thirds[4], will die prematurely as a result of their smoking behaviour, on average eight years earlier than if they hadn't smoked[5]. Smokers are also at risk of conditions which, although they might not kill them, result in significant loss of quality of life, such as asthma, osteoporosis, cataracts and hip fracture[2].

In 2003, at least 12,000 deaths in the United Kingdom (UK) were attributable to non-smokers' exposure to environmental tobacco smoke[6], and, in addition, young people exposed to role-models who smoke are more likely to become smokers themselves[7]. Expectant mothers exposed to tobacco smoke, through either active or passive smoking, place the health and survival of their unborn child at significant risk[8].

Smoking also places a considerable economic burden on both individuals and society. In March 2010 the cost of a typical packet of 20 cigarettes in the most popular price category stood at £6.29, rendering the yearly cost of smoking 20 cigarettes daily just less than £2300[9]. This cost hits the poor, who spend a larger

proportion of their income on cigarettes than more affluent smokers, the hardest[10]. The financial cost of smoking for a country's healthcare system is staggering; the direct cost of smoking to the National Health Service (NHS) was an estimated £5.2 billion in 2005-6[11].

1.2. TRENDS IN SMOKING BEHAVIOUR

Cigarette consumption in the UK rose steadily after the opening of the nation's first commercial cigarette production factory in the 1850s, following a pattern seen throughout the industrialised world whereby the behaviour was adopted by men first, with the 'innovation' then diffusing to boys, women, and, finally, girls[12]. Figure 1.1 shows the prevalence of cigarette smoking (and, for men, the prevalence of smoking all types of tobacco) in Britain since 1948. Figures from the General Lifestyle Survey (GLF), now the standard point of reference for smoking statistics[*], are broadly comparable to those from the Tobacco Advisory Council (TAC), the main source of statistics from 1948 to 1971.

As Figure 1.1 illustrates, major reductions in adult smoking prevalence were achieved in Britain between 1972 and the early 1990s. However, throughout the mid- to late-1990s, and during the first part of the 21st century, there was relatively little further decline in the proportion of men and women smoking, though there was evidence of renewed decline in the second half of the 2000s. The most recent figures from the 2008 GLF suggest that 22% of men and 21% of women in Britain are regular cigarette smokers[13]. However, these crude figures disguise significant variations in smoking prevalence and quitting behaviour between sub-groups within the population.

[*] Prior to 2008 the General Lifestyle Survey was known as the General Household Survey

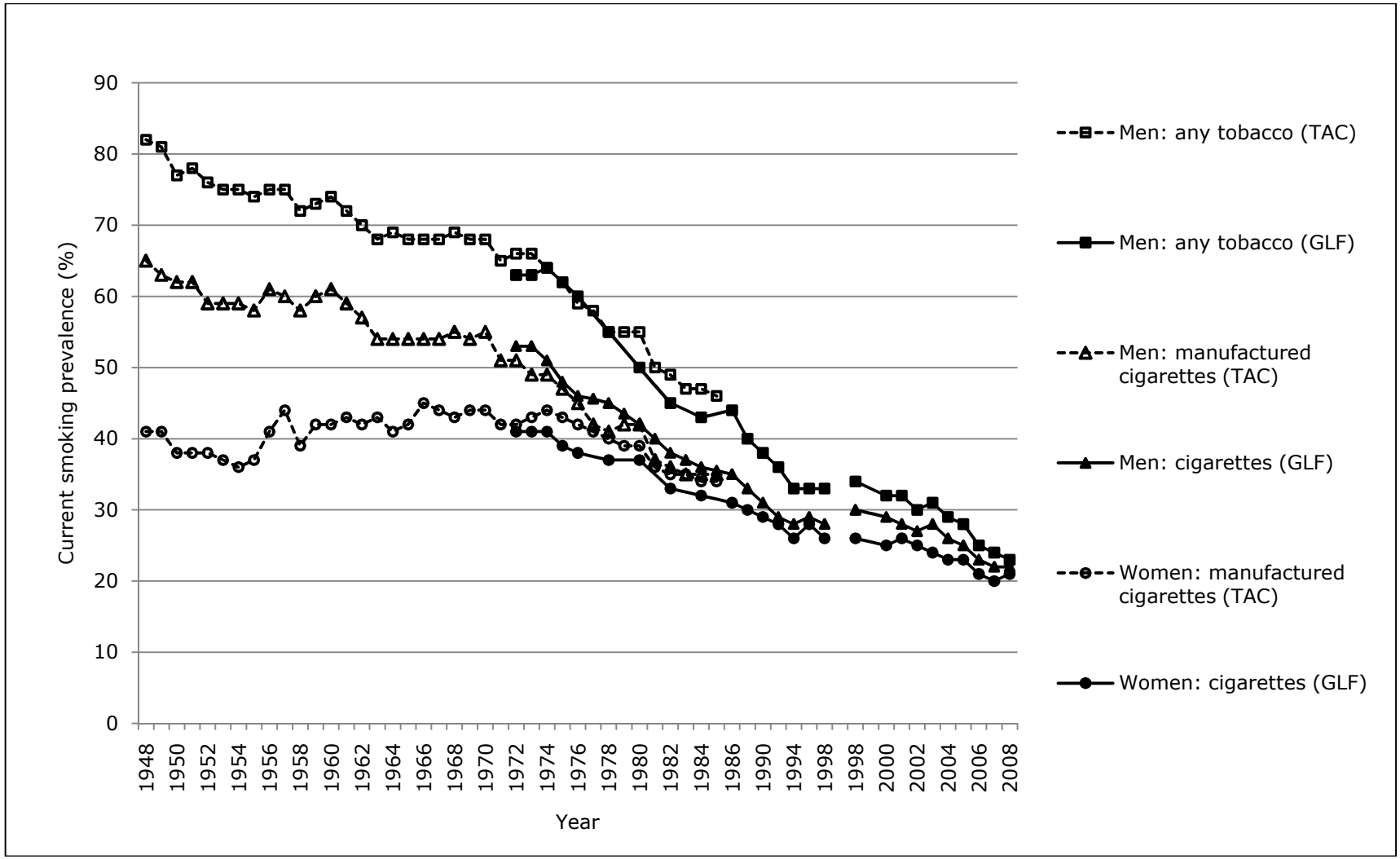


Figure 1.1 The prevalence of smoking in Britain amongst adults aged 16+ (1948-2008)

GLF data weighted from 1998 onwards to account for non-response; weighted and non-weighted data shown for 1998 for comparison.

Source: TAC[14] and GLF[13]

Smoking is a behaviour that more often than not begins during the teenage years[13]; in the UK about 450 children start smoking every day[15], with 5% of boys aged 11-15, and 7% of girls, smoking at least one cigarette per week[16]. The prevalence of smoking has been highest amongst adults aged 20 to 24 since the late 1980s, and the lowest smoking rates are seen in the oldest age group. Whilst members of this oldest age group are more likely to have ever been smokers, they are also more likely to have given up smoking, or died as a result of their smoking behaviour[13].

A gradient in smoking prevalence across social classes seems to have been present in the 1930s, and has persisted to the present day[17], driven by differential uptake of smoking in young people, and differential quit rates as a cohort ages[18]. Men and women living in households headed by someone in a manual occupation have always been more likely to be smokers compared to those where the head of household is in non-manual employment. In 1972, smoking prevalence amongst men and women in manual households in England was 58% and 49% respectively, falling to 28% and 26% respectively by 2008[13]. For men living in non-manual households, smoking prevalence fell from 45% in 1972 to 16% in 2008, with the prevalence for women declining from 40% to 16%. Variations in smoking prevalence by social class are a major driver of health inequalities; it is estimated that half the difference in survival to age 70 observed between those in social class I and those in social class V in the UK is due to a higher smoking prevalence in the more deprived group[10].

Finally, the prevalence of smoking varies with geographical location throughout the UK. Arguably, only a part of this variation is attributable to geographical variations in demographic and socioeconomic characteristics, with the role of area-level contextual factors over and above individual characteristics being vigorously debated[19, 20]. Whilst the prevalence of current smoking in both England

and Wales in 2008 was 21%, in Scotland 24% of adults were smokers[13]. Smoking prevalence estimates for Northern Ireland, obtained from the Continuous Household Survey (CHS), a survey comparable to the British GLF, suggest an adult smoking prevalence of 24%[21]. The proportion of adults who have never smoked regularly is the same in all jurisdictions of the UK, so, assuming the survey designs of the GLF and CHS produce nationally representative indicators of smoking behaviour, the variation in prevalence is likely to be due to different proportions of smokers having quit[13]. GLF data for England is also available at the level of the nine Government Office Regions, showing a clear north-south divide in the prevalence of current smoking. This pattern is mainly the result of variations in the number of heavy smokers (those smoking over 20 cigarettes a day) in each region[13].

1.3. THE IMPORTANCE OF SMOKING CESSATION

The most recent figures from the GLF suggest that two thirds of smokers over the age of 16 would like to quit altogether[13], with health and financial motivations commonly being cited as reasons to do so[22]. Indeed, it is never too late for smokers to benefit from quitting; regardless of the age at which they give up, ex-smokers can expect to live longer than those who continue to smoke[5]. Positive health changes begin to take effect just eight hours after smoking the last cigarette as the amount of nicotine and carbon monoxide in the blood falls, blood oxygen levels return to normal and blood circulation improves[23]. Health benefits continue to accrue with increasing duration of cessation, such that after ten years of abstinence an ex-smoker's risk of developing lung cancer falls to about 30-50% of the risk for a continuing smoker, and continues to fall with increasing abstinence[24]. A smoker's excess risk of coronary heart disease is reduced by half after one year of cessation, and after 15 years their risk is similar to that of a never-smoker[24].

1.4. TOBACCO CONTROL INITIATIVES IN THE UK

Figure 1.2 summarises the major tobacco control strategies which have been implemented in the UK since 1999 in an attempt to reduce smoking uptake, increase the number of smokers who quit, reduce non-smokers' exposure to environmental tobacco smoke and reduce the health and economic burdens of tobacco use. A more detailed history is available from Action on Smoking and Health (ASH)[25].

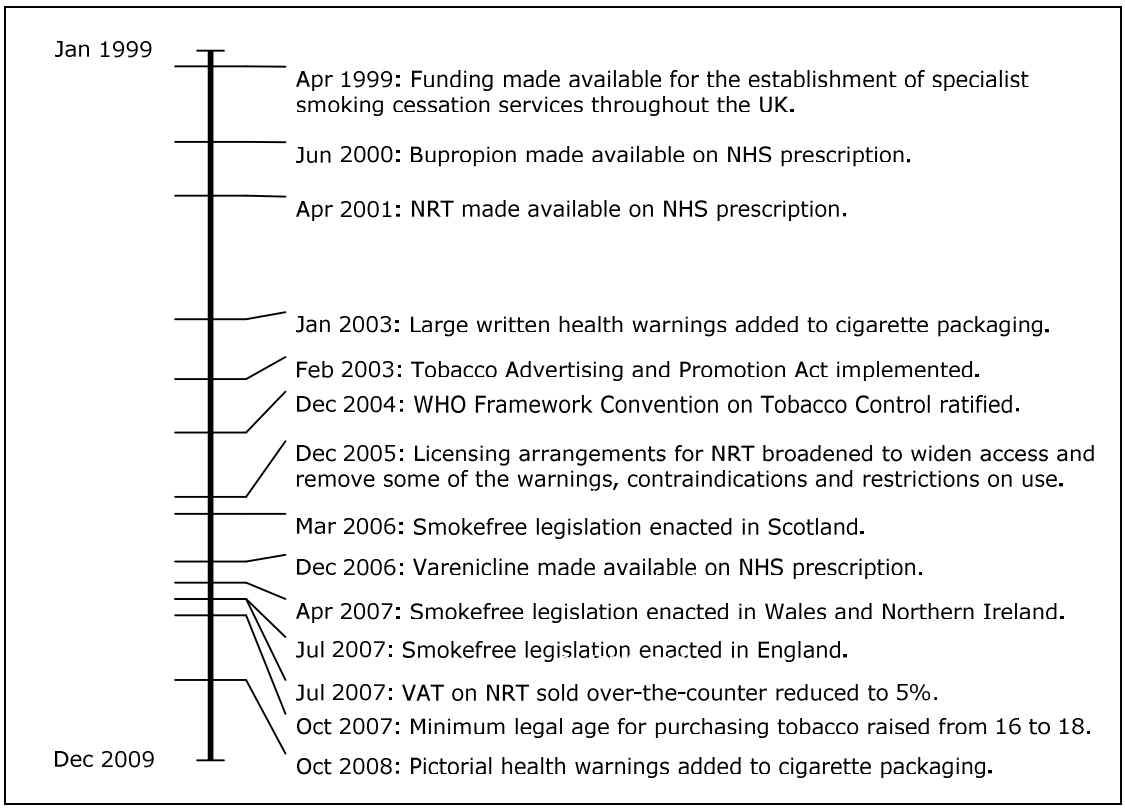


Figure 1.2 Major tobacco control initiatives implemented in the UK

Arguably the most groundbreaking and publicised of these changes is the introduction of smokefree legislation, introduced primarily as a means to reduce non-smokers' exposure to environmental tobacco smoke but also in the hope that legislation would prompt changes in existing smokers' smoking behaviour. Since the turn of the 21st century, more than 50 countries and states worldwide have implemented legislation at least partially banning smoking in enclosed or

substantially enclosed public places[26]. Pressure to introduce smokefree legislation in the UK first began to mount in the late 1990s, with the publication of evidence highlighting the harmful effects of passive smoking[27]. Figure 1.3 summarises the main events since 2003 which concluded with the introduction of smokefree legislation in each jurisdiction of the UK, and Table 1.1 details the legal requirements of this legislation and the penalties for breaking the law.

Table 1.1 Summary of smokefree legislation in the UK

<table>
<tr><th>Country</th><th>Date enacted</th><th>Extent of the legislation</th><th>Penalties for breaking the law</th></tr>
<tr><td>England[28]</td><td>1st July 2007</td><td rowspan="3">It is illegal to smoke in:
- virtually all 'enclosed' and 'substantially enclosed' public places and workplaces
- public transport and work vehicles used by more than one person
- staff smoking rooms and indoor smoking areas are no longer allowed
Exemptions include designated rooms in:
- mental health units (though illegal in England from 1st July 2008)
- residential care/nursing homes
- prisons
- adult hospices
- hotels</td><td rowspan="3">Individual smokers:
- fixed penalty notice of £50 (reduced to £30 if paid in 15 days) or a maximum fine of £200 if prosecuted and convicted by a court.
Failure to display no-smoking signs:
- a fixed penalty notice of £200 (reduced to £150 if paid in 15 days) or a maximum fine of £1000 if prosecuted and convicted by a court.
Failing to prevent smoking in a smokefree place:
- a maximum fine of £2500 if prosecuted and convicted by a court.</td></tr>
<tr><td>Northern Ireland[29]</td><td>30th April 2007</td></tr>
<tr><td>Wales[30]</td><td>2nd April 2007</td></tr>
<tr><td>Scotland[31]</td><td>26th March 2006</td><td>It is illegal to smoke in:
- most indoor places other than private homes
- almost all workplaces, including lorries and vans.
- staff smoking rooms and indoor smoking areas are no longer allowed
Exemptions include designated rooms in:
- adult care homes.
- adult hospices.
- psychiatric hospitals and psychiatric units.
- Hotels</td><td>Individual smokers:
- fixed penalty notice of up to £50 or a maximum fine of £1000 if prosecuted and convicted by a court.
Those in control of no-smoking premises:
- a fixed penalty notice of £200 for allowing people to smoke or failing to display warning notices. Refusal to pay or failure to pay could result in prosecution and a fine of up to £2,500.</td></tr>
</table>

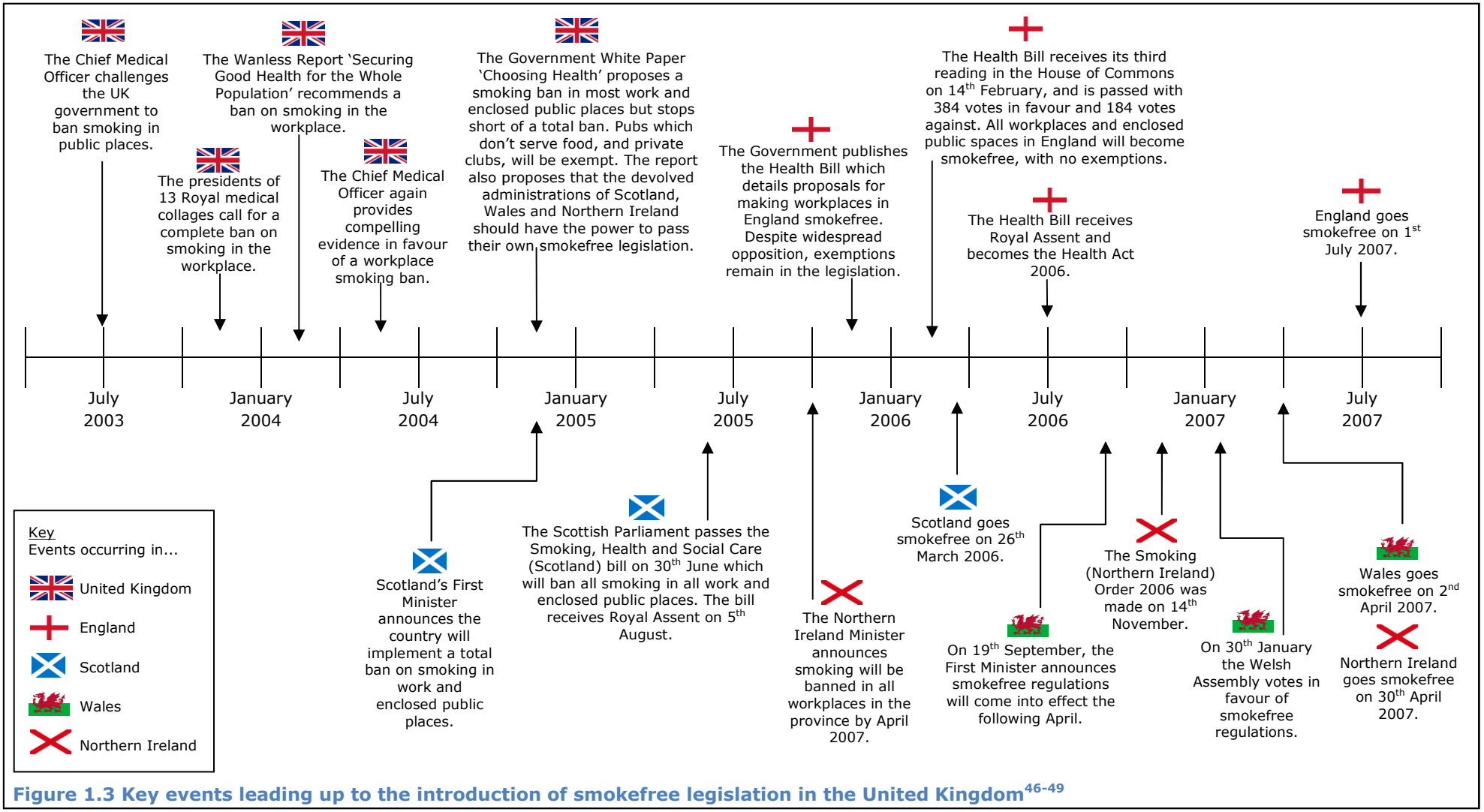


Figure 1.3 Key events leading up to the introduction of smokefree legislation in the United Kingdom[46-49]

1.5. HOW EFFECTIVE IS SMOKEFREE LEGISLATION IN CHANGING SMOKING BEHAVIOUR?

National smoking bans have proved an undoubted success in meeting their primary aim of reducing non-smokers' exposure to environmental tobacco smoke[32], but the effect of legislation on current smokers' smoking behaviour is less certain. It is hoped the introduction of smokefree legislation will encourage smokers to attempt to quit by increasing social pressures not to smoke, reducing opportunities and sensory cues to do so, and creating an enabling environment which helps smokers who wish to quit to succeed in doing so[33].

Before the recent trend towards state-wide and national smoking bans, many individual workplaces in the UK and elsewhere had already introduced worksite smokefree policies. Early studies which focused on the impact of these workplace smokefree policies on employees' smoking behaviour identified reductions in cigarette consumption and suggested a small decline in smoking prevalence. For example, a systematic review of evidence from 26 studies carried out in the United States, Australia, Canada and Germany between 1984 and 1993 concluded that totally smokefree workplaces are associated with a fall of 3.8% in smoking prevalence (95% CI 2.8-4.7%) and continuing smokers consuming 3.1 fewer cigarettes per day (95% CI 2.4-3.8)[34].

A more recent systematic review of peer-reviewed literature published to June 2005 also examined the impact of legislation on workers in companies or worksites introducing smokefree policies, either independently or alongside wider community restrictions[35]. This reported a median reduction in cigarette consumption of 2.2 cigarettes per day (interquartile range -1.7 to -3.3), a median increase of 4.1% in self-reported attempts to quit smoking (interquartile range -

0.7 to +6.8%) and a median reduction in the self-reported prevalence of tobacco use among employees of 3.4% (interquartile range -1.4 to -6.3%).

Recently, attempts have been made to synthesise evidence assessing the impact of the state and national smokefree regulations introduced in the last decade. A Cochrane review published in April 2010 attempted to evaluate the impact of legislative smoking bans for reducing exposure to environmental smoke as well as on measures of smoking prevalence, tobacco consumption and smoking cessation[36]. This review concluded that the effect of smoking bans on smoking prevalence is unclear; ten studies reported changes in smoking prevalence as an outcome measure, with eight indicating a slight fall in prevalence and two reporting no change. Small reductions in prevalence were noted in most population-based studies, particularly amongst working men, but prevalence remained unchanged or inadequately assessed in workplace-based studies. Similarly, there was inconsistent evidence for declines in tobacco consumption and increases in smoking cessation activity associated with the introduction of smoking bans. However, there are several reasons why the conclusions from this review must be interpreted with caution.

The extent of smokefree legislation varies considerably between locations, with exemptions applying in some places but not others. The Cochrane review mixes evidence from locations with comprehensive and partial legislation, and the criteria used to differentiate comprehensive legislation from partial legislation are unclear. Some locations, such as Norway, Sweden, Kentucky and California, where designated smoking rooms are allowed under the terms of the smokefree law, are listed as having comprehensive legislation, despite recognition that such exemptions greatly weaken or completely eliminate the effectiveness of smokefree legislation[2]. Arguably, it may be more appropriate to consider only the evidence from countries with comprehensive legislation, so as not to potentially dilute the

estimated effect of such laws. Similarly, no mention is made about the degree of enforcement of smokefree legislation in various locations. If legislation is poorly enforced it is perhaps not surprising that the effects of a ban on smoking behaviour appear limited.

The Cochrane review does not always separate evidence from studies of smoking prevalence and cigarette consumption in particular subgroups of the population, such as hospitality workers, with evidence from the general population. Again, it would perhaps have been more appropriate to consider general population data only. When smokefree legislation was introduced, hospitality workers, for example, may suddenly have found themselves unable to smoke indoors whilst working, whereas workers in other occupations may have already been subject to workplace smoking restrictions for many years. Therefore, a greater change in smoking behaviour may be expected amongst hospitality workers, and mixing this evidence with that from the general population could overestimate the apparent impact of smokefree legislation in the population as a whole.

The criteria used to assess the quality of the studies included in the Cochrane review are most appropriate for assessing randomised controlled trials, though no such studies are actually included in the review. An alternative quality-assessment scale may be more appropriate in this context to allow assessment of factors other than the risk of bias, such as the representativeness of the results and applicability of conclusions to the general population.

Individual studies are only included in the Cochrane review if the outcome was measured six months or more after the introduction of smokefree legislation. However, this criterion may exclude evidence of temporary, short-term changes in smoking behaviour which occurred in the initial six months after the introduction of a ban. It is reasonable to suggest that smokers might also attempt to quit

ahead of the introduction of smokefree legislation, in preparation for the impending ban, but by potentially excluding relevant studies the Cochrane review may fail to capture some of this complexity surrounding the effects of smokefree legislation on smoking-related behaviour.

Finally, the Cochrane review pays little attention to the difficulties of evaluating smoking bans when they are introduced as just one part of a programme of tobacco control measures in a given location, and does not discuss other control initiatives that may have been introduced at the same time as smokefree legislation in the locations studied. It is very difficult to attribute apparent changes in smoking behaviour to smokefree legislation if there are other tobacco control interventions taking place at the same time.

The above discussion highlights just how difficult it is to synthesise the evidence regarding the effect of smokefree legislation on population smoking behaviour, and another, non-systematic, review of academic and grey literature was beset by similar problems[37]. To address these issues and to try to isolate the population-level effects of comprehensive smokefree legislation a new systematic review was conducted as part of this thesis, including only peer-reviewed studies examining national or state-level population impacts of comprehensive smokefree laws. This review excludes evidence from countries where smokefree legislation makes provisions for designated smoking rooms, and excludes studies which evaluate the effect of legislation only in specific subgroups of people, such as hospitality workers. The studies included examined the impact of smokefree laws on smoking behaviour in jurisdictions which implemented legislation independently of other major tobacco control measures, allowing an assessment of the effects of smokefree legislation in isolation. Finally, the review evaluates changes in population smoking behaviour both before and after the introduction of smokefree legislation and places no restrictions on the length of the follow-up period

necessary for inclusion. The following section of this chapter presents the methods and results of this review.

1.6. A SYSTEMATIC REVIEW OF THE EFFECT OF COMPREHENSIVE SMOKEFREE LEGISLATION ON POPULATION SMOKING BEHAVIOUR

1.6.1. Methods

1.6.1.1. Inclusion criteria

The legal requirements of smokefree legislation vary considerably between locations worldwide, as does the degree of enforcement and compliance with any ban. Only countries and states which, by the 31 December 2008, had enacted comprehensive legislation (defined as covering at least all workplaces, including bars and restaurants, with no provision for designated smoking rooms) were included in the search (see Table 1.2 for included locations). No language restrictions were applied, and the search was not limited to particular study designs. Studies were only included if they reported effects of smokefree legislation in the general population. No criteria for the length of follow-up were set, given that it is unclear whether any response to the introduction of a smoking ban will be immediate or delayed, temporary or sustained.

1.6.1.2. Search strategy

PubMed, CINAHL, PsycINFO and the Conference Proceedings Citation Index-Science (CPCI-S) were searched for studies, published between January 2002 and November 2009, presenting evidence on smoking prevalence, cigarette consumption, quitting behaviour, and beliefs about the impact of smokefree legislation. The search syntax included terms for 'smoking' and 'legislation', based on the Cochrane Tobacco Addiction Group's core search strategies (see Appendix

8.1 for the complete search syntax). In addition, experts in the field were contacted to identify any additional relevant studies not previously identified, and the bibliographies of retrieved references were also scanned for further relevant publications. All article titles identified in the literature search were screened by one author, and the abstracts of articles deemed potentially relevant to this review were assessed by two authors. In the event of disagreement, the opinion of a third author was sought.

Table 1.2 Countries and states with comprehensive smokefree legislation and no provision for designated smoking areas[38, 39]

Country (and state)	**Date of implementation**	**Country** (and state)	**Date of implementation**
Bermuda	01.04.06	**United States of America**	
Colombia	04.12.08	Arizona	01.05.07
Guernsey	02.07.06	Colorado	01.07.06
Iran	22.12.07	Delaware	27.11.02
Isle of Man	30.03.08	District of Columbia	02.01.07
Jersey	02.01.07	Hawaii	16.11.06
New Zealand	10.12.04	Illinois	01.01.08
Panama	24.01.08	Iowa	01.07.08
Puerto Rico	02.03.07	Maine	01.04.04
Republic of Ireland	29.03.04	Maryland	01.01.08
Uruguay	01.03.06	Massachusetts	05.07.04
		Minnesota	01.10.07
United Kingdom		New Jersey	15.04.06
England	01.07.07	New Mexico	15.06.07
Northern Ireland	30.04.07	New York	24.07.03
Scotland	26.03.06	Ohio	07.12.06
Wales	02.04.07	Rhode Island	31.03.05
		Washington	08.12.05
Canada			
Alberta	01.01.08	**Australia**	
British Columbia	31.03.08	Australian Capital Territory	01.12.06
New Brunswick	01.10.04	New South Wales	02.07.07
Nova Scotia	01.12.06	Queensland	01.07.06
Nunavut Territory	01.02.04	South Australia	31.10.07
Ontario	31.05.06	Tasmania	01.01.06
Quebec	30.05.08	Victoria	01.07.07
Yukon Territory	15.05.08	Western Australia	31.07.06

The initial searches identified 3,204 studies, of which 37 abstracts appeared potentially relevant and were read in full. Of these, eight met the inclusion criteria and full papers were obtained. The abstracts of five further articles were judged unclear; these papers were read in full to assess their relevance to the aims of this review. Figure 1.4 details the process of article-identification after searching. Excluded studies did not report outcomes relevant to the aims of this review or

summarised the findings of studies that had already been identified for inclusion (n=15), reported findings in specific population sub-groups only, such as bar workers (n=3), or reported data from locations where smokefree legislation is not comprehensive in coverage (n=11).

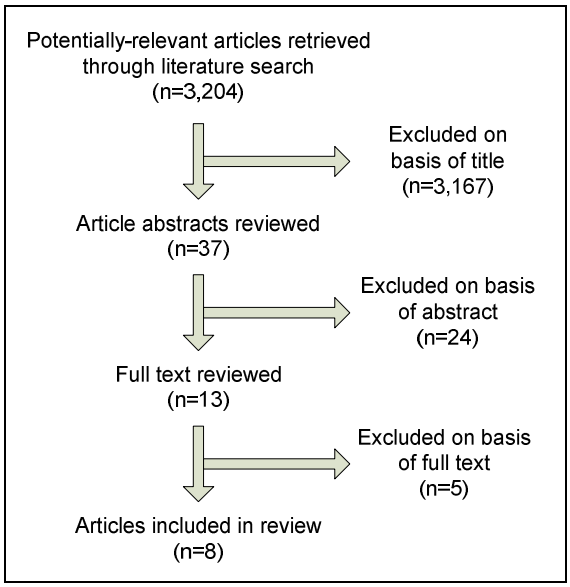


Figure 1.4 Study identification procedure

1.6.1.3. Critical appraisal

The methodological designs used in the studies deemed eligible for inclusion in this review were varied, and no single quality assessment tool was appropriate for appraising all studies. The criteria defined by the Cochrane Effective Practice and Organisation of Care (EPOC) Group[40] were used to assess the quality of studies employing time series analytic methods, giving a score out of six for each study. The Newcastle-Ottawa Scale[41] was used to assess the methodological quality of prospective cohort, quasi-experimental and cross-sectional studies; scale items were not always relevant and thus quality score denominators vary with study design and are presented in Table 1.3.

1.6.1.4. Data extraction and analysis

Where appropriate, the results of studies include in this review have been combined using meta-analysis. However, many of the studies are heterogeneous in their research design and outcome measures and, thus, it was not possible to undertake meta-analysis to pool their results. In these instances, a narrative synthesis is presented.

1.6.2. Results

Of the eight studies included in this review, three report findings from Scotland[42-44], two from England[45, 46], two (based on the same dataset, though with different study periods and using different analytical methods) from New Zealand[47, 48], and one from the Republic of Ireland[49]. In all these locations, enforcement of the ban and compliance with the legislation has been excellent[2].

Two studies employed a quasi-experimental prospective cohort design, comparing behaviour trends from a location where smokefree legislation had been introduced with trends in a cohort from a different location without smokefree legislation. Five presented analyses of repeated cross-sectional data collected before and after the introduction of a smokefree policy and two modelled repeated cross-sectional data from multiple time points pre- and post-legislation using time series analysis methods. The quality scores of studies included in this review are mixed, though all studies with the exception of one[44] met at least three quarters of the assessed criteria relevant to that study design. The variations in the quality score denominators between different study designs means it is not possible to synthesise the scores further.

Table 1.3 summarises the methods and results of the eight included studies, subdivided to show evidence relating to the impact of the introduction of smokefree legislation on smoking prevalence, cigarette consumption, smoking cessation behaviours and smokers' beliefs about smokefree legislation.

Table 1.3 Evidence tables

a) Smoking prevalence

Citation	Location	Quality Score	Date legislation introduced	Methods	Main results
Elton PJ, Campbell P. 2008[45]	England	6/8 (Newcastle Ottawa Scale)	01.07.07	Repeated cross-sectional postal survey of 2,054 people 3 months before the introduction of the smoking ban, and 1,938 respondents 3 months post-ban.	The age and sex-standardised prevalence of smoking was 22.4% in the pre-legislation survey, and 22.6% in the post-legislation survey, a non-significant change.
Haw SJ, Gruer L. 2007[42]	Scotland	6/8 (Newcastle Ottawa Scale)	26.03.06	Repeated cross-sectional face-to-face survey carried out 0-7 months pre-legislation and 6-12 months post-ban.	Smoking prevalence was 35.6% (646/1815) pre-legislation and 35.1% (644/1834) post-legislation.

b) Cigarette consumption

Citation	Location	Study quality	Date legislation introduced	Methods	Main results
Elton PJ, Campbell P. 2008[45]	England	6/8 (Newcastle Ottawa Scale)	01.07.07	Repeated cross-sectional postal survey of 2,054 people 3 months before the introduction of the smoking ban, and 1,938 respondents 6 months later.	The proportion of smokers reporting smoking 20 or more cigarettes per day declined significantly from 27.6% of smokers pre-legislation to 21.8% post-ban (p=0.044).

c) Smoking cessation behaviours

Citation	Location	Study quality	Date legislation introduced	Methods	Main results
Hackshaw L, McEwen A, West R and Bauld L. 2010[46]	England	7/8 (Newcastle Ottawa Scale)	01.07.07	Repeated cross-sectional surveys analysing data from 10,560 adults surveyed between January 2007 and December 2008 who reported having smoked in the past 12 months.	8.6% smokers reported having made a quit attempt in July and August 2007, significantly more than the 5.7% who reported doing so in July and August 2008 (Fisher's Exact = 0.022). Younger age groups were more likely to report making a quit attempt in response to legislation, though there were no significant differences with respect to gender, social grade or cigarette consumption.
Hyland A, Hassan LM, Higbee C, Boudreau C, Fong GT, Borland R et al. 2009[44]	Scotland	6/9 (Newcastle Ottawa Scale)	26.03.06	Quasi-experimental prospective cohort study involving telephone surveys of a nationally-representative sample of adult smokers and non-smokers in Scotland (n=1122) and the UK (n=1474), surveyed in February and March 2006, before the introduction of the Scottish legislation, and one year later.	No statistically significant differences in the number of respondents reporting having quit smoking or having made a cessation attempt by 2007 were observed comparing Scotland to rest of UK. The number of respondents reporting having used NRT in the six months prior to the baseline survey was higher in Scotland compared to the rest of the UK (OR 1.9; 95% CI 1.2-2.9), though there was a significantly greater decrease in NRT use in Scotland after the enactment of legislation than in the rest of the UK.
Lewis SA, Haw SJ, McNeill A. 2008[43]	Scotland	5/6 (Cochrane EPOC scale)	26.03.06	Interrupted time series analysis of data from January 2004 to December 2006 of over-the-counter (OTC) nicotine replacement therapy (NRT) sales data, comparing Scotland to rest of the UK.	The usual New Year peak in NRT sales was accentuated in Scotland in 2006 but not in the rest of the UK. The number of units of NRT sold from January to June 2006 in Scotland increased by 13,766 units per month compared to the same period in the previous two years, and the value of sales increased by £116,459 per month. No significant increase was seen in the rest of the UK. There was no significant increase in NRT sales in the second half of 2006 in Scotland compared to previous years.
Wilson N, Thomson G, Grigg M, Afzal R. 2005[47]	New Zealand	8/8 (Newcastle Ottawa Scale)	10.12.04	Repeated cross-sectional surveys comparing the number of smokers registering with the national Quitline between 1 December 2004 and 31 January 2005 (the 'intervention period') with the same period 12 months earlier (the 'pre-intervention' period).	In the intervention period the caller registration rate was 395 per 100,000 smokers aged 15+ per month, compared to 272 per 100,000 in the pre-intervention period (RR 1.44, 95% CI 1.39-1.51). The rate of distribution of vouchers for subsidised NRT also increased significantly between the two periods (RR 1.92, 95% CI 1.82-2.03). The proportion of registrations in the 35-44 year age group increased in the intervention period (p = 0.01), but no other significant changes in the distribution of callers by sex or ethnic group. The weekly caller registration rate also increased in the week in which the smoking ban was introduced relative to the average for the three weeks beforehand (RR 1.69, 95% CI 1.52-1.88). This increase persisted into the following week, even though it was the week preceding Christmas day (RR 1.27, 95% CI 1.14-1.42).
Wilson N, Sertsou G, Edwards R, Thomson G, Grigg M, Li J. 2007[48]	New Zealand	6/6 (Cochrane EPOC scale)	10.12.04	Interrupted time series analysis of data from December 2002 to November 2005 of the number of smokers registering monthly with the national Quitline and the volume of NRT vouchers issued by the Quitline service.	The usual southern-hemisphere summer dip in caller registration and issuing of NRT vouchers disappeared in December 2004 and January 2005, despite a concurrent reduction in advertising expenditure on cessation promotion. The number of monthly callers increased significantly in December 2004 (p=0.025) compared to the rest of the study period. There was no significant increase in the number of NRT vouchers issued per month as a result of smokefree legislation.

d) Beliefs about smokefree legislation

Citation	Location	Study quality	Date legislation introduced	Methods	Main results
Fong GT, Hyland A, Borland R, Hammond D, Hastings G, McNeill A et al. 2006[49]	Republic of Ireland	7/9 (Newcastle Ottawa Scale)	29.04.04	Quasi-experimental prospective cohort study involving telephone surveys of a nationally-representative sample of smokers in Ireland (n=769) and the UK (n=416), surveyed before the introduction of smokefree legislation in Ireland (December 2003 - January 2004) and 8-9 months after its implementation (December 2004 - January 2005).	Post-legislation, 60% of continuing smokers said law had made them cut down on the amount they smoke (95% CI 55-64%), 46% more likely to quit (95% CI 41-50%) and 14% (95% CI 11-17%) said the law had led them to use stop smoking medications like the nicotine patch or gum. Of those who had quit by the second wave, 80% of quitters said the law made them more likely to have quit smoking (95% CI 71-88%), 88% (95% CI 81-95%) said it helped them stay quit, and 34% (95% CI 24-45%) said it made them more likely to use pharmacotherapy.
Hackshaw L, McEwen A, West R and Bauld L. 2010[46]	England	7/8 (Newcastle Ottawa Scale)	01.07.07	Repeated cross-sectional surveys analysing data from 10,560 adults surveyed between January 2007 and December 2008 who reported having smoked in the past 12 months.	In July and August 2007, 19% of all smokers making a quit attempt reported doing so in response to the introduction of the smoking ban.

1.6.2.1. Smoking prevalence

Two studies presented data illustrating the effect of the introduction of smokefree legislation on smoking prevalence. In Bury, England, the self-reported smoking status of adults questioned three months before the introduction of the smoking ban and again six months later showed no significant reduction in age and sex-standardised smoking prevalence[45]. In Scotland, there was a marginal, but non-statistically significant, decrease in smoking prevalence, from 35.6% 0-7 months before smokefree legislation was enacted to 35.1% 6-12 months afterwards[42]. Figure 1.5 shows the results of a meta-analysis combining the results of these two studies using a fixed effects model. As can be seen, this meta-analysis suggests that smoking prevalence declined non-significantly by 0.1% between the pre- and post-legislation surveys (95% CI -3.4 to 3.3%).

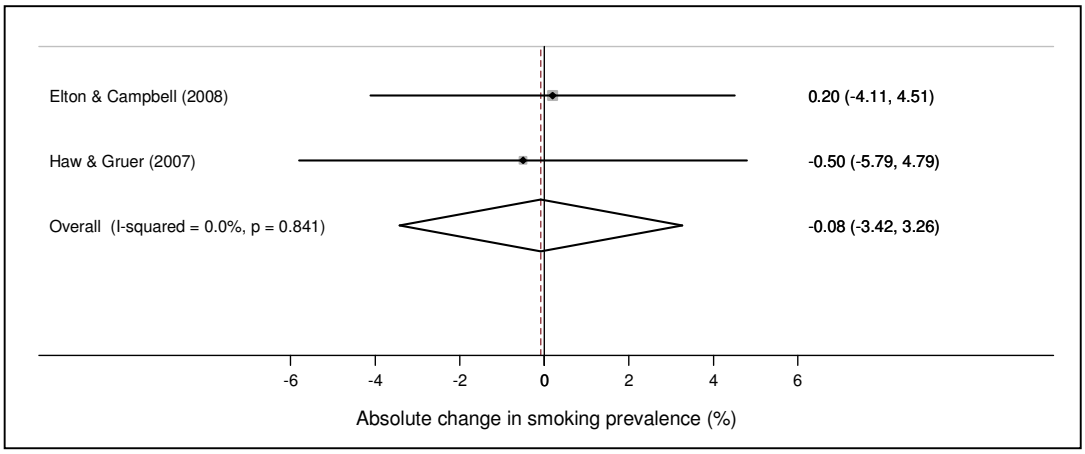


Figure 1.5 Forest plot showing meta-analysis of changes in smoking prevalence

1.6.2.2. Cigarette consumption

Just one study presented data quantifying the effect of smokefree legislation on self-reported cigarette consumption. In England, the proportion of 'heavy' smokers (who consumed 20 cigarettes a day or more) declined significantly from 27.6% respondents three months pre-ban to 21.8% respondents three months post-legislation (p=0.044)[45].

1.6.2.3. Smoking cessation behaviours

Two studies presented data on self-reported quit attempts comparing survey responses before and after the introduction of smokefree legislation. In England a significant increase in the number of smokers reporting making a quit attempt was seen in the two months after the introduction of smokefree legislation compared to the same period in the following year[46]. Conversely, in Scotland there was no significant increase in the number of smokers who reported having quit smoking or having made a cessation attempt in the year after the introduction of smokefree legislation[44].

Several studies reported increases in markers of cessation activity in the months before and after the introduction of a smokefree policy. In New Zealand there was an increase in the number of callers registering with the national Quitline in the month before and month after smokefree legislation was enacted compared to previous years, despite the legislation being introduced just before Christmas and during the southern-hemisphere summer, factors which in other years have reduced cessation activity[47, 48]. Four studies presented data illustrating the effect of the introduction of smokefree legislation on smokers' use of NRT. Two studies from Scotland found that the proportion of smokers reporting using NRT[44], as well as the volume and value of NRT sales[43], increased in the months before the introduction of legislation. In New Zealand an increased number of NRT vouchers were issued through the national telephone Quitline in the two month period spanning the introduction of smokefree legislation, despite a concurrent reduction in the amount of money spent advertising cessation programmes[47]. However, the same data, when analysed as a monthly time series rather than two cross-sectional surveys, failed to find a significant increase in the number of NRT vouchers issued per month at the time smokefree legislation was introduced[48].

1.6.2.4. Smokers' beliefs about the effects of smokefree legislation

In two surveys respondents were asked about the impact of smokefree legislation on their smoking behaviour. Respondents believed that the introduction of smokefree legislation made them more likely to quit[49], prompted them to attempt to quit[46], and helped them to remain abstinent[49]. In the Republic of Ireland, 60% of continuing smokers self-reported that the introduction of smokefree legislation made them cut down on the amount they smoke (95% CI 55-64%)[49].

1.6.3. Discussion

In populations where well-enforced, comprehensive smokefree policies have been implemented, there is some evidence that quitting activity increased in the run up to, and/or following, the introduction of the legislation. In all jurisdictions, substantial proportions of smokers and successful quitters reported that smokefree legislation helped them make positive changes in their smoking behaviour, and there is consistent evidence that heavier smokers succeed in reducing their average daily cigarette consumption after the introduction of a smokefree policy. However, there is no evidence to date to suggest that these changes in smoking behaviour translate into population-level reductions in smoking prevalence.

Despite the large number of nations and states worldwide which have implemented comprehensive smokefree legislation, the published literature included in this review represents the experiences of just four jurisdictions, perhaps reflecting the relatively recent introduction of smokefree legislation, delays in the publication of research findings or difficulties in designing and conducting studies to identify and attribute changes in smoking behaviour to national bans. Further evidence is needed to determine whether the experiences

of the places included here differ from those of other locations with comprehensive smoking bans in place.

The evidence presented here is drawn from studies with diverse methods and outcome measures, making synthesis difficult. A limitation of many studies is their failure to take into account secular trends in smoking behaviour prior to the implementation of smokefree legislation. For example, as Figure 1.1 showed, smoking prevalence has shown a general downward trend in the UK since the 1970s[13] and it is crucial to isolate any additional effect of smokefree legislation over and above this longer-term trend. Though no additional weight is given here to studies with particular designs, many are limited by reliance on observational data, self-reported smoking behaviour and short follow-up periods. Though many of the repeated cross-sectional surveys scored highly against the criteria of the Newcastle Ottawa Scale for measuring study quality, they fail to account for trends in the outcome measure beyond a few months before the introduction of smokefree legislation.

Attention must also be paid to the analytical techniques used in different studies; data from New Zealand's telephone Quitline, when analysed as two cross-sectional surveys, showed a significant increase in the rate of distribution of NRT vouchers after the introduction of smokefree legislation[47], though when this same dataset is analysed as a monthly time series no significant increase is reported[48]. The timing and duration of data collection in the pre- and post-legislation survey waves may also be important given evidence of increased quitting activity in the months preceding the introduction of smokefree laws. Additionally, it has been suggested that the full effect of smokefree laws may not be seen immediately, particularly if they are introduced during the summer months when going outside to smoke is no deterrent[45]. It may also be the case that any positive effects of smokefree legislation on cigarette consumption and quitting behaviour are short lived, with

these returning to previous levels once the 'novelty' of the legislation has worn off. However, none of the included studies had data points beyond 18 months post-legislation and so examination of the long-term impact of legislation is not possible.

The evidence synthesised in this review points to an increase in the number of smokers attempting to quit and seeking support to do so in the months immediately before and after the introduction of a comprehensive smokefree policy, a finding not reported by the recent Cochrane review given its requirement for included studies to have at least a six month follow-up period[36]. Three of the studies included in the review undertaken here are based on objective, routinely-collected data[43, 47, 48], strengthening the validity of the evidence they provide. Increased quitting activity in the run-up to a law being enacted may follow periods of public consultation, legal proceedings, and media publicity which render it likely that people are aware of impending regulations before their implementation date. One potential explanation for there being no change in either quit attempts or successful cessation rates in Scotland compared with the rest of the UK after the introduction of the Scottish smokefree policy could be because many Scottish smokers made their cessation attempts in the run-up to the legislation, rather than after its introduction[44] and the pre-legislation survey in this study was carried out only one month prior to the smokefree policy being implemented. This explanation is supported by the increase in over-the-counter (OTC) NRT sales in Scotland in the months before smokefree legislation was enacted[43]. In addition, in the 'control' sample (the rest of the UK), the follow-up survey was carried out just prior to the introduction of smokefree policies in those countries, where enhanced quitting activity might already have been occurring. In England, for example, legal proceedings were completed in February 2006 (17 months before the ban was enacted) and 20% of general medical practitioners surveyed the following month

reported having seen an increase in patients asking about quitting following media publicity of the parliamentary vote[50].

The failure to detect a significant decline in smoking prevalence following the introduction of a smoking ban may reflect a lack of statistical power in these studies to detect small changes in prevalence, a problem which remained despite combining the results of two studies using meta-analysis. Just one study presented a power calculation, indicating it was powered to detect an absolute decline in smoking prevalence of 3.5%[45]. This effect size is similar to the decline in prevalence reported in the early reviews of the effects of workplace smoking bans[34, 35]. However, national and state-wide smoking bans might not realistically be expected to have such a large effect on prevalence, particularly in locations where there are already extensive workplace smoking restrictions. The evidence of increased quitting behaviour and reductions in cigarette consumption may instead suggest that, with the introduction of a smoking ban, although smokers may succeed in reducing their cigarette consumption many do not succeed in finally breaking their addiction.

Although data for NRT sales in Scotland[43] and the use of the telephone Quitline in New Zealand[48] suggest that the effects of introducing smokefree legislation were short-lived, it remains possible that the quitting behaviour stimulated by the bans could translate into a decline in prevalence if a significant proportion of those who attempted to quit succeeded in remaining abstinent in the long-term. It is also possible that the introduction of smokefree legislation may not lead to an absolute increase in the number of smokers attempting to quit, but just change the way in which quit attempts are distributed over the course of a year, as observed in the English dataset[46]. These competing hypotheses do suggest that it may be necessary for media campaigns and cessation support associated with smokefree policies to be offered in a more sustained way if more smokers are to succeed in

stopping. In Scotland, an intensive mass media cessation campaign did not continue beyond the introduction of the legislation[43], and there was a restriction in the promotion of New Zealand's Quitline in the period following smokefree policy implementation[48]. Rather than seeing smokefree policies as the culmination of efforts, their impact on smoking behaviour might be maximised by more sustained activity, perhaps through the media and health services, around the importance of cessation and promotion of sources of support to help smokers quit. Galvanising support for the smokefree policy itself might also be important. In Scotland, support for smokefree legislation just prior to its implementation was associated with increased quit intentions one year later[51].

In all the locations studied, smokefree legislation was introduced largely independently of other major tobacco control measures. However, it is still difficult to attribute any changes in smoking behaviour to the introduction of legislation. Many of the studies reviewed here indicate increased quitting activity before the actual date legislation was implemented, and it is not known just how long before a law is enacted smokers may begin to take preparatory action. The preparatory period may overlap with the introduction of other tobacco control measures, such as the introduction of a new medication to aid smoking cessation, varenicline, in England six months before the smoking ban was introduced, and some of the changes in behaviour reported here may in fact be the result of these other measures.

Finally, although some studies attempted to assess the differential impact of smokefree legislation by characteristics such as age, sex and social class, there were insufficient data to synthesise and draw meaningful conclusions. More research is needed to understand whether smokefree legislation prompts different changes in smoking behaviour across different sociodemographic groups.

1.6.4. Conclusions

In conclusion, the introduction of smokefree policies seems to have influenced quitting activity and reduced daily cigarette consumption amongst heavier smokers, though there is insufficient evidence to determine whether or not this translates into reduced population smoking prevalence. Smokers may need further support to ensure that the increased quitting activity and positive attitudinal changes which bans appear to cause are fully capitalised on and lead to sustained decreases in population smoking prevalence.

There is a lack of research examining the pathways by which the introduction of smokefree legislation might exert an impact on smoking behaviour. Similarly, it is not known whether other tobacco control policies or interventions could, when introduced alongside smokefree legislation, ensure that as many smokers as possible succeed in quitting. If the introduction of smokefree legislation encourages smokers to attempt to quit, as suggested by the results of this systematic review, smokers may seek help to stop from appropriate sources. One potential source of cessation support is from primary health care professionals. In the UK, all people are entitled to register with a general practitioner (GP), and GPs and practice nurses have a range of interventions at their disposal to aid cessation. The introduction of smokefree legislation may prompt smokers to seek cessation support from primary care, or prompt health care professionals to offer support even if this is not directly solicited by their patients. No studies to date have investigated rates of cessation activity in primary care at the time smokefree legislation is introduced. If there is no change in the rate of delivery of cessation advice to smokers, prescription of various pharmacological cessation aids, or referral of smokers to other sources of cessation support, this may highlight missed opportunities to increase impact of smoking bans. When smokefree legislation is introduced, simultaneous improvements in the provision of cessation

support to smokers through primary care could be one way of maximising the number of smokers who attempt to quit and who remain permanently abstinent.

The following section of this chapter will consider the role primary health care professionals can play in changing smokers' behaviour, discussing the effectiveness of the cessation interventions at their disposal and the factors that influence whether they are indeed likely to intervene with a smoker.

1.7. WHAT ROLE CAN HEALTH CARE PROFESSIONALS WORKING IN PRIMARY CARE PLAY IN CHANGING SMOKERS' BEHAVIOUR?

1.7.1. The effectiveness of interventions delivered in primary care

GPs are well-placed to encourage and support smokers to quit smoking, having at their disposal a range of interventions proven to increase the likelihood of successful cessation (Table 1.4). On average, adults in England see a GP 3.2 times per year[52], and, given an average workload of 81 surgery consultations per week[53] and a national smoking prevalence of 21%[13], GPs may see 17 smokers during the course of each week. In addition, practice nurses may see 13 smokers weekly, assuming a workload of 60 patients[53]. Each consultation represents an opportunity for health care professionals to assess a patient's smoking behaviour and, if appropriate, advise and support them to quit.

The reductions in morbidity and mortality achieved through smoking cessation mean that even cessation interventions with a limited success rate can be justified as cost-effective[54]. Indeed, ensuring that all smokers who want to quit receive effective smoking cessation interventions can prevent more premature loss of life, at greater value for money, than almost any other simple intervention known to medicine[55].

Table 1.4 Effectiveness of smoking cessation interventions delivered in primary care – evidence from Cochrane systematic reviews

Intervention	Control	Size of effect (risk ratio)	95% CI	Number needed to treat[c] (NNT) to achieve one quitter
Brief advice as part of a minimal[a] intervention[56]	No advice / usual care	1.66	1.42 to 1.94	53 to 119 assuming unassisted quit rate of 2%
Intensive advice as part of an intensive[b] intervention[56]	No advice / usual care	1.84	1.60 to 2.13	44-83 assuming unassisted quit rate of 2%
Intensive intervention[56]	Minimal intervention	All smokers: RR 1.27	1.20 to 1.56	51-143 assuming quit rate of 3.5% with a minimal intervention
		Smokers without smoking-related disease: 1.20	1.02 to 1.43	66-1429 assuming quit rate of 3.5% with a minimal intervention
		Smokers with smoking-related disease: 1.56	1.35 to 2.03	28-82 assuming quit rate of 3.5% with a minimal intervention
Nicotine replacement therapy[57]	Placebo / no NRT	All types: 1.58	1.50 to 1.66	76 to 100 assuming unassisted quit rate of 2%
		Gum: 1.43	1.33 to 1.53	94-152 assuming unassisted quit rate of 2%
		Patch: 1.66	1.53 to 1.81	61-94 assuming unassisted quit rate of 2%
		Inhaler: 1.90	1.36 to 2.67	30-139 assuming unassisted quit rate of 2%
		Oral tablets / lozenges: 2.00	1.63 to 2.45	34-79 assuming unassisted quit rate of 2%
		Nasal spray: 2.02	1.49 to 3.73	18-102 assuming unassisted quit rate of 2%
Bupropion[58] (Zyban)	Placebo / no pharmacotherapy	1.94	1.72 to 2.19	42-69 assuming unassisted quit rate of 2%
Varenicline[59] (Champix)	Placebo	2.33	1.95 to 2.80	28-53 assuming unassisted quit rate of 2%
Varenicline[59] (Champix)	Bupropion[58]	1.52	1.22 to 1.88	28-114 assuming quit rate of 4% with bupropion

[a] A minimal intervention was defined as that provided during a single consultation lasting less than 20 minutes, with or without the provision of a leaflet, and with up to one follow-up visit.
[b] An intensive intervention was defined as that involving a greater time commitment at the initial consultation, the use of additional materials other than a leaflet, or more than one follow-up visit.
[c] Number needed to treat = 1 ÷ |risk difference|

1.7.2. Factors influencing the delivery of smoking cessation interventions in primary care

GPs are more likely to deliver cessation interventions where a systematic approach is taken to identifying smokers and documenting this in their medical records[60], and current UK guidelines laid down by the National Institute of Health and Clinical Excellence (NICE) recommend that general practices establish monitoring systems to ensure that all health care professionals have access to information on the current smoking status of their patients[61]. In addition, these guidelines, summarised in Table 1.5, outline the systematic approach that health care professionals should take to offering cessation advice and interventions to help smokers to quit.

Despite these recommendations, previous work has suggested that GPs often do not take a systematic approach to identifying smokers and supporting all smokers to quit. A large body of literature from the UK and elsewhere has shown that GP and practice nurses' management of smokers is influenced by several factors, which can be broadly grouped into patient characteristics, characteristics of the GP or nurse, cessation-specific knowledge and skills and structural factors[62]. These factors will now be discussed in turn. Given the likely variation between countries in tobacco control policies, health care systems and attitudes towards health promotion, this section will focus upon evidence from the UK.

Table 1.5 UK guidelines for managing smoking in primary care

	NICE guidance[61, 63]	HEA recommendations (updated)[64]
Identification of smokers	• Monitoring systems should be set up to ensure health care professionals (HCPs) have access to information on the current smoking status of their patients. This should include information on the most recent occasion on which advice to stop was given, the nature of advice offered and the response to that advice.	• Patients should be asked about their smoking at least once a year and a note kept of when the question was last asked.
Assessment of readiness to quit	• People who smoke should be asked how interested they are in quitting. • Advice to stop smoking should be sensitive to individual preferences, needs and circumstances. • The smoking status of those who are not ready to stop should be recorded and reviewed once a year. Smokers not ready to quit should be advised to consider the possibility and advised to seek help in the future.	
Delivery of brief cessation advice	• Everyone who smokes should be advised to quit, except in exceptional circumstances. • GPs and nurses in primary and community care should take the opportunity to advise all patients who smoke to quit when they attend a consultation.	• GPs should advise current smokers to stop during routine consultations at least once a year, offer a prescription for NRT or bupropion, offer further support by way of referral to a specialist service, record the response to that advice, and arrange follow up where appropriate. • Advice should not be limited to patients with smoking related diseases but it may help to link advice to patients' reasons for consulting. • Practice nurses should be prepared to encourage known smokers to stop and offer assistance where possible. • GPs and practice nurses should receive sufficient practical and theoretical training to enable them to deliver opportunistic advice to encourage and support a cessation attempt, and to offer accurate advice on NRT or bupropion.
Prescription of pharmacotherapy	• HCPs should offer NRT, varenicline or bupropion, as appropriate, to people who are planning to stop smoking. • HCPs should not favour one medication over another, but choose the one that seems most likely to succeed. • If a smoker's attempt to quit is unsuccessful using NRT, varenicline or bupropion, HCPs should not offer a repeat prescription within 6 months unless special circumstances have hampered the person's initial attempt to stop smoking.	
Referral to NHS Stop Smoking Services	• HCPs should offer smokers a referral to the NHS Stop Smoking Service. • Nurses who are trained stop smoking counsellors may 'refer' to themselves.	
Special groups of smokers	• HCPs should target all women who smoke and who are either pregnant or are planning a pregnancy, and their partners and family members who smoke. • HCPs should monitor pregnant women's smoking status and offer smoking cessation advice, encouragement and support throughout the pregnancy and beyond. • Varenicline and bupropion should not be offered to young people under 18 nor to pregnant or breastfeeding women. • If a pregnant woman expresses a clear wish to receive NRT, HCPs should use professional judgement when deciding whether to offer a prescription. • Local policy makers and commissioners should target hard to reach and deprived communities including minority ethnic groups, paying particular attention to their needs.	

1.7.2.1. Patient characteristics

Patient-level socio-demographic factors including sex, age, level of education and deprivation, as well as their medical history and motivation to quit may influence the way in which GPs and other health care professionals manage smokers, though in some instances the evidence is mixed.

In one study from the late-1990s, 24.2% of smokers attending a consultation with their GP recalled discussing smoking when asked in a post-consultation questionnaire, and there was no variation by sex or age[65]. This is at odds with the findings of a more recent study of English NHS patients, where men and those aged 16-35 or 81+ who had visited their GP or practice nurse in the past year were less likely to recall having received cessation advice from a primary health care professional in the previous 12 months[20]. However, no account was taken of the fact that men and young people visit their GP less frequently over the course of the year[13] and therefore have fewer opportunities to receive advice.

There is some evidence to suggest that men may be less likely to receive other cessation interventions. Amongst patients contributing data to a large database of electronic primacy care records, male smokers were less likely than females to receive a prescription for NRT and/or bupropion in a two-year period, after adjustment for age, deprivation and co-morbidities (OR 0.68, 95% CI 0.62-0.75)[66]. Smokers aged 25-74 were more likely to receive a prescription than those aged 18-24 and 75+. However, it is not clear whether this study adjusted for the number of visits each patient made to their GP in this period.

A smoker's socioeconomic status may also influence their management by primary health care professionals. After adjustment for sex, age and perceived health, one study reports an education-related gradient in the probability of a smoker

recalling receiving cessation advice – the older the age at which the smoker left education the less likely they were to report having received advice[20]. Similarly, after adjustment for sex, age and co-morbidities, smokers living in the most deprived areas were more likely to receive a prescription for NRT and/or bupropion in a two-year period than smokers living in the least deprived areas (OR 1.50, 95% CI 1.26-1.78) [66].

Smokers perceiving they have a smoking-related health problem, or those reporting poor self-rated health, are considerably more likely to recall having being given advice to quit[20, 65, 67, 68], and there is consistent evidence from several studies that GPs prefer to discuss smoking with patients in the context of smoking-related health concerns. In one survey, 65% of GPs reported that linking the delivery of cessation advice to the complaints their patients present with was one of their three most-preferred approaches to discussing smoking, and 97% agreed that cessation advice was more effective when delivered in this way[69]. Some GPs feel that a smoker with smoking-related health problems is more likely to see quitting smoking as part of the treatment for relieving their symptoms, and will be more receptive to cessation advice[70]. On the other hand, some GPs suggest that raising the issue of smoking with patients displaying no smoking-related symptoms may be perceived by the patient as antagonistic and any cessation advice delivered may be less effective[71]. Smokers with health problems likely related to their tobacco use may also be more likely to receive pharmacotherapy to help them quit. Amongst patients contributing data to a large database of electronic primacy care records, those with a recorded history of asthma, chronic obstructive pulmonary disease (COPD), ischemic heart disease, hypertension or stroke were more likely to have received a prescription for NRT and/or bupropion[66].

GPs may also be more likely to deliver cessation interventions where they perceive the patient will be receptive to advice and support and motivated to attempt to quit[72]. In one study, smokers who recalled receiving advice in a GP consultation were more likely than those who didn't to report having thought about stopping or trying to stop (74% vs 43%, p=0.002), were more likely to be intending to stop (50% vs 22%, p=0.003), and more likely to have made at least one quit attempt in previous year (68% vs 42%, p=0.012)[67], though these findings do not, of course, imply a causal relationship. In another study, intending to give up smoking in the next four weeks was the only variable independently associated with smokers' recalling having discussed NRT with their GP (OR 2.58, 95% CI 1.20-5.57)[73].

1.7.2.2. Characteristics of health care professionals

International literature suggests that four main health care professional-level factors may be important in influencing the management of smoking in primary care – demographic characteristics, the doctor or nurse's own smoking behaviour, their attitudes towards delivering smoking cessation advice and interventions, and a concern not to jeopardise the doctor-patient relationship.

Reassuringly, in the only UK-based study to consider the effect of primary health care professionals' demographic characteristics on their engagement in smoking cessation activity there was no evidence of associations between the age or sex of either GPs or practice nurse and whether they routinely monitored patients' smoking status, gave cessation advice, recommended or prescribed NRT, provided other cessation assistance or referred smokers to other professionals to help them to quit[74].

To my knowledge there are no recent studies from the UK investigating the relationship between health care professionals' own smoking status and their engagement in smoking cessation activity. However, evidence from Finland, where primary care is also available free at the point of delivery, and the prevalence of smoking amongst GPs is similar to that in the UK, can perhaps be used to infer some conclusions. In 2001, 5% of male Finnish GPs, and 3% of females smoked (compared to 4% of GPs in England and Wales[74]), and, on the whole, a GP's smoking status did not affect the proportion of their smoking patients they reported having delivered cessation advice to[75]. However, female GPs who smoked were less likely than non-smokers to advise pregnant women or those using oral contraceptives to quit, and male GPs who smoked daily were less likely than non-smokers to report that they always advise patients with tobacco-related disease to stop smoking (71% vs 96%)[75].

The majority of GPs and practice nurses consider intervening against smoking to be part of their professional role, though a small minority of GPs' attitudes are unlikely to facilitate their engagement in smoking cessation activity and provision of effective cessation support[71]. In 1992, 11% of GPs and 7% of practice nurses surveyed did not agree at least somewhat that smoking prevention should be an important part of their profession's work[76], and in 1994 13.3% of GPs agreed with the statement that 'giving anti-smoking advice during routine consultation should not be part of my job'[69]. On a more positive note, there is evidence to suggest this situation has improved; in 1999, 96% of surveyed GPs accepted that intervening against smoking was part of their role, perhaps reflecting societal changes in attitudes towards smoking[74].

There is consistent evidence from several studies that a desire not to jeopardise the doctor-patient relationship is an important factor influencing GPs' management of smokers, and in one study 9.8% of surveyed GPs agreed that one

of their top three problems encountered when discussing smoking with patients was that unwanted advice upsets this relationship[69]. GPs are keen to preserve a good relationship with their patients, and consider that a discussion of smoking in the context of smoking-related symptoms is more likely to be well-received than an abstract conversation[72]. GPs are also more likely to discuss smoking with patients they know well and with whom they have built up a good relationship[72].

1.7.2.3. Cessation specific knowledge and skills

Some GPs and practice nurses report lacking the skills and knowledge to allow them to effectively support smokers to quit. Indeed, 5.6% of GPs surveyed in 1994 agreed that one of their top three problems encountered when discussing smoking with patients was their own lack of skill[69]. In Scotland, 15% of GPs and 33% of practice nurses surveyed in 1992 reported that a lack of skill was 'very much' or 'quite a lot' a factor limiting their smoking cessation activity[76].

Health care professionals may also be unaware of treatment options available for smokers who wish to quit and the effectiveness of these interventions. A 2002 survey of GPs in England and Wales found that a minority were not prescribing NRT or bupropion to patients who had requested treatment, feeling that these products should not be available on NHS prescription, expressing concerns about their cost-effectiveness and, in the case of bupropion, the safety of the drug[77]. The findings of some studies suggest a lack of awareness amongst GPs about the safety of NRT in pregnancy; whilst 62% of GPs surveyed in one study believed NRT to be effective in pregnancy, and 70% believed it to be safer than smoking, only 45% believed NRT to be safe in pregnancy per se[78].

A substantial proportion of GPs and practice nurses report views that betray a lack of confidence in their ability to help smokers to quit. In Scotland, 37% of GPs and

47% of practice nurses surveyed in 1992 reported that feeling ineffective was 'very much' or 'quite a lot' a factor limiting their smoking cessation activity[76]. In another study, only 40% of GPs reported feeling effective or very effective at helping smokers to quit, though 64% thought they would potentially feel so if they were to receive adequate training and support[79]. The findings of other studies are more encouraging – in a 1994 study a higher proportion of GPs, 84.8%, agreed that they were effective in persuading some patients to stop smoking[69].

1.7.2.4. Structural factors

Several structural factors beyond the control of individual patients and health care professionals have been identified as potentially important in determining the extent of GPs' and practices nurses' engagement in smoking cessation promotion – their training, the time they have available to intervene with smokers, financial considerations and remuneration for smoking cessation activity.

A Cochrane review concluded that training health professionals to deliver smoking cessation interventions increases the number of patients identified as smokers and the number offered advice and support to quit (though there is no strong evidence that this results in more smokers quitting)[80]. Despite the proven effectiveness of training, a lack of training at both undergraduate and postgraduate level has been raised in several studies as a factor limiting health care professionals' engagement in smoking cessation activities. Amongst 303 GPs surveyed in 1999, just 28% reported having received training on the delivery of smoking cessation advice. However, in this study there was no relationship between a GP's training and whether they routinely monitored patients' smoking status, delivered cessation advice, recommended or prescribed NRT, provided other cessation assistance or referred smokers to other professionals to help them quit[74]. Amongst 459 practice nurses surveyed at the same time, those who reported having received training

on the delivery of advice were more likely than those who had not to say that they provided assistance such as counselling and leaflets for smokers wanting to quit, ran a stop smoking group and received referrals from GPs in the practice. Trained nurses were also more likely to report advising patients to telephone the national Quitline and to report recommending NRT[74].

Although the majority of newly-qualified doctors in 2001 reported feeling well-prepared to advise their patients on the health risks of smoking, only 11% rated their ability to deliver practical guidance on smoking cessation in accordance with national guidelines as excellent or good. Just 17% of doctors felt well prepared to deliver advice on NRT and only 5% felt able to deliver good advice on the use of bupropion for smoking cessation[81]. A more recent study does not suggest much improvement in these figures – of 656 London medical students surveyed in 2006, 33.2% reported feeling competent to counsel smokers (95% CI 29.6-36.8%), though perceived competence was higher (44%) amongst students in more advanced stages of their training compared to those in the pre-clinical years[82]. When asked to rate the effectiveness of various smoking cessation interventions on a 4-point Likert scale, the same medical students rated 'willpower alone' and advice from a GP in a similar manner[82], suggesting a lack of awareness of the effectiveness of different means of helping smokers to quit.

Pregnancy arguably provides a unique opportunity to support smokers to quit, at a time when they are perhaps more receptive to health promotion advice. Indeed, 91% of Scottish GPs surveyed in 1992 reported raising smoking cessation routinely with pregnant women though only 49% said they would raise the topic with general patients[76]. However, at the same time 26% of GPs strongly agreed or agreed that they had not had sufficient training to enable them to deliver cessation counselling in pregnancy, perhaps going some way to explaining why

38% of GPs agreed or strongly agreed that they found delivering smoking cessation counselling to pregnant women difficult[83].

GPs frequently cite a lack of time as a factor limiting their engagement in smoking cessation activities – 26.9% of GPs surveyed in 1994 agreed that one of their top three problems encountered when discussing smoking with patients was that a lack of time prevented detailed discussion[69]. In another study also carried out in the mid-1990s, 61% of GPs and 51% of practice nurses in Scotland reported that a lack of time was 'very much' or 'quite a lot' a factor limiting their smoking cessation activity[76]. In a more recent study, patients in England were less likely to recall having received cessation advice from a primary health care professional if they perceived the length of their consultation to have been inadequate[20].

There is mixed evidence whether offering GPs financial incentives to intervene with smokers may lead to their increased engagement with smoking cessation. In 1990 a contract for GPs was implemented in the UK which directly linked their income to undertaking activities related to the prevention of cardiovascular disease. A fee was paid to GPs for running designated health promotion clinics targeted at particular high-risk groups within their practice population. However, the quality of these clinics was uneven, and often those patients most at risk of cardiovascular disease were the most unlikely to attend[84]. As a result, this payment structure was replaced in July 1993 by a banded payment scheme which, amongst other activities, rewarded GPs for opportunistically collecting and recording information about their patients' smoking status, offering appropriate cessation advice and interventions to smokers and working with other individuals and agencies able to help with smoking cessation[84].

A survey of practices undertaken first in 1991 and repeated in 1994 showed a small increase (from 68% to 76%) in the proportion of practices who reported

that they always investigated patients' smoking behaviour as part of opportunistic risk assessment, and an increase, from 25% to 37%, was also seen in the proportion of practices reporting routinely referring smokers to a stop smoking group[84]. No change, however, was reported in the number of practices offering simple verbal advice or literature or leaflets containing information on quitting. Analysis of patient records held within a large database of primary care records showed a temporary increase in the rate of recording of patients' smoking status and the delivery of advice between 1993 and 1995[85].

A small scale study of the introduction of a health promotion payment in a deprived area of Leicester, England, reported no significant impact on clinical activity[86]. Practices were able to claim £15 for each patient they identified who had smoked in the past year but who was not currently smoking and hadn't done so for at least three months; in total, it was estimated GPs could claim between £285 and £1125 annually. However, there was no significant difference in the proportion of smokers who recalled receiving smoking cessation advice before and after the introduction of the payment[86] and GPs themselves did not report having substantially changed their clinical practice or practice organisation in order to claim the new payments[87]. A qualitative study of GPs' attitudes towards the payments highlighted strong negative views, with GPs feeling that the scheme would be viewed negatively by their patients and that the opportunity to claim payment would not make them raise smoking with patients where to do so might be perceived as confrontational[87]. Those GPs who claimed the largest amount of money under the scheme seemed simply to change the way they recorded their patients' smoking status, rather than raising the topic of smoking more frequently with patients[87].

A major change to the organisation of UK primary care came with the introduction of a new contract for GPs in April 2004 which, though voluntary, was adopted by

all but a handful of practices[88]. Figure 1.6 outlines the key dates in the development and implementation of this contract[89].

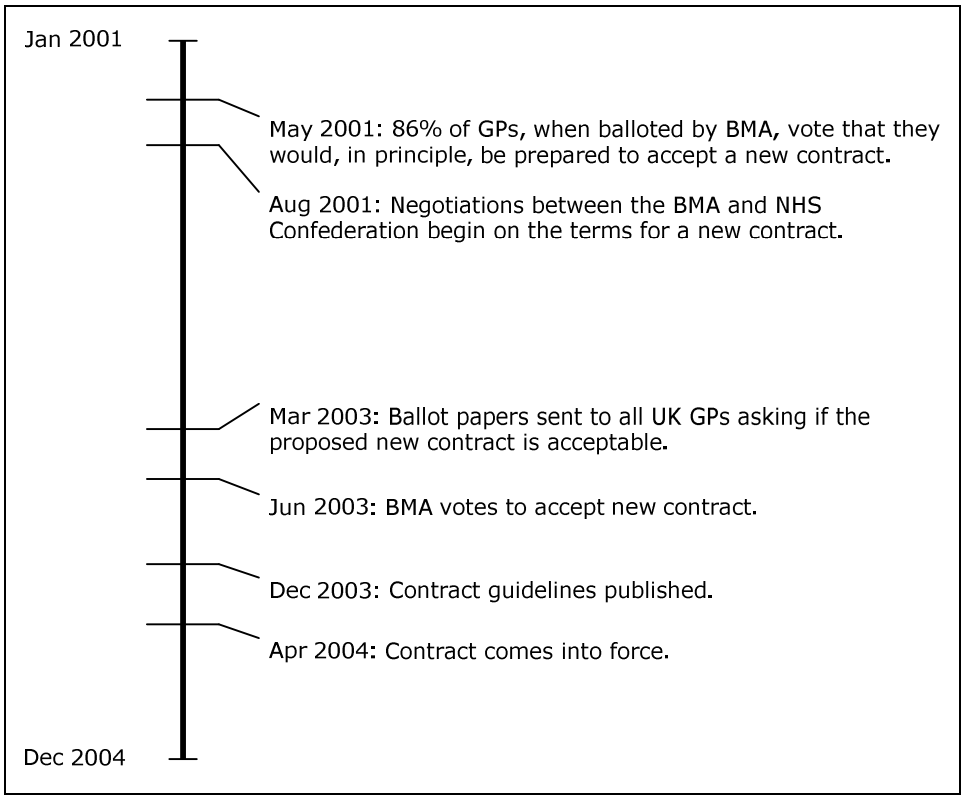


Figure 1.6 Key dates in the development and implementation of the 2004 primary care contract

One aim of the 2004 contract was to improve the management of patients with chronic diseases and, to this end, a number of pay-for-performance targets were introduced, known as the Quality and Outcomes Framework (QOF). Under the terms of the QOF, approximately 8% of the payments available to GPs (the equivalent of approximately £10,800 per year) are related to the management of smoking, with practices' performance against several specific targets being assessed. The precise requirements of these targets have changed slightly over time with revisions of the QOF, and Table 1.6 details the changes to the smoking-related targets.

Table 1.6 QOF requirements for recording of patient smoking status and delivery of cessation advice[90]

<table>
<tr><th></th><th></th><th>2004/05</th><th>2005/06</th><th>2006/07</th><th>2007/08</th><th>2008/09</th><th>2009/10</th></tr>
<tr><td rowspan="8">Recording of smoking status in those with specific conditions</td><td>Hypertension</td><td colspan="5" rowspan="6">The notes of patients with any one or combination of these conditions should contain a record of smoking status in the previous 15 months, except those who have never smoked where the smoking status need only be recorded once since diagnosis.</td></tr>
<tr><td>Coronary heart disease</td></tr>
<tr><td>Diabetes mellitus</td></tr>
<tr><td>COPD</td></tr>
<tr><td>TIA or stroke</td></tr>
<tr><td>Asthma</td></tr>
<tr><td>Chronic kidney disease</td><td colspan="4" rowspan="2"></td></tr>
<tr><td>Schizophrenia, bipolar disorder or other psychoses</td></tr>
<tr><td rowspan="8">Recording of cessation advice given to those with specific conditions</td><td>Hypertension</td><td colspan="2" rowspan="6">The notes of current smokers should contain a record that smoking cessation advice has been offered within the last 15 months.</td><td colspan="3" rowspan="6">The notes of current smokers should contain a record that smoking cessation advice has been offered or the patient has been referred to a specialist service, where available, within the last 15 months.</td></tr>
<tr><td>Coronary heart disease</td></tr>
<tr><td>Diabetes mellitus</td></tr>
<tr><td>COPD</td></tr>
<tr><td>TIA or stroke</td></tr>
<tr><td>Asthma</td></tr>
<tr><td>Chronic kidney disease</td><td colspan="4" rowspan="2"></td></tr>
<tr><td>Schizophrenia, bipolar disorder or other psychoses</td></tr>
<tr><td colspan="2">Recording of smoking status in the general population</td><td colspan="2">The notes of patients aged 15-75 should contain at least one record of smoking status.</td><td colspan="2">The smoking status of patients aged 15+ should be recorded in every 27 months, except those who have never smoked where smoking status need be recorded only once.</td><td>The smoking status of patients aged 15+ should be recorded every 27 months, except those who have never smoked where smoking status is to be checked annually until age 25. Ex-smokers are to be asked about smoking status on an annual basis until they have been a non-smoker for 3 years.</td></tr>
<tr><td colspan="2">Information provision</td><td colspan="6">The practice supports smokers in stopping smoking by a strategy which includes providing literature and offering appropriate therapy.</td></tr>
</table>

A study using primary care data from over 300 practices throughout the UK found that the introduction of the QOF led to increased rates of smoking cessation activity in primary care[85]. Though rates of recording of smoking status in patients' electronic medical records had been increasing gradually since the year 2000, the rate of improvement was more marked from 2003, with an 88% increase observed between the first quarter of 2003 and the same period in 2004, just before the introduction of the QOF. The higher rate of recording of smoking status was sustained to the end of 2005 (the end of the period analysed in this study). A similar pattern was observed in rates of recording of cessation advice delivered to current smokers.

1.7.3. Conclusions

The evidence presented above suggests that primary health care professionals may not be equally likely to intervene with all smokers; characteristics of the smokers themselves, as well as the health care professional, may result in some smokers being more likely to be advised and supported to quit than others. Additionally, GPs may be receptive to external influences which may serve to alter the number of smokers with whom they intervene to encourage them to quit. Thus, GPs and other members of the primary healthcare team may potentially be influenced by national tobacco control initiatives, which, although not offering financial incentives to deliver cessation advice and support, may heighten their awareness of the importance of cessation and lead them to intervene with more smokers, regardless of whether their intervention is solicited by the patient.

The next part of this chapter will evaluate the methods that have been used previously to measure the impact of health promotion interventions on clinical practice in primary care. This evaluation will allow the identification of a suitable

method that can be used to evaluate the impact of the introduction of smokefree legislation on the management of smoking in primary care.

1.8. A REVIEW OF METHODS USED PREVIOUSLY TO EVALUATE THE IMPACT OF HEALTH PROMOTION INTERVENTIONS ON CLINICAL PRACTICE IN PRIMARY CARE

As stated previously, to my knowledge no previous studies have evaluated the impact of the introduction of smokefree legislation on clinical practice in primary care, and, therefore, no precedent has been set defining the most appropriate way to do so. In order to select a method to use to undertake such an evaluation, this section outlines study designs that have been used previously to evaluate the introduction of health promotion interventions in primary care, focussing on policies intended to increase smoking cessation activity. The evidence presented here does not claim to represent a systematic search of the literature, but simply aims to illustrate the potential advantages and disadvantages of different ways of monitoring cessation activity in primary care and measuring the effect of interventions. The types of study design used can be broadly grouped into randomised controlled trials (RCTs), repeated cross-sectional studies with a before and after design, and interrupted time series analyses, which will now be discussed in turn.

1.8.1. Randomised controlled trials

RCTs are generally accepted as the study design which can provide the best quality of evidence for the effectiveness of an intervention. RCTs have been used, for example, to evaluate the effectiveness of training primary health care professionals to provide smoking cessation interventions[91], offering financial

rewards to GPs and reimbursing patients' drug costs[92], theory-based interventions to increase physicians' recommendations of smoking cessation services[93] and the use of a desktop resource to prompt GPs to offer cessation advice[94]. However, the use of an RCT to evaluate the effect of smokefree legislation on the management of smoking in primary care is not possible. Even if this study was being designed before the legislation was introduced it would not be practically feasible, or perhaps even ethical, to randomise half the population to be subject to the new law whilst the other half were not. Thus, an alternative study design will be needed to evaluate the effect of the nation-wide smokefree law.

1.8.2. Before and after designs

Repeated cross-sectional studies have been used to measure and compare clinical activity before and after the introduction of an intervention. For example, medical records from 310 general practices in Scotland were analysed to assess the impact of the QOF on the management of patients with coronary heart disease (CHD). The proportion of patients with CHD registered with a practice on 31st March 2004 (defined as the pre-QOF period) who had their smoking status recorded within the previous 15 months was compared with an identical measure calculated exactly one year later (designated post-QOF)[95]. Similarly, comparison of data collected before (June – September 2003) and after (November 2005 – January 2006) the introduction of the QOF has been used to assess the impact of the financial incentive on the provision of support for smoking cessation and smoking prevalence among patients with diabetes[96]. Both of these studies acknowledge the difficulty in directly attributing any observed changes in the phenomenon measured to the QOF – changes might in fact be the result of other interventions, improvements in the quality of data recorded in primary care, or just a continuation of a long-term trend. Additionally, the timing of the pre- and post-intervention surveys may influence the magnitude of any change detected.

As noted already, there was an 88% increase in rates of recording of smoking status between the first quarter of 2003 and the first quarter of 2004, even though the QOF was not implemented until 1st April 2004[85]. As Figure 1.6 shows, GPs would have been aware of the impending introduction of the QOF and its requirements as early as March 2003 and it is not unreasonable to suggest they may have begun to alter their data recording habits accordingly. In assessing the recording of smoking status in patients with CHD, the timing of the pre-QOF survey one day before the policy came into force may have resulted in the underestimation of the effect of the QOF on recording habits[95]. Ideally, clinical activity in primary care needs to be monitored for several months, if not years, before the introduction of smokefree legislation to ensure any changes in activity potentially attributable to the policy are not just a continuation of secular trends. A study design capable of achieving this is that of interrupted time series analysis.

1.8.3. Interrupted time series analyses

A time series is a set of observations or measurements collected on an individual or phenomenon at multiple, ordered, points in time. Such a series can be analysed statistically to look for changes in the outcome variable coinciding with an 'interruption' to the series, such as the introduction of an intervention, above and beyond any long-term trends. Using data from 1990 to 2005, a time series approach has been used to assess the impact of the QOF on the quarterly incidence of recording of patients' smoking status and, in smokers, the receipt of cessation advice and prescriptions for NRT and bupropion, though changes in the series were only described subjectively and no quantitative analysis was undertaken[85].

Time series analysis is being used increasingly frequently in the biomedical sciences and public health to evaluate the impact of interventions, though, to

date, has rarely been used in the evaluation of tobacco control interventions; Figure 1.7 illustrates the increase in the number of English-language articles indexed in PubMed since 1980 with the term 'time series analysis' in either the title or abstract.

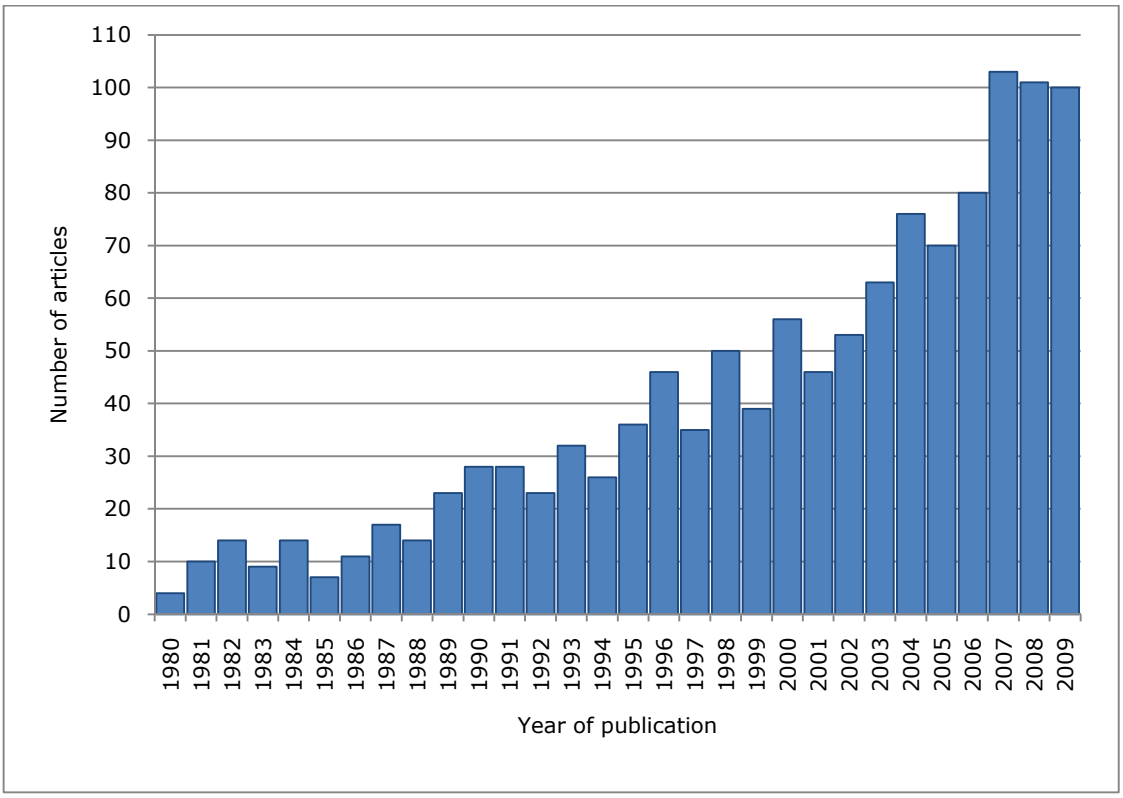


Figure 1.7 The number of research articles using time series analysis indexed in PubMed between 1980 and 2009

The rapid increase in the number of research studies utilising a time series analysis may reflect the fact that this method is argued to be the strongest study design which can be used when an RCT is not an option to evaluate the effect of interventions implemented at a known point in time[97]. Interrupted time series analysis allows the researcher to assess and quantify whether and how much an intervention changed an outcome of interest, whether any changes took place before the implementation of the intervention, coinciding with the intervention or were delayed, and whether the change was short-lived or sustained[97]. Given these advantages, and the drawbacks associated with other study designs, time series analysis provides the ideal method to use to assess the impact of smokefree

legislation on the management of smoking in primary care. The next section considers potential sources of data which can be subjected to a time series analysis to assess the impact of smokefree legislation on the management of smoking in primary care.

1.9. POTENTIAL SOURCES OF DATA FOR AN INTERRUPTED TIME SERIES ANALYSIS TO EVALUATE THE IMPACT OF SMOKEFREE LEGISALTION ON THE MANAGEMENT OF SMOKING IN PRIMARY CARE

Interrupted time series analysis can be undertaken using any data which has been collected repeatedly over time. There are potentially two options for gathering data on the extent of smoking-related clinical activity in primary care – collecting data specifically for the purposes of this study, or analysing secondary data which has already been collected. The merits and drawbacks of these two approaches will now be discussed.

1.9.1. Primary data collection

Data quantifying smoking-related activity in primary care could potentially be gathered by direct observation of clinicians' work, or through questionnaire surveys of health professionals and/or patients. However, earlier research suggests that such methods of data collection may be unlikely to produce a true representation of either the underlying rate at which GPs deliver smoking cessation interventions or any additional impact of the introduction of smokefree legislation. A 'Hawthorne effect'[98] can occur when GPs are aware their activity is being monitored. In one study, distributing questionnaires eliciting information about smoking to patients before and after they consulted with a GP significantly increased GPs' recording of having discussed smoking (OR 1.78, 95% CI 1.36-2.34)[99]. Many clinicians and patients may also refuse consent to take part in a

research study, and those who do refuse may not do so at random. For example, in one study GPs who agreed to be videotaped during consultations were younger, more likely to be working in teaching or training practices, and more likely to be known to the researcher[100]. Younger patients and those presenting with a mental health problem were more likely to withhold consent for video recording[101]. Directly questioning patients may also fail to produce unbiased estimates of the extent of cessation activity undertaken in primary care. Previous research has suggested that patients systematically over-report having being asked about their smoking behaviour by a GP, and smokers over-report having being advised to quit[102].

As the proposal for the work presented in this thesis was conceived only after smokefree legislation was introduced in the UK it was impossible to collect data at multiple time points before the smoking ban was enacted to enable assessment of secular trends in smoking-related clinical activity in primary care. An objective measure of clinical activity is needed which can provide data for the period prior to the introduction of smokefree legislation as well as afterwards. Analysing secondary data which has already been collected may be a way to achieve this.

1.9.2. Analysis of secondary data

A growing volume of information is now recorded electronically in primary care during the course of patient care. Improvements in the quality of this data have been driven by feedback to GPs, financial incentives and evidence-based guidelines, and advances in computing mean that this volume of data can now be more easily processed and analysed by researchers[103].

Many studies have been undertaken using electronic data collected from a small number of practices, often located close to the institution undertaking the

research. However, as discussed in Section 1.2, smoking prevalence is known to vary across the UK and therefore underlying rates of smoking-related clinical activity in primary care may vary geographically. Ideally, therefore, data for this study data are required from practices throughout the UK to enable a nationally-representative assessment of the impact of smokefree legislation on the management of smoking in primary care.

In addition, the underlying rate at which primary health care professionals intervene with smokers has been shown to vary according to patient characteristics, as discussed in Section 1.1.1, and it may be that smokers with particular sociodemographic characteristics are more likely to seek and receive cessation support from a GP as a result of the introduction of smokefree legislation. In investigating the impact of smokefree legislation on the management of smoking in primary care it will therefore be crucial to assess pre-legislation trends in the delivery of cessation interventions in different subgroups before considering any impact of smokefree legislation above and beyond these existing trends. In order to provide adequate statistical power to assess the impact of smokefree legislation in population subgroups, data from as many practices and patients as possible are needed, though obviously the time and cost of data collection will increase with the number of practices that must be visited.

Fortunately, the UK has several datasets containing the electronic medical records from a large number of practices nationwide. The most well-known of these datasets is arguably the General Practice Research Database (GPRD)[104], though QRESEARCH[105] and The Health Improvement Network (THIN)[106] are increasingly being utilised by researchers. The large size of these datasets potentially provides the power to split the population into subgroups and to explore variations in the impact of smokefree legislation on the management of smoking in primary care across the UK.

The use of such datasets is not, however, problem-free. There may be inaccuracies in the data recorded, and the practices who have chosen to contribute their data to a large dataset may not be representative of primary care in general – the self-selecting sample of practices may have received training or feedback to improve the quality of their record-keeping, and may only be included in the dataset once they prove their records exceed certain quality criteria[103]. Finally, but importantly, questions of data security, confidentiality and ownership arise when using data collected in primary care[103].

Despite these limitations, using a large dataset of primary care records would appear to offer the best source of data to analyse the impact of smokefree legislation on the management of smoking in primary care, offering a large amount of data for the period both before and after the implementation of the smoking ban, without the costs involved in primary data collection.

Data from The Health Improvement Network (THIN) are available for use at the University of Nottingham, and hence this dataset will now be described in more detail.

1.10. THE HEALTH IMPROVEMENT NETWORK DATABASE

The Health Improvement Network (THIN) is a dataset of electronic primary care medical records which, by July 2009, contained records for over 6.8 million patients from 446 practices throughout the UK. Data collection began in 2003 following collaboration between the Epidemiology and Pharmacology Information Core (EPIC)[107], who originally supplied data from the GPRD to researchers, and In Practice Systems (InPS), the developers of the Vision electronic practice management software[108]. Approximately half of the patients whose medical records are included in THIN to date are alive and contributing data prospectively

to the dataset; historical data are available for the remaining patients, who have either died or transferred out of the practice. All practices participating in THIN use the Vision software for their prospective data recording. However, on joining THIN a practice uploads all its historical data to the dataset, much of which was recorded using the Value Added Medical Products (VAMP) practice management system.

THIN contains details not only of consultations with members of the primary healthcare team, but also test results, issued prescriptions and the outcomes of hospital admissions. Clinical information, including patient smoking status, is recorded in THIN using Read Codes, a hierarchical dictionary of medical nomenclature[109]. Appendix 8.2 provides technical details about the recording of smoking information in THIN and how Read Codes can be used to determine a patient's smoking status at a given point in time. A new, updated, version of the THIN dataset is released three or four times each year, with a lag of three to eight months between data being entered into a practice computer and that information being made available to researchers. With each new release of the dataset the number of practices contributing data to THIN increases as a result of recruitment of new practices, though a small number of practices also leave the scheme. These changes, along with individual patients registering or deregistering with a contributing practice, means the size of the THIN dataset is continually changing. The work presented in this thesis uses THIN version 0907, which contains data from 446 practices up to the end of July 2009. Data were used from 1 January 2000 onwards, enabling the effects of the tobacco control initiatives introduced over the last decade to be captured. Inspection of the THIN data suggested there were very few changes in the recording of the outcomes of interest analysed in this thesis prior to 2000, justifying the selection of this start date.

1.10.1. Are the patients in THIN representative of the UK population?

All children and adults living in the UK are eligible to be registered with a GP. Care is provided free at the point of delivery, and therefore ability to pay is unlikely to influence the likelihood of an individual accessing medical care. Provided that the general practices contributing to THIN are representative of all UK practices, patients whose medical records are included in THIN are potentially representative of all sections of society, making the dataset a useful epidemiological resource for drawing conclusions relevant to the whole population.

Figure 1.8 illustrates the demographic (age and sex) structure of the patient population registered with a THIN practice on 1st July 1996, 2000, 2004 and 2008. For comparison, the UK population structures at these dates, derived from Office for National Statistics (ONS) mid-year population estimates[110], are also shown. In all years there is generally good agreement between the age and sex structure of the THIN and UK populations. THIN slightly under-represents older teenagers and young adults, though the extent of under-representation has diminished over time. In each year there are marginally fewer children under the age of five registered with THIN practices compared to national population estimates, though this is of limited importance when using THIN to assess the management of smoking, given that smoking rarely begins this young.

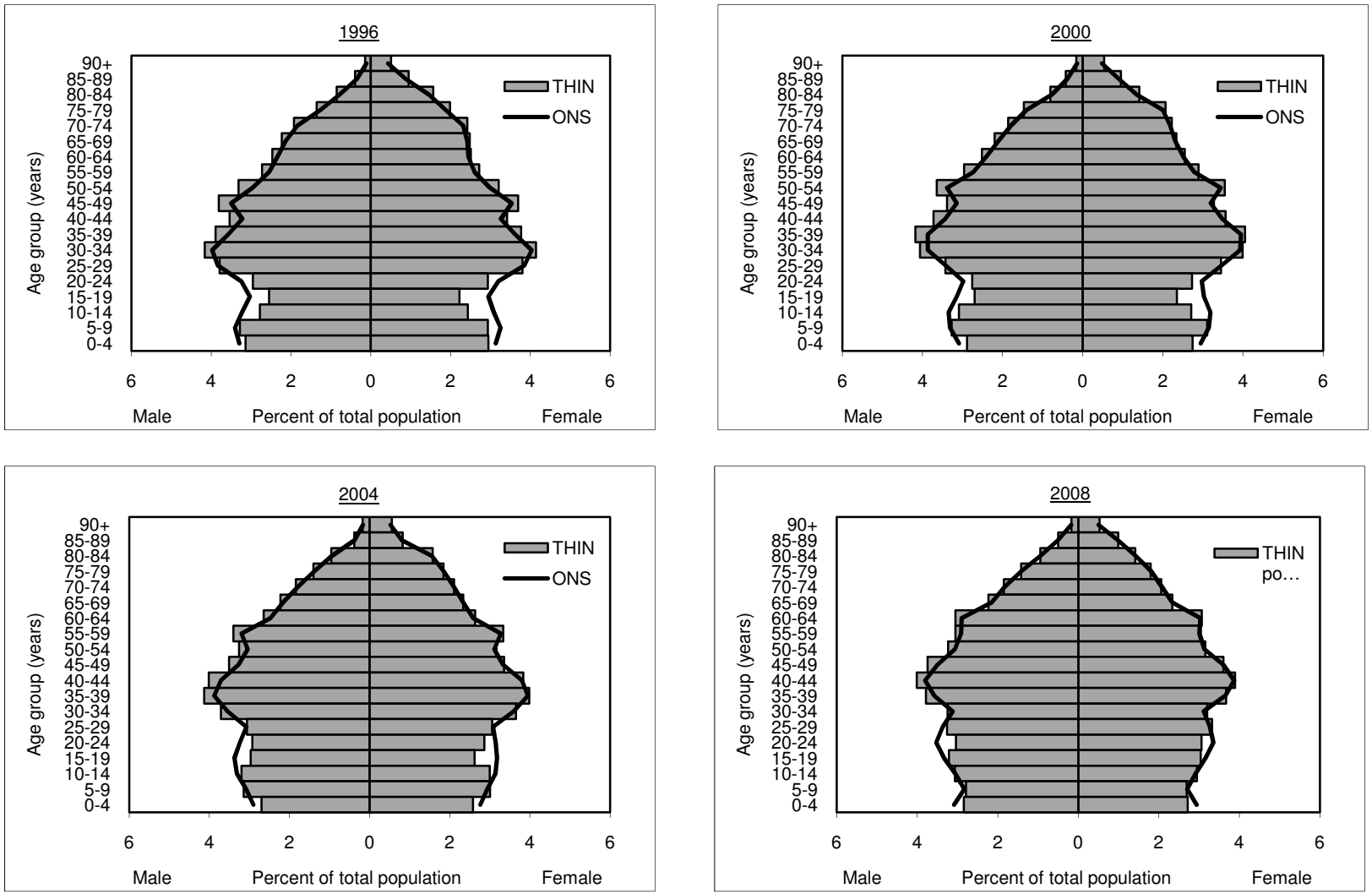


Figure 1.8 Population pyramids to compare the structure of the THIN population on 1st July with ONS mid-year population estimates

There is some evidence to suggest that THIN may not be truly representative of the whole UK population in terms of patients' socio-economic characteristics. Since 2000, the number of recorded deaths in THIN has been approximately 5% lower than the number that would be expected if UK national age and sex-specific death rates are applied to the THIN population[111]. Over-representation of more affluent, and therefore more healthy[112], patients with consequently lower mortality in THIN could be one explanation for this observation.

Figure 1.9 shows the proportion of patients (of all ages) registered with a THIN practice on 1st July 2008 who are from Scotland, Wales, Northern Ireland and each Strategic Health Authority in England, expressed as a percentage of the ONS mid-2008 estimate of the population of each region. A figure of 100% indicates the same proportion of patients in THIN are from that region as in the national population estimate. The figures inside each bar indicate the number of people in the THIN dataset in each region.

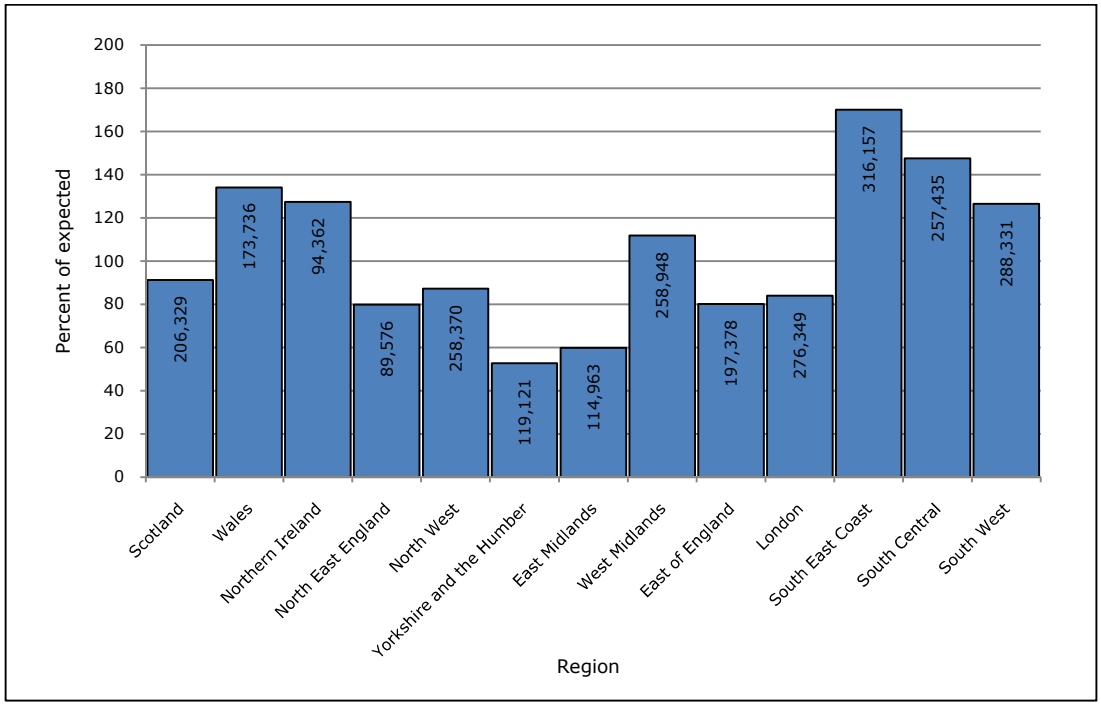


Figure 1.9 Proportion of patients in 2008 mid-year THIN population from each UK region as a percentage of the ONS mid-year population estimate

As Figure 1.9 shows, there is some disagreement between THIN and ONS data; the THIN dataset over-represents patients from the relatively more affluent areas of the UK, such as the South East Cost and the South Central regions, whilst under-representing those from generally more deprived areas, such as the North West and North East of England.

A measure of socio-economic status for each patient in THIN is available in the form of a national quintile of the Townsend Index of Deprivation[113]. This measure combines information about unemployment, car ownership, housing tenure and overcrowding, albeit calculated at an ecological, rather than individual, level. Appendix 8.3 provides further details about the calculation of this index. Figure 1.10 shows the proportion of patients aged 16+ registered in THIN on 1st July 2008 in each quintile of the Townsend Index of Deprivation. If the THIN data are nationally representative it would be expected that 20% of THIN patients would be in each quintile of deprivation. However, it appears that THIN over-represents patients from the least deprived quintiles of the Townsend Index. A Townsend classification is missing for 4.2% of patients aged 16+ in THIN, perhaps because their postcodes had not been accurately entered onto their practice's computer system.

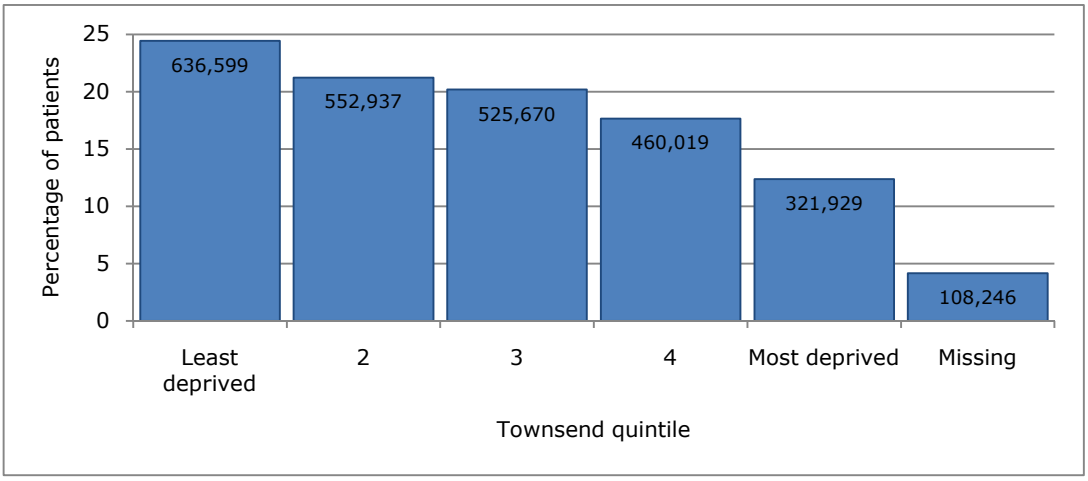


Figure 1.10 Proportion of patients in 2008 mid-year THIN population in each quintile of the Townsend Index of Deprivation

In conclusion, the THIN dataset offers the opportunity to track pre-legislation trends in smoking-related clinical activity in primary care over many years, thereby enabling the best possible assessment of any additional impact of the introduction of smokefree legislation. As shown above, the dataset is representative of the UK population in terms of the age and sex of patients, allowing conclusions about the impact of smokefree legislation to be extrapolated to the whole population. In addition, the large size of the dataset increases the power to investigate the management of smoking in different population subgroups. Some questions do, however, remain about the socio-economic and geographic representativeness of THIN, which must be borne in mind when analysing the data and drawing conclusions. Overall, providing the smoking-related data recorded in THIN are of good quality, the THIN dataset offers an excellent source of data with which to evaluate the effect of smokefree legislation on the management of smoking in primary care.

1.11. AIMS AND OBJECTIVES OF EMPIRICAL STUDIES

The ultimate aim of the work presented in the remainder of this thesis is to assess the impact of smokefree legislation on the management of smoking in primary care, using The Health Improvement Network (THIN) database of electronic primary care medical records. In order to meet this aim, the following objectives will be addressed:

1) To assess the quality of smoking-status recording in THIN to determine whether patients who are smokers can be identified as such from their medical records.

2) To assess the quality of the recording of smoking cessation interventions in THIN to determine the utility of the dataset for evaluating the impact of the

introduction of smokefree legislation on health care professionals' management of smoking.

3) To assess which analytical approach is most appropriate when using THIN data to evaluate the impact of smokefree legislation on the management of smoking in primary care.

4) To compare rates of recording of patients' smoking status in THIN before and after the introduction of smokefree legislation.

5) To compare rates of recording in THIN of the following cessation interventions delivered to smokers before and after the introduction of smokefree legislation:

   a) Delivery of brief cessation advice by a member of the primary care team
   b) Referral to NHS Stop Smoking Services
   c) Prescriptions for NRT, bupropion and varenicline

6) To assess whether the introduction of smokefree legislation had a differential impact on the management of smokers with different demographic and socio-economic characteristics.

Ethical approval for the use of THIN for the work that follows was granted by the Leicestershire and Rutland Research Ethics Committee.

1.12. OUTLINE OF THESIS CHAPTERS

Chapter 2 reviews previous research investigating the quality of recording of patients' smoking status in electronic primary care records, and presents several empirical studies assessing the quality of such data in THIN.

Chapter 3 summarises existing knowledge about the quality of recording of smoking cessation interventions in electronic primary care records, and presents several empirical studies assessing the quality of this data in THIN.

Chapter 4 describes the technique of interrupted time series analysis and considers how robust this method is when used to quantify the impact of an intervention on a time series.

Chapter 5 uses interrupted time series analysis to evaluate the impact of smokefree legislation on rates of recording of patient smoking status and the delivery of smoking cessation medications in the four countries of the UK.

Chapter 6 uses interrupted time series analysis to assess whether the introduction of smokefree legislation in England had a differential impact on the management of smokers with different demographic and socio-economic characteristics.

Chapter 7 summarises the main findings of the work presented in this thesis, discusses their implications, and suggests avenues for further research.

2. HOW COMPLETE AND CORRECT IS THE RECORDING OF PATIENTS' SMOKING STATUS IN THE HEALTH IMPROVEMENT NETWORK DATABASE?

2.1. INTRODUCTION

At the end of the previous chapter The Health Improvement Network (THIN) database was introduced as a source of data which can potentially be used to monitor the impact of smokefree legislation on the management of smoking in primary care. If THIN is to be used for this purpose it is essential to understand the quality of the smoking information recorded in the database.

If the introduction of smokefree legislation leads more smokers to seek cessation support from primary care, an increase in the rate at which patients' smoking status is documented in THIN may be seen at this time. However, it is crucial to understand any longer-term trends in the rate of recording of smoking status to ensure that any observed change at the time smokefree was introduced is related to the legislation and not simply a continuation of a secular trend. In the context of this research it is also important to appreciate whether the information recorded in THIN can identify those patients who were active smokers at the time smokefree legislation was introduced and who were, therefore, the potential subjects of any increased delivery of cessation interventions as a result of the smoking ban. Therefore, this chapter evaluates the quality of the smoking status information recorded in THIN and, following this, Chapter 3 evaluates the quality of recording of smoking cessation interventions.

Previous research has highlighted several potential shortfalls in the quality of smoking status data recorded in primary care records. This body of evidence will now be discussed and any potential data quality issues which must be addressed in THIN will be identified.

2.2. REVIEW OF PREVIOUS STUDIES INVESTIGATING THE QUALITY OF SMOKING STATUS RECORDING IN PRIMARY CARE DATA

In an ideal world, all smoking status information recorded in THIN should be complete, correct and current - that is, all observations a GP makes about a patient should be recorded[114], these notes should be an accurate reflection of real life[114], and they should be up-to-date[115]. However, the data recorded in THIN reflect routine clinical practice on the part of health care professionals and the quality of smoking information recorded in electronic medical records may be influenced by several factors, which may vary both between practices and over time. To date, few studies have attempted to assess the quality of smoking status data recorded in THIN, though analysis of other databases of primary care medical records highlights a pressing need to do so, as will be discussed below. Those studies that have attempted to evaluate THIN data have restricted their analysis of the quality of recorded smoking status information to particular age groups of patients or those with specific medical conditions. Therefore, the validity of THIN data for young, healthy populations remains unknown.

In a 2002 survey of 336 GPs in England, 98% reported routinely recording a patient's smoking status, either on the practice computer system or in the patient's paper notes[116], when the patient first registers with the practice, a figure which has changed little since 1999[74]. There is no reason to suggest this figure may have worsened since 2002, particularly given that current UK guidelines recommend that general practices establish monitoring systems to ensure that all

health care professionals have access to information on the current smoking status of their patients[61], and because the Quality and Outcomes Framework (QOF) rewards GPs for regularly updating their records of patients' smoking status. It could, therefore, be expected that the majority of patients should have a record of their smoking status documented and available to clinicians or researchers, though in some cases this may not be available in a patient's electronic notes and may not have been updated since it was recorded during the registration process.

Studies of electronic primary care medical records suggest that it is impossible to determine the smoking status of all patients from their notes, with the magnitude of the shortfall varying according to the study inclusion criteria. In 2004, just less than 40% of the 1.6 million patients aged 15-75 registered in THIN had one or more smoking status Read Codes recorded in their medical records *in that year*, a relatively small proportion though an increase from approximately 13% of patients in 2000[85]. The incidence of recording of smoking status rises when the denominator is restricted to those with particular morbidities - over 80% of patients with a diagnosis of chronic obstructive pulmonary disease (COPD), ischemic heart disease or diabetes had their smoking status recorded, 75% of those who had suffered a stroke or transient ischemic attack (TIA), 66% of those with hypertension, and 57% of asthmatics. Similar findings are reported in studies assessing the completeness of smoking status recording in other databases of primary care records, such as the General Practice Research Database (GPRD)[117], as well as smaller studies in selected practices[118]. Ascertainment bias may well be in operation in these cohorts, whereby doctors record the smoking status of the 'worst first' - those who are most unwell, or showing signs of smoking-related disease[119, 120].

The completeness of smoking status recording may vary according to patient age and gender. In 2006, 9.9% of women and 31.1% of men aged 21-30 from 21 general practices in England had no smoking status recorded in their electronic notes[118], despite official statistics suggesting this is the age group with the highest smoking prevalence[13]. For both men and women, the proportion of patients with no smoking record fell with increasing age up to the age of 80, before beginning to increase again.

Between April 2004 and April 2006 GPs were rewarded financially for meeting targets defined in the QOF requiring that the notes of patients aged 15-75 contained at least one record of smoking status, and that patients with particular chronic conditions had their smoking status documented at least every 15 months. A study using THIN data from 1990 to March 2005 highlighted an 88% increase in the proportion of patients whose notes contained a record of their smoking status between the first quarter of 2003 and first quarter of 2004, during which time GPs were aware of the impending contractual changes, with the higher rate of recording being sustained to the end of the study period[85]. No studies have assessed the recording of smoking status in THIN beyond 2005, though amendments to the QOF (see Table 1.6), requiring the more frequent recording of smoking status in the general 'healthy' population, are likely to have increased the incidence of smoking status documentation in recent years.

Many practices which contribute data to THIN have contributed data to the GPRD at some point in the past, and thus conclusions reached about one database may be equally applicable to the other. In a study comparing the electronic medical records of 138 GPRD patients with inflammatory bowel disease with their GPs' personal recollections of their patients' smoking histories, taken to be the gold standard, the GPRD was found to have a sensitivity of 78% (95% CI 52-94%) for identifying current smokers, and a positive predictive value of 70% (95% CI 46-

88%). The GPRD performed less well in identifying former smokers, having a sensitivity of 53% (95% CI 28-77%) and a positive predictive value of 60% (95% CI 32-84%)[121]. However, the use of GPs' personal recollections of their patients' smoking histories as the gold standard in this study is highly questionable. Additionally, this study was carried out using data from 1988-1997, long before recent incentives were introduced to encourage the frequent updating of records of patients' smoking status, and so the findings may be different if the study was repeated now.

The same authors also studied a cohort of 225,308 GPRD patients without inflammatory bowel disease, of whom 21.5% were recorded as current smokers on 31 December 1996. Using indirect standardisation to estimate the true prevalence of current smoking, based on age and sex-specific smoking rates from the 1996 General Lifestyle Survey (GLF), the recorded prevalence of current smokers was found to be 79% of the expected prevalence[121]. Recording of ex-smokers in the GPRD is much less complete than would be expected – just 7.7% of patients were identified as ex-smokers, 29% of the expected proportion. Of course, the use of indirect standardisation will produce estimates of the expected number of current and ex-smokers only as good as the GLF rates used for standardisation. The GLF relies on survey respondents to self-report their smoking status, and the relatively small sample size of the survey (a little over 7,000 adults in 1996) means the results may not be representative of smoking behaviour throughout the whole of Great Britain.

A study carried out in 2005 suggests discrepancies still persist between patients' true smoking status and that recorded in their medical records. Of 87,861 patients aged 18+ registered with practices in Nottingham, UK, 13.9% had no record of smoking status in their medical records, with wide variation in the completeness of recording between practices[122]. Of those patients with no recorded smoking

status, 30.9% of those who responded to a questionnaire identified themselves as current smokers. 27.3% of patients who were recorded in their notes as current smokers denied smoking in the last 12 months, varying from 6.3% to 58.1% between practices. Taking patients' questionnaire responses as the 'gold standard' indicator of smoking behaviour there were no significant differences in misclassification between men and women, though the proportion misclassified as current smokers did increase with increasing age. Bias may well have been introduced into this study if the proportion of patients returning the questionnaire in which they were asked to identify their current smoking status varied according to their current smoking behaviour or success of past quit attempts. Also, some misclassification would not be surprising if a patient's smoking status was last recorded in their primary care notes a long time before they completed the questionnaire.

All work using databases of electronic medical records requires assumptions to be made about how GPs use Read Codes (or other similar medical nomenclature) to record patient smoking status and other clinical information. However, these assumptions are not easily tested and may not always be correct. For example, many GPs have been found to use Read Code 137 (Tobacco Consumption) to record a patient as a current smoker, despite the fact that, in the hierarchical Read Code system, this is actually a parent code which has several child codes underneath it which give more specific detail about smoking status[118]. Read Codes may also have numbers attached to them which quantify a patient's smoking behaviour, and some GPs may use the 'Tobacco Consumption' Read Code accompanied by a zero to indicate that the patient is not currently smoking[118]. Many studies highlight the use of Read Codes labelling a patient as never having smoked though earlier records suggest they were, at one point in time, a current smoker; this was the case in 4.4% of the 34.8% of patients recorded as never-smokers in one study[118]. Researchers defining a patients' smoking status using

their last recorded Read Code may well misclassify some people on these grounds. It is also possible that smoking information is not entered onto a practice computer using Read Codes, but instead is entered as free text which at present is not available to researchers using THIN.

2.3. ISSUES TO BE INVESTIGATED IN THIS CHAPTER

The review of the literature presented in the previous section has highlighted several potential problems that might be encountered in the quality of smoking status data recorded in THIN. The following issues will be investigated in this chapter to address these questions of data quality and help judge whether THIN can be used to evaluate the impact of smokefree legislation on the management of smoking in primary care.

Section 2.4 investigates the completeness of smoking status data recorded in THIN, assessing how many patients have a record of their smoking status in their medical notes and whether this has changed over time.

Section 2.5 compares the prevalence of smoking recorded in THIN patients with national survey data to gauge whether THIN data provide nationally-representative measures of smoking prevalence and help conclude whether all patients who are current smokers at any given point in time can be identified as such from their medical records.

In both of these sections, variations in the quality of recording by patient sex and age, as well as by practice, will be considered. In addition, **Section 2.6** investigates whether the quality of smoking status recording varies according to a patient's medical history.

Finally, **Section 2.7** discusses whether it is possible to identify, and exclude from further analyses, those THIN practices with particularly poor recording of smoking-related information.

The results of three smaller studies are included as appendices to this thesis:

Appendix 8.4 presents the results of a study, published in *Family Practice*, which assesses whether all patients registering with a practice in THIN do indeed have their smoking status recorded at registration as GPs claim to do.

Appendix 8.5 considers whether an individual smoking-status Read Code documented in a patient's notes is a correct reflection of their smoking behaviour at that point in time.

Appendix 8.6 examines how up-to-date records of patients' smoking status in THIN are and whether this has improved over time.

2.4. WHAT PROPORTION OF PATIENTS IN THIN HAVE A RECORD OF SMOKING STATUS IN THEIR ELECTRONIC MEDICAL NOTES AND HAS THIS CHANGED OVER TIME?

2.4.1. Introduction

The literature reviewed in Section 2.2 suggests that some patients in THIN may not have their smoking status recorded in their electronic medical records, despite GPs' claims that they routinely record the smoking status of all new patients who register with their practice. This section assesses whether there is a shortfall in

the recording of patients' smoking status in THIN, whether this varies by patient demographic characteristics, and how these figures have changed over time.

2.4.2. Methods

For each year from 2000 to 2009 all patients were identified from the THIN dataset who were aged 16+ and registered with a practice on an index date of 1st July of that year. All records of smoking status, identified by relevant Read Codes (see Appendix 8.2), entered into patients' notes on or after their registration date were extracted, and the proportion of patients each year with no record of smoking status on or before the index date was calculated. In addition, the proportion of patients with no recorded smoking status was assessed separately for subgroups of the population defined by sex and age group, and individually for each practice contributing data to THIN. The age groups used here, and throughout this thesis, are those used in the General Lifestyle Survey (GLF), the main source of smoking statistics in the UK at present, and are designed to capture and show variations in smoking behaviour across the life course.

2.4.3. Results

The number of patients aged 16+ registered with a THIN practice on 1st July of each year increased from 2,194,498 patients in 2000 to 2,575,195 in 2009, of whom 49% each year were male, with a mean age of 47 years (interquartile range 32-61). The average number of years of medical records available for inspection for each patient increased from 13.9 years in 2000, to 15.8 years in 2009.

Figure 2.1 shows the proportion of patients each year for whom it was impossible to assign a smoking status, having inspected all records recorded since the patient registered with the practice.

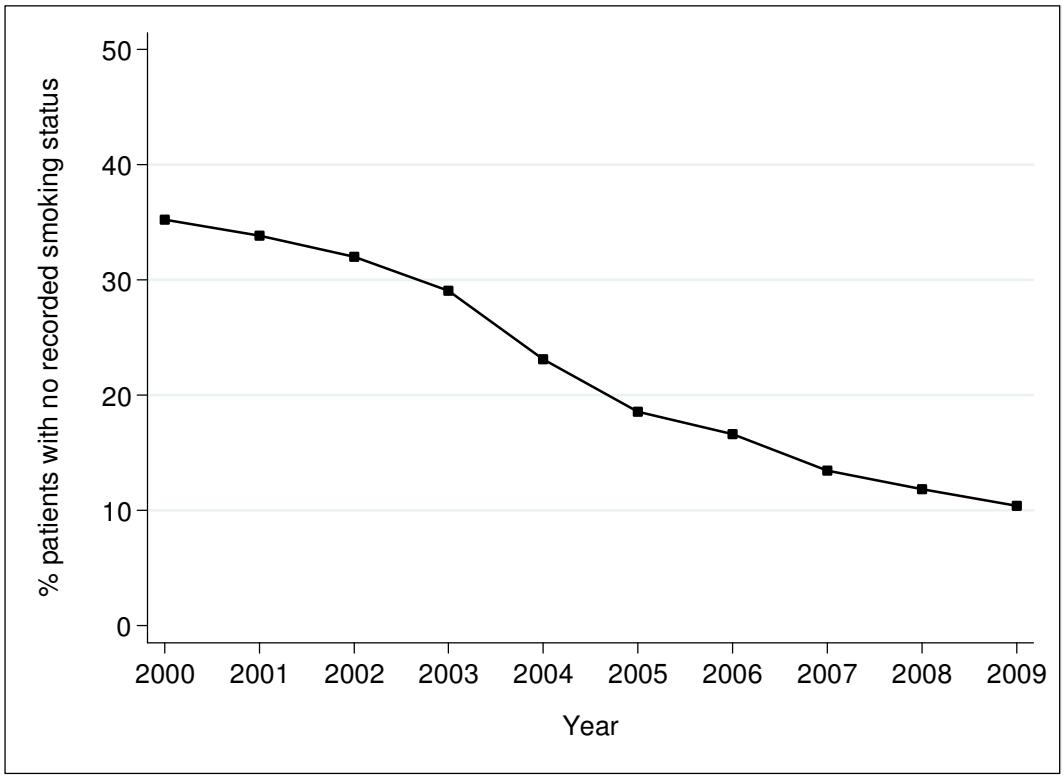


Figure 2.1 The proportion of THIN patients aged 16+ with no smoking status recorded in their medical records

In 2000, 36.6% patients had no smoking status recorded in their notes since registering with their practice, improving to 10.1% in 2009. In all years there was considerable variation in the completeness of recording by practice, although this variation has reduced over time. In 2009, 53.5% of patients in the worst-performing practice had no record of smoking status in their notes, compared to just 1.4% in the best-performing practice (interquartile range 6.5-11.9%).

As shown in Figure 2.2, the percentage of patients with no smoking status recorded differs by patient age group and sex. The percentage of patients with no smoking status recorded falls with increasing age group, and the older the age

group, the small the smaller the difference between men and women in the proportion of patients with missing data.

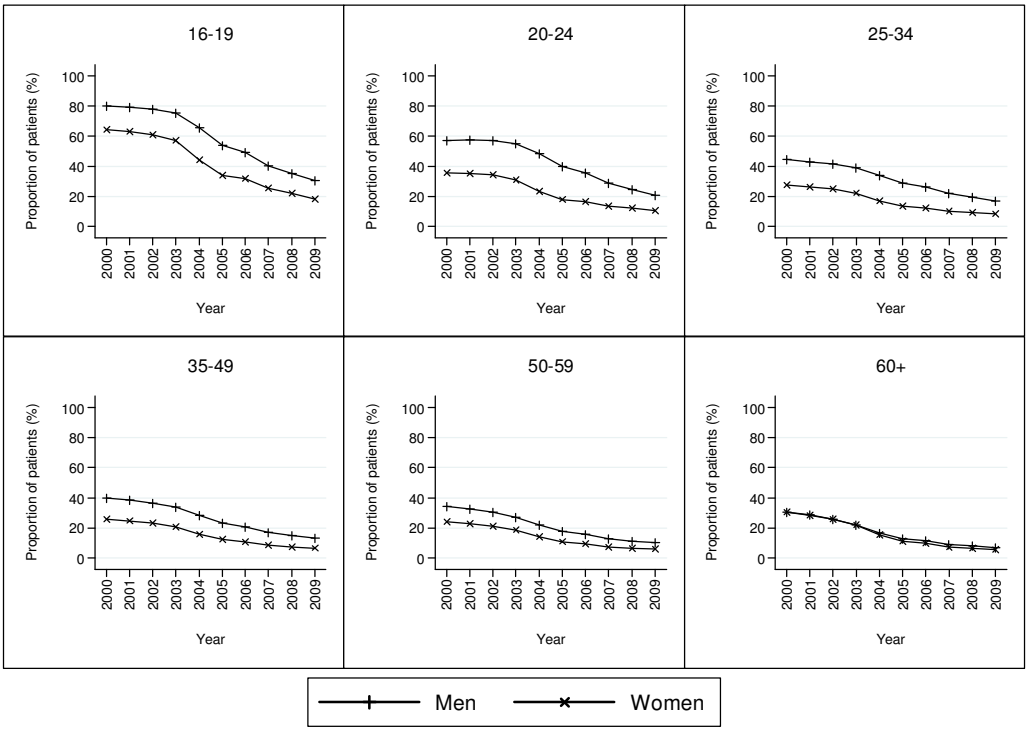


Figure 2.2 The proportion of THIN patients aged 16+ with no smoking status recorded in their medical records, by age group and sex

2.4.4. Discussion and conclusions

Historically, many practices may have used paper records instead of, or alongside, computerised clinical information systems, and patients' smoking status may not have been comprehensively documented electronically. However, the vast majority of practices are now computerised, with electronic records forming the main means of documenting patient care and proving compliance with QOF targets. Since the introduction of the QOF it is likely that practices will try hard to ensure all patients' smoking status is documented in their notes. However, this study shows that in 2009 10.1% patients aged 16+ had no mention of smoking in their electronic medical records (and, as shown in Appendix 8.4, a small study undertaken as part of the work for this thesis suggests that many practices do not record the smoking status of all new patients at registration, despite GPs' claims

to the contrary). Though this figure represents an improvement over time, if some of these patients with missing data are smokers it will be impossible to identify all patients who were the potential subjects of increased delivery of smoking cessation interventions at the time smokefree legislation was introduced.

The fastest rate of improvement in the proportion of patients with a record of smoking status in their notes was seen between 2003 and 2005, suggesting that practices may have begun to improve their data recording in anticipation of the introduction of the QOF. The proportion of patients with a record of their smoking status has, however, continued to improve to the end of the study period, and thus the analytical method used to assess the impact of smokefree legislation on rates of recording of smoking status must be able to take this underlying trend into account.

There is considerable variation in the completeness of smoking status recording and patterns of change over time between different demographic groups. This variation must be kept in mind when analysing the impact of smokefree legislation on the recording of patient smoking status. Indeed, as well as investigating the impact of legislation in the population as a whole, it may be appropriate to assess the impact of the smoking ban on recording separately in different population subgroups to take into account the different underlying trends.

Additionally, there is considerable variation in the completeness of smoking status recording between practices. As the practices contributing data to THIN are anonymous it is impossible to approach them for further information to help understand any reasons for the inter-practice variation. As the recording habits of the general practices contributing data to THIN may not be representative of all UK practices, caution must be taken in extrapolating conclusions about the impact

of smokefree legislation on the recording of patient smoking status to UK primary care in general.

2.5. CAN ALL PATIENTS WHO ARE CURRENT SMOKERS AT ANY GIVEN POINT IN TIME BE IDENTIFIED FROM THIN DATA?

2.5.1. Introduction

The previous section has shown that there have been recent improvements in the proportion of THIN patients with a record of their smoking status in their medical notes. However, these records may not necessarily be correct and may not allow the identification of all patients who were current smokers at the time smokefree legislation was introduced and who, therefore, would be potential subjects for an increase in the delivery of cessation interventions.

Ideally, the optimal way to assess whether all patients who are current smokers at any point in time are recorded as such in THIN would be to approach patients directly and compare their self-reported smoking status with that recorded in their medical notes. However, this is impossible as all records in THIN are anonymised to protect practice and patient anonymity and, even if this were not the case, the size of the THIN dataset would be prohibitive. Arguably the best alternative is to compare the prevalence of particular smoking behaviours in the THIN population with prevalence measures from other sources, standardising where possible to ensure the populations being compared are comparable in terms of their demographic characteristics.

Currently, the main source of statistics for monitoring smoking prevalence in Great Britain is a national, annual survey, the General Lifestyle Survey (GLF)[13], with a comparable survey (the Continuous Household Survey) being undertaken in

Northern Ireland[123]. The GLF samples approximately 17,000 adults aged 16+ each year throughout England, Scotland and Wales, and provides self-reported measures of the prevalence of current smoking. The work presented in this section compares the smoking prevalence recorded in patients in THIN with prevalence estimates from the GLF.

2.5.2. Methods

To enable comparison of smoking prevalence estimates from THIN with those of the British GLF, the 23 THIN practices in Northern Ireland were excluded from this study (there is a mistake in the recording of smoking status in the data files for the Northern Irish Continuous Household Survey, making it impossible to include these practices in this analysis). For each year from 2000 to 2009 all patients were identified from the THIN dataset who were over the age of 16 and registered with a practice on an index date of 1st July of that year. Patients who registered with a practice within the previous three months, who may not have had their smoking status recorded, were excluded from this analysis (the QOF requires that the smoking status of newly-registering patients is recorded within three months for this recording to be financially rewarded[90]).

Each patient's year of birth and sex was identified, as well as the Strategic Health Authority within which their GP surgery was located. All records of smoking status, identified by relevant Read Codes, entered into patients' notes on or after their registration date were extracted. Patients were classified as current smokers at a given index date if the most recent smoking status Read Code in their medical records prior to this index date identified them as such. All patients with no smoking information recorded in their notes were assumed not to be current smokers at that point in time. Previous authors have shown that the majority of

patients with missing smoking records in both THIN and the GPRD are either ex or non-smokers[121, 124], so it can be argued that this assumption is valid.

A direct comparison of smoking prevalence in THIN and the GLF is not appropriate because THIN has a slightly different demographic structure to the national population; even if THIN contained valid smoking data for all patients within this database one would expect smoking rates based on THIN data to differ from GLF estimates of national smoking prevalence. Therefore, the following standardisation procedure was used to calculate what the smoking prevalence amongst THIN patients might be if THIN did have the same demographic structure as the British population (called the 'GLF-predicted' prevalence) and compared this with the recorded prevalence in THIN. For each year between 2000 and 2007, region, age group and sex-specific rates of current smoking were identified from the relevant GLF survey, weighted for non-response to give nationally representative indicators of smoking behaviour (at the time of writing, GLF data were not available for 2008 and 2009). These rates were applied to strata of the THIN population (similarly defined by age group, sex and region) at each index date using indirect standardisation[125] to produce annual 'GLF-predicted' prevalence estimates for current smoking; these predicted prevalence estimates were then compared with the recorded prevalence figures.

To investigate variations in the recording of current smokers between practices the expected prevalence of current smokers in each practice was calculated in the manner described above, again using age group, sex and Government Office Region as variables in the standardisation procedure. These predicted prevalence estimates were then compared with the proportion of patients in each practice recorded in their notes as current smokers.

2.5.3. Results

The number of patients registered with a British THIN practice on 1st July of each year who had been registered for at least three months increased from 2,086,891 patients in 2000 to 2,447,903 in 2009.

Figure 2.3 shows changes over time in the predicted prevalence of current smoking in the THIN population, derived from GLF data, compared to the prevalence determined from patients' notes.

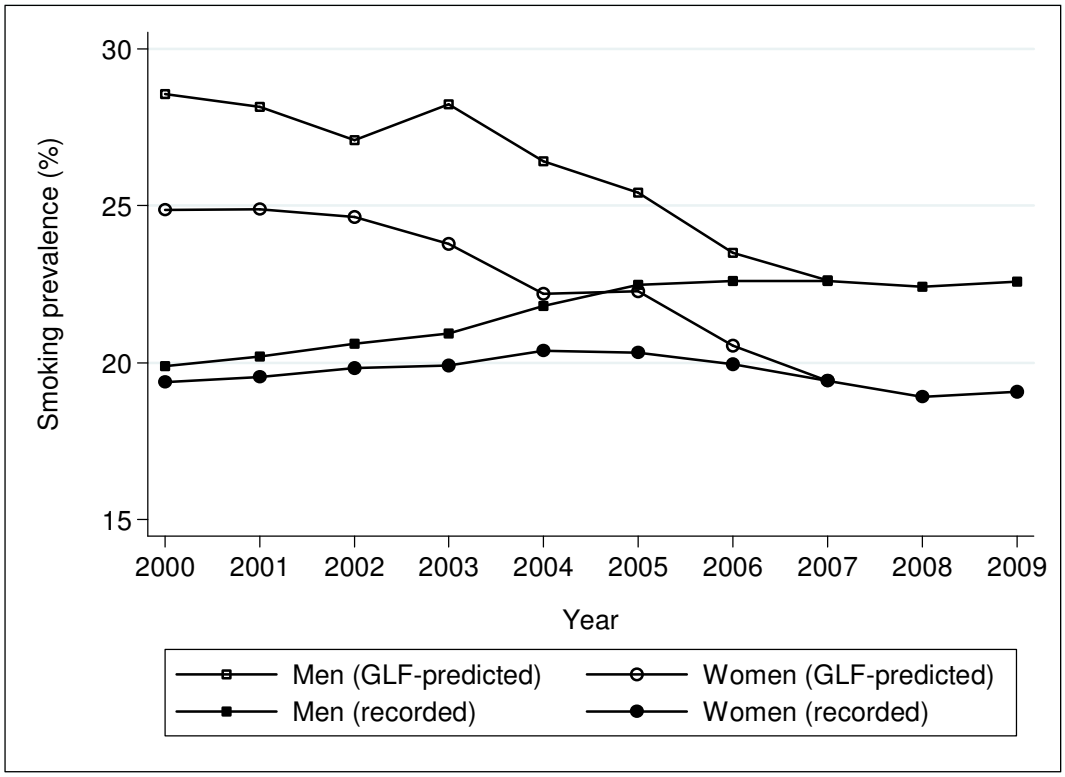


Figure 2.3 Predicted and recorded smoking prevalence in THIN (patients aged 16+)

The GLF-predicted prevalence of current smoking in the THIN population has declined over time, such that in 2007 22.6% men and 19.4% women were predicted to be current smokers. The recorded prevalence of current smokers in THIN has in recent years approached the predicted smoking prevalence. In 2000, 19.9% of men and 19.4% women were identified as current smokers, 69.6% and

78.0% of the predicted prevalence respectively. The gap between the recorded and GLF-predicted prevalence of smoking has closed over time, such that by 2007 22.6% of men and 19.4% of women were recorded as current smokers, figures which, to one decimal place, are the same as the predicted prevalence figures. These national figures disguise significant variations between practices. For men and women combined, in 2007 the worst performing practice recorded just 33.8% of the predicted number of current smokers, whilst on the other hand one practice identified 190.3% of the predicted number of smokers (interquartile range 84.1-116.3%).

There are some variations in the completeness of recording of current smoking by age group and sex, as shown in Figure 2.4. The recorded prevalence of current smoking in both men and women over the age of 50 is very similar to the predicted prevalence throughout the entire study period, and the agreement is also close for patients aged 35-49. In younger patients the agreement between the GLF-predicted and recorded prevalence is closer for women than men, though there have been improvements over time in both genders.

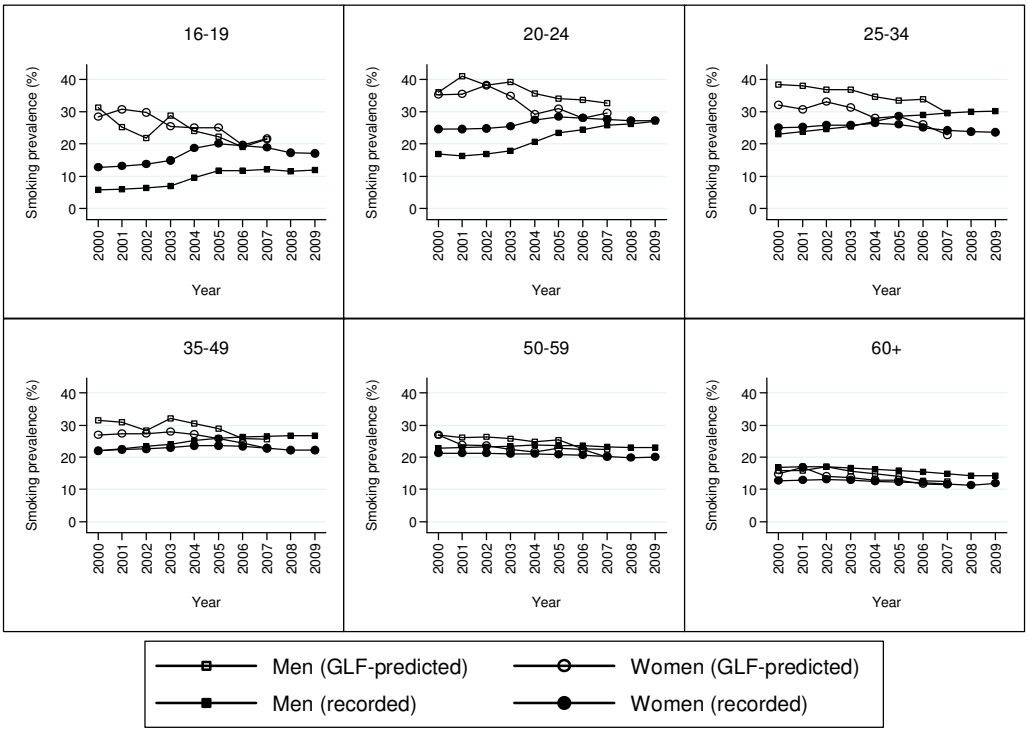


Figure 2.4 Predicted and recorded smoking prevalence in THIN, by age group and sex

2.5.4. Discussion and conclusions

In 2007 there is excellent agreement between the national smoking prevalence estimate derived from the electronic medical records in THIN and the estimate produced by the current 'gold standard', the GLF, and the agreement is also close in 2006. Though this does not mean that all patients recorded in THIN as smokers truly are, simply that a similar number of patients are recorded as smokers as predicted by the GLF, this is the best available evidence to suggest that THIN patients who were current smokers at the time smokefree legislation was introduced in the UK can be identified from their medical records.

The assumption that all patients with no smoking status recorded in their THIN records are not current smokers may lead to the underestimation of smoking prevalence, though, as noted already, other work suggests this assumption is valid[124]. As Appendix 8.5 discusses, a small minority of patients have

contradictory smoking status Read Codes recorded in their notes on the same day, classifying them, for example, as both a current and non-smoker. Such patients were classified as having an unknown smoking status at that point in time, essentially labelling them as non-smokers for the purposes of this analysis and potentially leading to slight underestimation of the smoking prevalence in THIN. Similarly, that a substantial minority of patients' most recent smoking status was recorded several years before the index may also bias prevalence estimates. However, this is perhaps not a problem in older patients recorded many years previously as never smokers, as very few people begin smoking after the age of 25[126], and smoking status records are more up-to-date now than in the past, as discussed in Appendix 8.6.

It is recognised that reliance upon self-reported measures of smoking behaviour in surveys such as the GLF may underestimate smoking prevalence, particularly among younger age groups. Although 16 and 17 year olds complete the GLF questionnaire in private, this is unlikely to be totally successful in encouraging honest answers, and rates of under-reporting might not be constant over time[126], especially given reductions in the social acceptability of smoking. However, if patients misrepresented their smoking behaviour to their doctor there could also be a degree of underreporting in primary care data. Observed individual-level agreement between patients' smoking status records in their medical notes and those ascertained through questionnaires suggests there are minimal data entry errors in primary care records[120]. However, the lack of biochemical data to validate patients' self-recorded smoking status in THIN (and similarly in the GLF) means one cannot be sure whether smoking status records in either data source are a true reflection of reality. It is unlikely, however, that validated smoking outcomes would ever be used routinely in national population surveys due to the expense incurred.

A study similar to this, undertaken in 1996 using GPRD medical records data, found a 20 percent shortfall in the proportion of primary care patients registered as current smokers compared to national prevalence estimates[121]. The THIN dataset, which is similar in structure to the GPRD, also shows a shortfall in recording historically[85], though the situation has improved over time, suggesting that primary care data can now be used more confidently to identify current smokers. This is arguably a result, at least in part, of the QOF requirement for GPs to regularly record the smoking status of all patients[85].

General practices which contribute to the THIN dataset undergo assessment to ensure they are using their computer systems correctly, and thus they may not be representative of all British practices. The substantial variation in the completeness of recording in individual practices warrants further investigation, and may, at least in part, be explained by differences in the social class structure of their patient populations. The lack of a comparable indicator of social class in the GLF* and THIN data means this couldn't be used as a variable in the standardisation procedure, though part of the effect of social class is likely to be accounted for by using Government Office Region as a standardisation variable.

In conclusion, the convergence between the recorded smoking prevalence of patients in THIN and the GLF-predicted estimate suggests that patients who were smokers at the time smokefree legislation was introduced, and who were the potential subjects of increased delivery of cessation interventions, can be identified from their medical records. The variation in the completeness of recording by patient sex and age group suggests again it might be important to investigate the impact of smokefree legislation on intervention recording in current smokers separately by subgroup. In addition, the observed variation by

* An Index of Multiple Deprivation quintile is available in the GLF though not in all years, so this could not be used in the standardisation procedure even if it was proved to be a similar measure of deprivation as the Townsend Index available in THIN.

practice means it may not be appropriate to extrapolate conclusions about the impact of smokefree legislation generated using THIN data to the whole of the UK.

2.6. IS THE RECORDING OF CURRENT SMOKING MORE COMPLETE AMONGST PATIENTS WITH SMOKING-RELATED HEALTH PROBLEMS?

2.6.1. Introduction

Previous studies have highlighted the differential recording of smoking status in patients with particular health concerns compared to those who are otherwise healthy. This may reflect a preference for GPs to discuss and record smoking behaviour in the context of smoking-related illness. Alternatively, smokers with health problems may have higher consultation rates, offering more opportunities for the discussion of smoking and subsequent documentation of their smoking status in their notes.

In this section, the recorded prevalence of current smoking in THIN in patients with one or more defined chronic conditions is compared with the smoking behaviour self-reported by patients with the same conditions in the GLF.

2.6.2. Methods

For each year from 2000 to 2009 all patients were identified from the THIN dataset who were aged 16+ and registered with a British practice on an index date of 1st July of that year. Each patient's year of birth and gender was identified, as well as the Strategic Health Authority within which their GP surgery was located. All records of smoking status, identified by relevant Read Codes, entered into patients' notes on or after their registration date were extracted and

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 date identified them as such. The diagnostic codes listed in Appendix 8.7 were used to identify whether patients had a history prior to each index date of one or more of six chronic conditions (coronary heart disease (CHD), chronic obstructive pulmonary disease (COPD), stroke or transient ischemic attack (TIA), hypertension, diabetes mellitus and asthma). In the case of asthma, patients were only counted as active cases if they also had a prescription for an asthma medication recorded in their notes in the previous year, in line with QOF reporting guidelines[90].

For each year from 2000 to 2007, GLF respondents were grouped according to whether or not they reported having one or more of these same six conditions. Medical history, region, age and sex-specific rates of current smoking were calculated for each year and weighted for non-response to give a nationally representative measure of smoking behaviour. These rates were applied to strata of the THIN population (similarly defined by medical history, age group, sex and region) at each index date using indirect standardisation[125] to produce annual 'GLF-predicted' prevalence estimates for current smoking; these predicted prevalence estimates were then compared with the recorded prevalence figures.

To investigate variations in the recording of smoking status between practices, the expected prevalence of smoking in each practice was calculated in the manner described above, again using medical history, age, sex and Government Office Region as variables in the standardisation procedure. These predicted prevalence estimates were then compared with the proportion of patients in each practice recorded in their notes as smokers.

2.6.3. Results

Table 2.1 shows the number of patients aged 16+ registered in THIN each year with Read Codes in their notes which indicate the prevalence of one or more of the six chronic conditions. For comparison, the unstandardised national prevalence estimates derived from the GLF are shown, with their 95% confidence intervals.

Table 2.1 Prevalence of patients with one or more chronic conditions

Year	THIN patients aged 16+	Patients with 1+ chronic conditions	THIN prevalence (%)	GLF prevalence (95% CI)
2000	2,086,891	351,805	16.9	13.1 (12.5-13.7)
2001	2,228,890	399,221	17.9	13.4 (12.9-14.0)
2002	2,305,027	436,447	18.9	14.8 (14.2-15.4)
2003	2,361,012	473,399	20.1	13.8 (13.2-14.3)
2004	2,383,267	501,005	21.0	13.8 (13.3-14.4)
2005	2,441,596	536,250	22.0	14.4 (13.9-14.9)
2006	2,472,815	558,173	22.6	15.3 (14.8-15.9)
2007	2,499,927	571,864	22.9	13.7 (13.1-14.3)
2008	2,511,909	578,345	23.0	-
2009	2,447,903	568,191	23.2	-

The proportion of THIN patients with a history of one or more chronic conditions recorded in their notes has increased over time, despite little change in the GLF self-reported prevalence. However, in each year the recorded prevalence in THIN is considerably higher than the upper confidence interval of the GLF estimate. Possible reasons for these differences, and the implications for this analysis, will be discussed shortly.

Figure 2.5 shows changes over time in the GLF-predicted and recorded prevalence of current smoking in the THIN population for patients with and without one or more of the six defined chronic conditions.

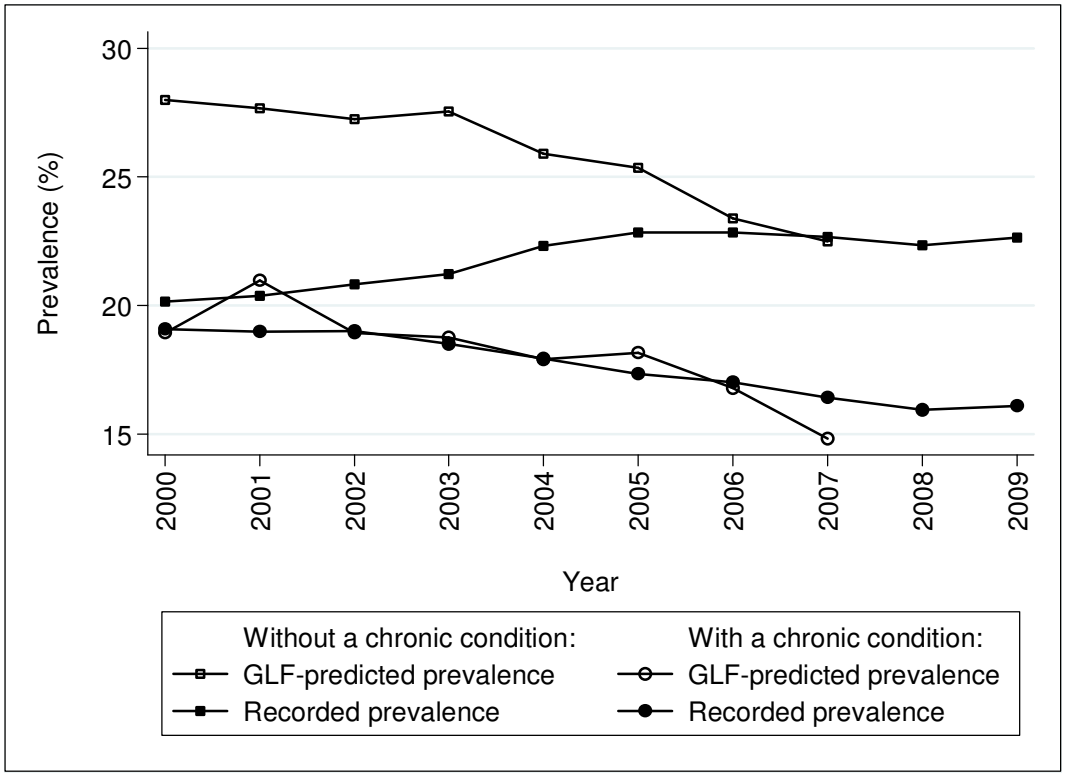


Figure 2.5 Predicted and recorded adult smoking prevalence in THIN in patients with and without a history of chronic illness

The extent of agreement between the GLF-predicted and recorded smoking prevalence is greater for the majority of the study period for patients with at least one of the six chronic conditions compared to those who are otherwise healthy. From 2000 to 2007 there is, on average, only 0.1% difference between the predicted and recorded prevalence of current smoking in patients with a history of chronic disease. Only in 2006 does the predicted and recorded smoking prevalence in patients without these six chronic conditions converge to the same extent.

There is still a large degree of variation between practices in the completeness of recording of current smoking amongst patients with a history of chronic illness. In 2007 the worst performing practice recorded 39.9% of the expected number of current smokers, whilst on the other hand one practice identified 339.0% of the expected number of smokers (median 110.7%, interquartile range 52.5-252.5%).

Smoking is a recognised risk factor for cardiovascular disease, type II diabetes and COPD, and worsens the symptoms of asthma. It could, therefore, be considered surprising that the prevalence of current smoking is lower in patients with one or more of these conditions than in those without. However, as Figure 2.6 shows, the GLF-predicted and recorded prevalence of ex-smoking is higher amongst patients with chronic conditions, suggesting that many of these patients with a history of chronic illness may have succeeded in giving up smoking.

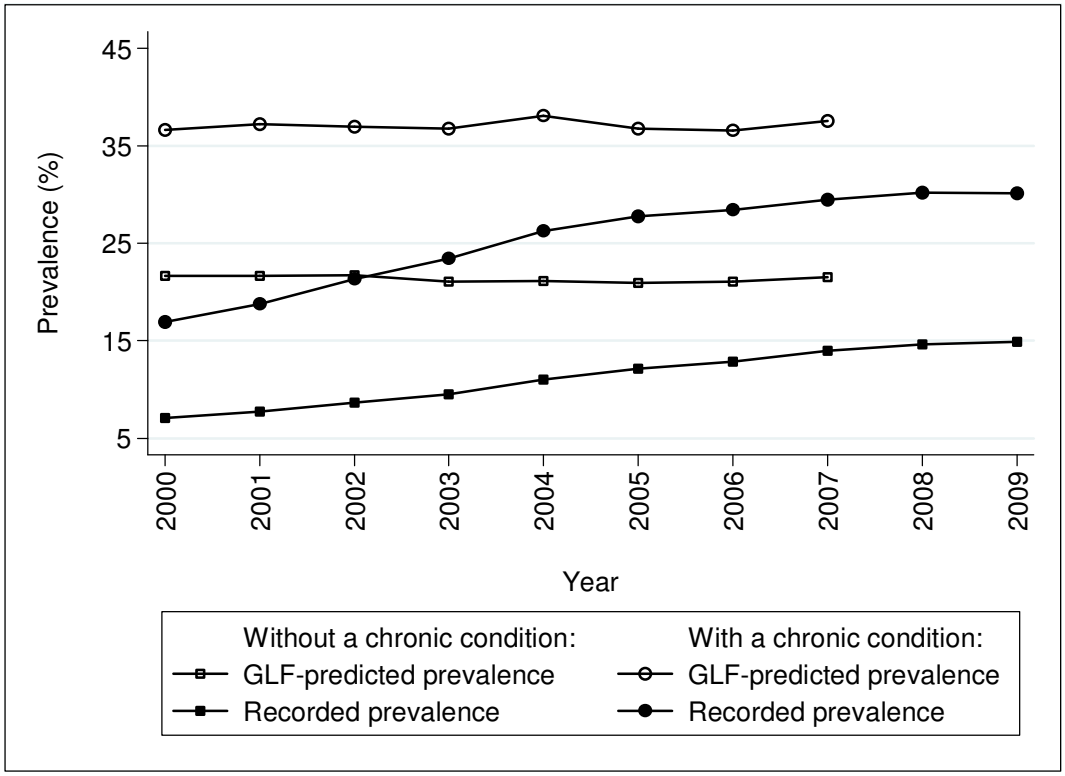


Figure 2.6 Predicted and recorded prevalence of ex-smoking in THIN in patients with and without a history of chronic illness

2.6.4. Discussion and conclusions

Since 2000 there is good agreement between the recorded smoking prevalence in THIN patients with one or more chronic conditions and the predicted prevalence of smoking derived from the GLF. The extent of agreement in patients with no recorded history of chronic conditions is less good, though has improved over time. These findings suggest that, at the time smokefree legislation was

introduced in the UK, smokers with and without chronic conditions can both be identified with relative confidence from their THIN records. However, identification of current smokers without a history of chronic disease may be more difficult before 2006.

This study is subject to the limitations outlined previously in Section 2.5.4, though in addition it is worth considering the reasons for, and implications of, the discrepancy between the proportion of THIN patients recorded as having a history of chronic disease and the proportion of GLF respondents who self-report having such conditions.

The Read Codes used to identify patients in THIN with chronic conditions are those that GPs must use from 2004 onwards in order to qualify for payments under the QOF. Once a patient is entered onto a disease register using one of these codes, GPs must then meet a number of other targets related to their care to qualify for QOF payments. Patients recorded as having coronary heart disease, for example, must have their blood pressure and cholesterol level measured and recorded every 15 months. Since 2004 it is, therefore, unlikely that a patient will be entered onto a disease register if they do not have the condition, as this will create work for the practice and may ultimately lose the practice money if the patient is not managed in the way demanded by the terms of the QOF.

The GLF relies on patients to self-report their chronic conditions, which may give less reliable prevalence estimates than GP records, at least since 2004. Patients may fail to report conditions, perhaps because they do not perceive their condition is of a severity worth mentioning, do not know the correct medical terminology or are even unaware they have the condition. This may result in lower self-reported estimates of the prevalence of chronic disease than are recorded in THIN data.

Table 2.2 shows the prevalence of each of the six chronic conditions amongst patients in THIN in 2007, alongside the unstandardised prevalence from the 2007 GLF with its 95% confidence interval. As can be seen, only the prevalence of diabetes recorded in THIN falls within the 95% confidence interval of the self-reported estimate of diabetes prevalence from the GLF, perhaps because a diagnosis of diabetes and the subsequent treatment regime are particularly memorable and diabetics play a large role in managing the condition themselves. The difference between the recorded and self-reported prevalence is particularly marked in the case of hypertension, with approximately three times the proportion of patients being recorded as having high blood pressure in THIN than self-report having the condition in the GLF. For asthma, CHD, COPD and stroke or TIA the medical records in THIN give slightly higher prevalence estimates than the GLF.

Table 2.2 Prevalence of individual chronic conditions in THIN and GLF in 2007

Year	THIN prevalence (%)	GLF prevalence (95% CI)
Asthma	5.4	4.6 (4.2-4.5)
CHD	4.1	1.6 (1.4-1.8)
COPD	1.7	0.5 (0.4-0.7)
Diabetes	3.9	3.7 (3.4-4.0)
Hypertension	14.0	4.5 (4.2-4.9)
Stroke/TIA	1.8	0.7 (0.6-0.9)

This disagreement between patients' self-reported medical history and that recorded in their medical records suggests that in comparing THIN and GLF data we are comparing measures of smoking prevalence in two very different groups of patients and, as a result, we can be less confident in concluding that the recording of smoking status is more complete in THIN patients with a recorded history of chronic conditions.

In conclusion, it appears that the ability to identify current smokers from their THIN records is historically more complete for patients with a history of chronic disease, though at the time smokefree legislation was introduced both smokers

with and without chronic conditions can potentially be identified. This conclusion is weakened by uncertainties over the accuracy of patients' self-reported medical history, and again there is considerable variation between practices which may reduce the external validity of any conclusions drawn using THIN data about the impact of smokefree legislation on the management of smoking in primary care in the UK.

Before 2006, the patients identified from their THIN records as smokers may represent relatively more of the patient population with a history of chronic disease than patients without. Smokers with a history of chronic disease may perhaps be more likely to seek or receive a cessation intervention, which may inflate the intervention rate seen in the period before smokefree legislation was introduced compared to that from 2006 onwards. If this is the case, any increased rate of intervention at the time smokefree legislation was introduced may not stand out as over and above the preceding trend. It will, therefore, be crucial to undertake a sensitivity analysis to determine whether the observed effect of the introduction of smokefree legislation on rates of intervention differ in smokers with and without a history of chronic disease compared to all smokers.

2.7. IS IT POSSIBLE TO IDENTIFY A SUBSET OF PRACTICES WITH GOOD DATA RECORDING?

The previous sections of this chapter have highlighted large variations between practices in the proportion of patients whose smoking status has been recorded in their THIN records and the discrepancy between the recorded and predicted practice-level smoking prevalence. In using THIN to assess the impact of smokefree legislation on the management of smoking in primary care it is desirable to be able to identify all smokers accurately. Therefore, it might be advantageous to identify practices who are particularly poor at recording smoking-related information and exclude them from further analyses.

It is difficult, however, to know how to identify practices whose data is below standard. One approach may be to only allow practices to contribute data to the planned studies investigating the impact of smokefree legislation once they have recorded the smoking status of at least a certain proportion of patients. This would, however, require the arbitrary selection of a cut-off point, though the impact of the choice of cut-off could be investigated. Figure 2.7 shows, for example, changes over time in the recorded and predicted prevalence of current smoking in the THIN population when practices are only allowed to contribute data once at least 75% of their patients aged 16+ have their smoking status recorded in their notes.

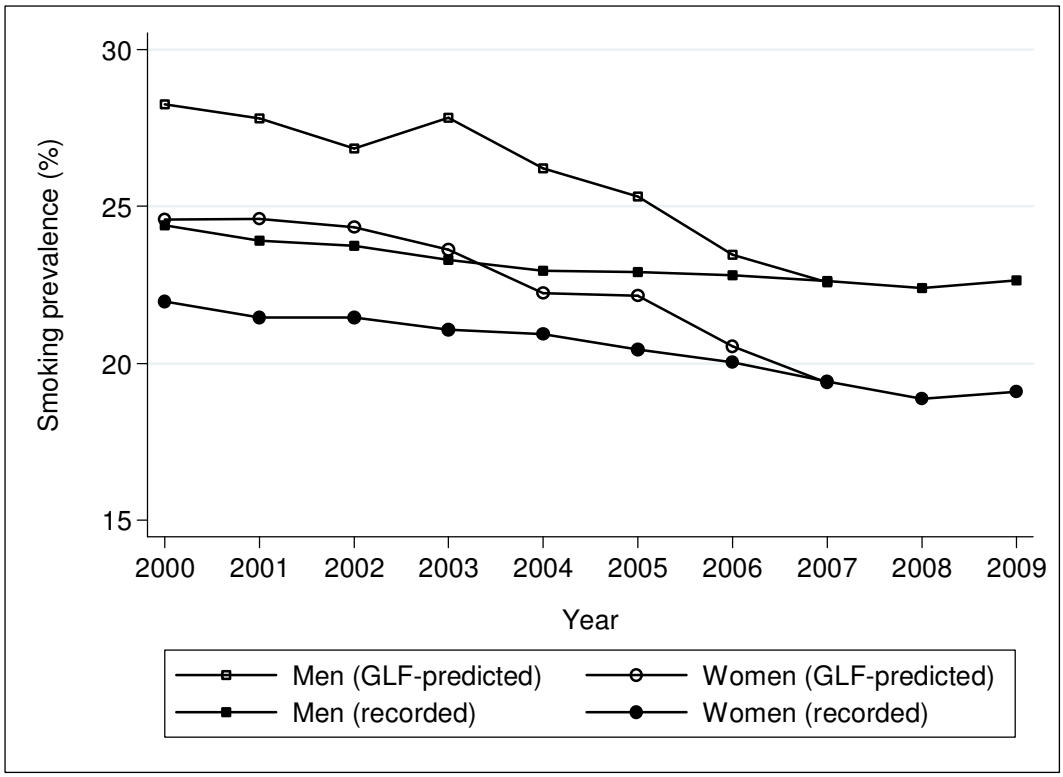


Figure 2.7 Predicted and recorded smoking prevalence in THIN, excluding data from practices who have recorded the smoking status of less than 75% of patients

Comparing Figure 2.3 and Figure 2.7 shows that excluding practices who have not recorded the smoking status of at least 75% of their patients increases the recorded prevalence of smoking in the early part of the study period. There remains, however, a shortfall in the proportion of patients recorded as current

smokers compared to the predicted smoking prevalence based on the results of the GLF. There also still remains substantial variation between practices in the extent of agreement between the predicted and recorded smoking prevalence. In 2007 the worst performing practice recorded 44.5% of the expected number of current smokers (compared to 33.8% when there was no restriction on practices contributing to the analysis), but there was no change in the upper extreme (190.3%) and interquartile range (84.1% - 116.3%). Restricting the number of practices which contribute data to analysis of the impact of smokefree legislation will as a result reduce the number of patients included in the study. Given the size of the THIN dataset, this may not be problematic when analysing the impact of smokefree legislation in the population as a whole, but may reduce the power to investigate the effect of the smoking ban in population subgroups. Increasing the cut-off point for smoking status recording above which practices are allowed to contribute data to any further analyses will only reduce the population size further and is, therefore, undesirable.

It is not possible to compare recorded and predicted smoking prevalence figures for individual practices as a means of identifying the point in time from which they were accurately recording current smokers as such in their medical records. A practice with a consistently lower recorded smoking prevalence than predicted may simply be in a more affluent area and serve fewer smokers, and vice versa. As noted previously, the lack of a comparable indicator of social class in the GLF and THIN data means this couldn't be used as a variable in the standardisation procedure, and so it is impossible to judge whether a practice with a relatively low or high recorded smoking prevalence is in fact documenting patients' smoking status accurately.

2.8. CHAPTER CONCLUSIONS

The data presented above suggests that the quality of smoking status information recorded in THIN has improved considerably since 2000, and provides evidence to support the use of THIN to evaluate the effect of tobacco control policies such as the introduction of smokefree legislation.

Since 2000, an increasing proportion of adults in THIN have had their smoking status recorded soon after registering with a general practice (see Appendix 8.4), and the number of patients whose smoking status can be identified from their primary care medical records has improved. The rate of reduction in the number of people with no smoking status documented in their medical record was greatest between 2003 and 2005, the period spanning the implementation of the 2004 GP contract, though improvements continue to be made to the point at which the THIN database ends in mid-2009. For the purposes of investigating the impact of smokefree legislation on rates of recording of smoking status it will be necessary to distinguish changes in clinical activity occurring at the time legislation was introduced from the longer-term trend of continued improvements in data recording.

Since 2000 the proportion of patients in THIN recorded as current smokers has gradually approached the number that would be expected if country, age group and sex-specific smoking rates from the GLF are applied to the THIN population; since 2006 the recording of current smokers is particularly complete. The ability to identify current smokers may differ by patient characteristics such as sex, age group and medical history, and thus it may be necessary to investigate the impact of smokefree legislation on rates of intervention delivery individually by subgroup.

As has been seen, there are sometimes large differences between practices in the quality of their recording of their patients' smoking status. However, it is not possible to identify which practices are failing to record current smokers as such in their medical records, and the reduction in sample size caused by restricting practices which are allowed to contribute data to assessing the impact of smokefree legislation is not desirable. Therefore, conclusions drawn using THIN about the impact of smokefree legislation on the management of smoking in primary care may not be generalisable to primary care throughout the UK.

Having evaluated the quality of the smoking status information recorded in THIN the next chapter of this thesis assesses the quality of recording of smoking cessation interventions.

3. HOW COMPLETE AND CORRECT IS THE RECORDING OF SMOKING CESSATION INTERVENTIONS IN THE HEALTH IMPROVEMENT NETWORK DATABASE?

3.1. INTRODUCTION

The previous chapter investigated the quality of the smoking status information recorded in THIN, concluding that the completeness of recording and ability to identify current smokers has improved in recent years, with improvements potentially being driven by the introduction of the Quality and Outcomes Framework (QOF) in 2004. Before using THIN data to investigate the impact of smokefree legislation on the management of smoking in primary care it is also crucial to understand trends in the recording of smoking cessation interventions delivered by primary health care professionals. As well as rewarding GPs financially for documenting their patients' smoking status, the QOF also rewards GPs for recording that they have offered cessation advice to smokers with specified chronic conditions. Thus, improvements in these data may also be seen in the period before and after the introduction of the QOF, which may potentially confound assessment of the impact of the introduction of smokefree legislation.

Since 2000, new smoking cessation interventions have become available to smokers via GPs, such as referral to specialist cessation services or a prescription for a cessation medication. Again, an assessment of the patterns of recording of these interventions is vital to be sure that any observed change in the rate of delivery of these interventions at the time smokefree was introduced is related to

the legislation and not simply a continuation of longer-term term trends towards increased delivery and/or recording of these interventions.

This chapter assess the quality of recording of smoking cessation interventions in THIN, beginning with a review of the existing literature to identify the data quality problems which might be encountered in the THIN data.

3.2. REVIEW OF PREVIOUS STUDIES EVALUATING THE RECORDING OF SMOKING CESSATION INTERVENTIONS IN PRIMARY CARE

If THIN is to be used to investigate the effect of smokefree legislation on GPs' management of smoking it is crucial to appreciate first how frequently GPs intervene with smokers and how completely they document this.

It is difficult to know exactly how frequently cessation support is offered to smokers, and therefore how frequently we would expect to see such an intervention documented in a patient's notes. As noted in Section 1.9.1, previous research has suggested that patients systematically over-report having being asked about their smoking behaviour by a GP, and smokers over-report having being advised to quit[102]. Large discrepancies have been reported between the proportion of patients who self-report having received cessation advice, the observed frequency with which GPs deliver advice, and the proportion of patients with advice documented in their medical records. In one study, conducted before the widespread adoption of electronic medical records, cessation advice was recorded in the notes of 30.9% of patients who reported having received advice and in just 28.6% of cases where advice was heard to have been delivered on an audio-tape of the consultation; in consultations where advice was heard, 26.1% of patients failed to report this intervention[127].

The introduction of the QOF provided a financial incentive for GPs to document in smokers' medical records that they have been offered cessation advice[90]. Specifically, GPs are rewarded for documenting having offered advice to smokers with specified chronic health conditions at least every 15 months, as noted in Table 1.6[90]. Unsurprisingly, the QOF increased the rate at which cessation advice was documented in electronic records within THIN – a tripling of rates of advice recorded in medical records occurred in the year following the introduction of the QOF[85]. However, in the same period there was no concomitant increase in prescribing of nicotine replacement therapy (NRT) or bupropion, for which there is no QOF incentive, suggesting that perhaps the QOF simply increased GPs' propensity to document cessation advice that they would have offered regardless, rather than actually increasing the rate at which they intervened with smokers[128]. It should be noted that in this study analysis was based on rates of interventions recorded in the notes of patients who were also identified as current smokers at that point in time. However, Section 2.4 showed that historically many patients had no mention of smoking status in their notes, and Section 2.5 suggests that the ability to identify current smokers was poor before 2006. Analysing intervention rates only in patients recorded as current smokers may exclude patients who were not recorded as a current smoker at a particular point in time but who had a cessation intervention recorded in their notes. This may lead to misunderstanding the rate at which smoking cessation interventions are delivered, as well as any changes in the intervention rate associated with the introduction the QOF.

There are few estimates of the proportion of smokers that are referred by a primary health care professional to specialist stop smoking services. In 2008, a sample of 26 GPs from north London reported that they had recommended or referred half of the smokers they had seen in their last ten clinical sessions to a community cessation advisor and 16% to a specialist cessation service[129].

However, from these data it is difficult to identify how many referrals this equates to over the course of, for example, one year.

In addition to offering cessation advice or a referral to a cessation service, GPs are also able to prescribe smokers NRT, bupropion or varenicline to help them quit. Prescriptions for smoking cessation medications are issued automatically through a practice's computer system, and thus a record of all prescriptions issued appears in THIN. Rates of prescribing derived from the THIN dataset are comparable to rates of prescription dispensing in England[130], suggesting that patients do indeed redeem their prescriptions, though of course some patients may not actually use the medication as directed.

3.3. DATA QUALITY ISSUES TO BE INVESTIGATED IN THIS CHAPTER

The review of the literature presented in the previous section has highlighted several potential shortfalls in the quality of smoking cessation intervention data that might be encountered in THIN. The following issues will be investigated in the remainder of this chapter to address these questions of data quality and judge whether THIN can be used to evaluate the impact of smokefree legislation on the management of smoking in primary care.

Section 3.4 assesses whether the proportion of patients with a record in their notes that they have been offered smoking cessation advice has changed over time, and considers whether these records are a true reflection of the amount of cessation advice delivered.

Section 3.5 investigates whether the proportion of patients who are recorded as having been referred to a smoking cessation service has changed over time, and

again considers whether these records are a true reflection of the number of patients who are truly referred.

Section 3.6 assesses whether all patients with a record of cessation advice, referral or prescription of a smoking cessation medication in their notes are also recorded as being a smoker at that point in time.

3.4. HAS THE PROPORTION OF SMOKERS OFFERED CESSATION ADVICE CHANGED OVER TIME AND IS ALL CESSATION ADVICE DELIVERED IN PRIMARY CARE DOCUMENTED IN PATIENTS' RECORDS?

3.4.1. Introduction

One way to investigate whether all patients in THIN who are offered cessation advice have this offer documented in their medical records is to approach patients directly and compare their recollections of advice with their medical notes. Alternatively, GPs could be observed directly or video-recorded as they consult with patients and then records inspected to see whether any cessation advice delivered is recorded. However, as noted previously, these study methods are impossible as all data in THIN are anonymised to protect practice and patient anonymity, and, as discussed in Section 1.9.1, GPs' behaviour may change if they know they are being observed. Given these difficulties, this section investigates changes over time in advice recording, and assesses the completeness of recording of cessation advice, by comparing rates of advice recorded in THIN with those recalled in a survey of NHS patients in England in the years since the introduction of the QOF.

3.4.2. Methods

For each year from 2000 to 2009, all patients from the THIN dataset who were over the age of 16 and registered with an English practice on an index date of 1st July in that year were identified. Each patient's year of birth, sex and the Strategic Health Authority (SHA) within which their GP surgery was located were identified. Patients' medical records were searched for Read Codes documenting the delivery of smoking cessation advice to that patient (see Appendix 8.8), and, for each year, the proportion of patients with a recording of cessation advice in the 12 months prior to the index date was calculated.

The Primary Care Trust (PCT) Patient Surveys monitor patients' experiences of NHS services[131]. In 2004, 2005 and 2008, a simple random sample of patients was selected from each PCT in England, and a postal questionnaire administered asking whether the respondent had 'definitely' or 'to some extent' received cessation advice from a health professional (GP or nurse) at their GP surgery within the last 12 months. Completed questionnaires were received from 122,113 patients in 2004, 116,939 in 2005 and 69,470 in 2008 (response rates of 47.4%, 45.4% and 38.3% respectively).

Previous work using the Patient Survey has shown that the provision of smoking cessation advice by primary health care professionals varies with patient sex and age[20]. Consequently, as Patient Survey respondents and patients in the THIN dataset have different demographic characteristics, directly comparing 'raw' data on smoking cessation advice received by patients in each source is not appropriate. Therefore, the following standardisation procedure was used to enable comparison of data from THIN and the Patient Surveys. For 2004, 2005

and 2008, age group*, sex and SHA-specific rates of patients reporting having received smoking cessation advice within the last 12 months at least 'to some extent' were calculated from Patient Survey responses. These rates were applied to strata of the THIN population (similarly defined by age group, sex and SHA) at the corresponding index date using indirect standardisation[125], producing estimates for annual rates of recalled cessation advice that might be expected from THIN patients, based on Patient Survey responses (referred to as 'predicted recall rates'). Predicted recall rates were then compared graphically with the actual cessation advice rates documented in THIN patients' medical records.

3.4.3. Results

Figure 3.1 shows, for each year from 2000 to 2009, the proportion of patients within THIN who had smoking cessation advice documented in their medical records in the previous 12 months and, for Patient Survey years, predicted recall rates.

The proportion of THIN patients with cessation advice documented in their medical records in the past year increased considerably over the study period, from 1.2% of patients in 2000 to 10.9% in 2009, with the majority of this increase occurring between 2003 and 2005. However, although similar in 2004, the proportion of THIN patients predicted to recall having received cessation advice was subsequently lower and increased less over the survey period (6.6% of patients in 2004, 8.3% in 2008). In 2004 there was good agreement between recording of cessation advice in THIN and recall rates adjusted for demographic differences in available data sources, but in both 2005 and 2008, agreement between recorded

* The age groups used in the Patient Survey are different to those used in the GLF, hence the age categorisation used in this section is different to that used in all other work presented in this thesis.

and recalled cessation advice was much less strong with recall rates being much lower.

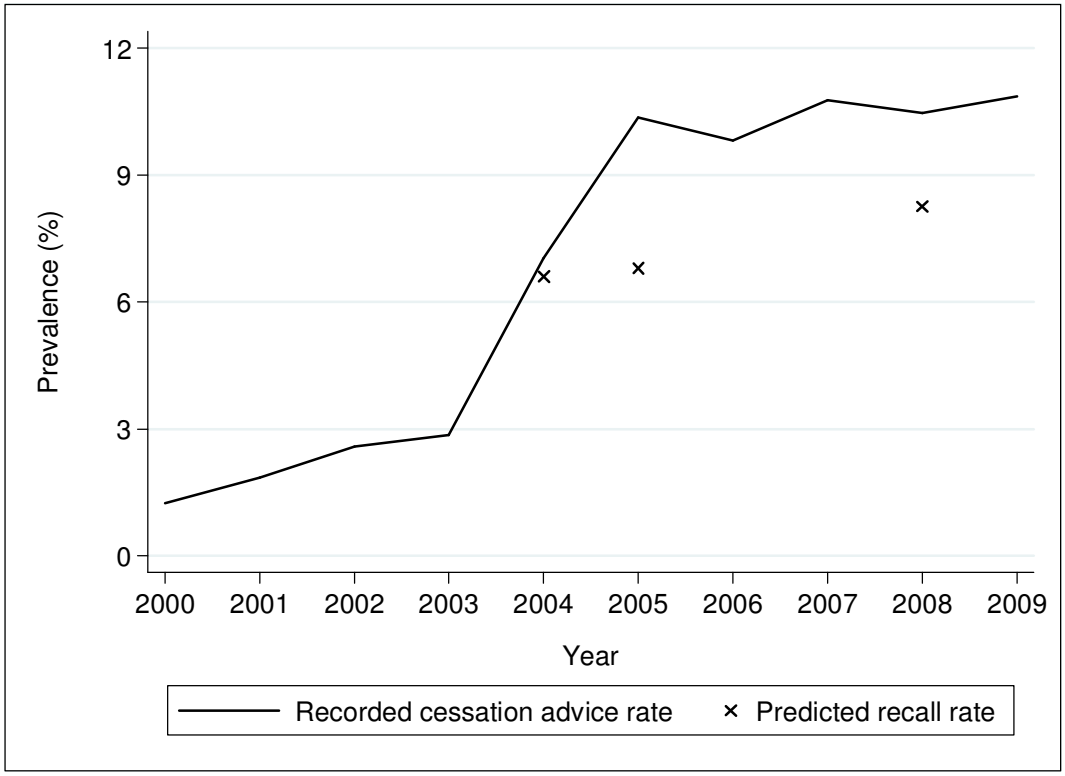


Figure 3.1 The proportion of THIN patients aged 16+ with recorded cessation advice and predicted recall rates

As was seen in the recording of patients' smoking status, there is considerable variation between practices in the extent of agreement between rates of recorded and recalled cessation advice. In 2008, the rate of recorded cessation advice in one practice was 40.0% of the predicted recall rate, and at the other end of the spectrum the rate of recorded cessation advice in another practice was 540.6% of the predicted recall rate (interquartile range 84.2-152.8%).

The patterns of recorded and recalled advice also differed by patient sex and age group, as shown in Figure 3.2. The proportion of THIN patients with a record of advice at the end of the study period, and the difference between men and women, varies by age group, though in each subgroup there is a large increase between 2003 and 2005 in the proportion of patients with recorded advice. In

some subgroups, notably men and women between the ages of 36 and 65, there is closer agreement between recorded and recalled cessation advice.

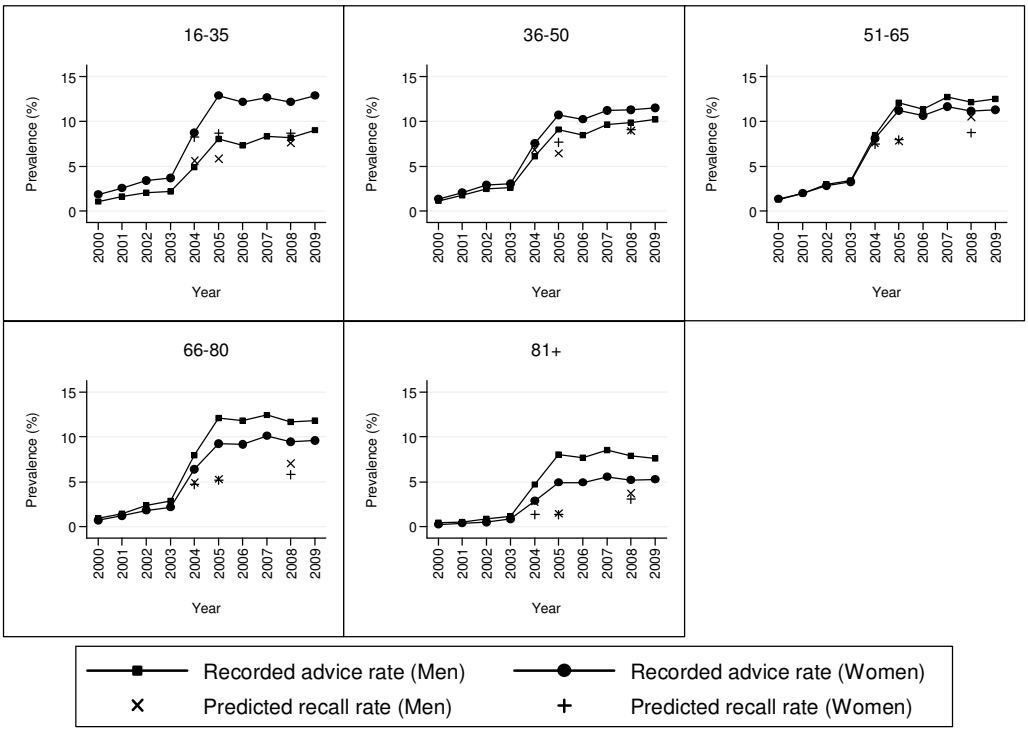


Figure 3.2 The proportion of THIN patients aged 16+ with recorded cessation advice and predicted recall rates, by sex and age group

3.4.4. Discussion and conclusions

To my knowledge this study is the first to compare, at a population–level, smoking cessation advice recorded in medical records with patients' recall of such advice reported in large surveys; in 2004 there was close agreement between both data sources but this decreased substantially in 2005 and 2008.

Some of the longitudinal changes in the proportion of patients recalling cessation advice, or having this documented in their medical records, may be due to changes in population smoking prevalence. Ideally, this study would have assessed recorded and recalled advice within smokers only, but, as Section 2.5 showed, the ability to identify smokers in THIN confidently was poor in the early

years of this analysis and it was impossible to identify respondents who were smokers from each Patient Survey. To allow interpretable, annual comparisons the results presented are, therefore, based on annual denominators of all patients (for THIN) and respondents (Patient Survey). However, between 2004 and 2005, the period when the gap between patient-reported and documented advice appears in Figure 3.1, there was little change in smoking prevalence in England[13], and thus changes in smoking prevalence are unlikely to explain the divergent data.

This study is limited by a lack of data on patients' recall of smoking cessation advice prior to 2004 (the first Patient Survey, in 2003, asked whether respondents had *tried* to get help to quit smoking from local health care services rather than whether they had received cessation support at their GP surgery). One explanation for the findings reported here is that patients' propensity to recall advice may have changed over time – in the latter years of this study patients may simply have found cessation advice from health care professionals less memorable. However, for diminished recollections of advice to explain findings, patient recall would have to have diminished quite substantially in a relatively short period, so it seems likely that other reasons account for the difference.

The relatively low Patient Survey response rates raise the possibility of response bias, with smokers or patients recalling advice perhaps being more or less likely to complete the survey. However, the response rates in 2004 and 2005 are very similar and the characteristics of respondents completing the survey in these two years are unlikely to have changed substantially. Again, therefore, it seems rational that other reasons also account for the divergence in recorded and recalled advice rates.

The findings presented here are contrary to those from other studies, discussed in Section 3.2, which showed more patients recalling receiving advice than had this

documented in their medical records[102, 127]. Historically, GPs may not have documented all cessation advice delivered to smokers, though when asked a majority claim to have done this[116]; with the introduction of the QOF, from 2004 onwards GPs may simply be documenting more of the advice that they give[128]. The failure to observe large increases in patients' recall of cessation advice, with no concurrent increase in rates of prescribing of stop smoking medications[128], tends to support this, and this finding is similar to that of a study mentioned earlier, where GPs who claimed the largest amount of money under a new health promotion payment scheme seemed simply to change the way they recorded their patients' smoking status, rather than raising the topic of smoking more frequently with patients[87].

The divergence between rates of recording of advice and patient recall seen in Figure 3.1 is less easy to explain, unless there was an increase in the amount of advice being delivered in such a way that patients did not perceive it as advice. GPs have different approaches to advice giving[132], and thus advice documented in patient records could reflect simply the briefest mention of smoking and not be of sufficient duration or intensity to be recalled as 'advice' by smokers[133]. Alternatively, GPs could be recording offers of advice that were not actually made or which were refused; if the latter occurred, patients would not necessarily report receiving advice whereas the offer could legitimately be recorded in medical records.

In conclusion, this study shows an increase in the proportion of patients who have smoking cessation advice recorded in their medical records, though the proportion has increased much more slowly since 2005 than the rate of increase seen in the two years prior to this. The method used to assess whether there was a change in the rate of advice recording at the time smokefree legislation was introduced must be able to account for these underlying, long-term trends. Although this study

finds substantial increases in the number of patients with a record of cessation advice having been delivered in their primary care medical records, and a smaller increase in the proportion self-reporting having received advice, the discrepancies between these data sources and the inherent difficulties involved in interpreting each mean we cannot be sure whether the proportion of smokers being advised to quit by primary care health professionals has improved in recent years as much as the improved documentation rates would have us believe. Similarly, any changes in the rate of recording of cessation advice seen at the time smokefree legislation was introduced may not necessarily reflect a change in the number of smokers being advised to quit.

3.5. HAS THE PROPORTION OF SMOKERS REFERRED TO SMOKING CESSATION SERVICES CHANGED OVER TIME AND HOW COMPLETELY ARE REFERRALS DOCUMENTED IN PATIENTS' RECORDS?

3.5.1. Introduction

As discussed in Section 3.2, little is known about how frequently primary health care professionals refer smokers in their care to specialist stop smoking services and how completely they record their referrals in patients' medical records. There are no financial incentives for GPs to refer smokers to stop smoking services, but the QOF incentives to record patients' smoking status and the delivery of cessation advice may have increased GPs' engagement in other types of cessation activity such as directing smokers who want to quit to specialist services which can help them do so.

A secular change in the recording of referral of smokers to stop smoking services may confound assessment of changes in the rate of referral at the time smokefree legislation was introduced. In addition, any discrepancy between recorded and

actual referrals at the time the smoking ban was enacted will make it difficult to be certain that any observed changes in recording truly reflect a change in the number of smokers being referred for cessation support.

In order to investigate changes over time in the recording of referrals to smoking cessation services and assess the completeness of recording, this study compares rates of referral recorded in THIN with those recalled in the ONS Omnibus Survey, a nationally-representative survey of adults in Britain, which has sampled approximately 1,600 people in October and November each year since 2000.

3.5.2. Methods

For each year from 2000 to 2008, all patients from the THIN dataset who were aged 16+ and registered with a practice in England, Scotland or Wales on an index date of 1st November in that year were identified. These patients' electronic notes were searched for Read Codes documenting referral to a smoking cessation service (see Appendix 8.9) and for each year the proportion of patients with a recorded referral in the 12 months prior to the index date was calculated.

The ONS Omnibus Survey provides a measure of the number of self-reported smokers who also self-report having been referred or self-referred to a stop smoking group, clinic or service within the past year. There is no way to separate Omnibus Survey respondents who were referred to a cessation service by a primary care health professional from those who self-referred, and so this measure may not be directly comparable with referrals recorded in primary care records. However, there are no other sources of referral data, and so Omnibus Survey data will be used in the absence of a better alternative.

Omnibus Survey respondents and patients in the THIN dataset have different demographic characteristics, so directly comparing 'raw' data on referrals to smoking cessation services received by patients in each source is not appropriate. Therefore, the following standardisation procedure was used to enable comparison of data from THIN and the Omnibus Surveys. Given the small monthly sample size of the Omnibus Survey, data from October and November each year was combined. For each year, age group, sex and SHA-specific rates of patients reporting having been referred or self-referred to a cessation service within the last 12 months were calculated from Omnibus Survey responses. These rates were applied to strata of the THIN population (similarly defined by age group, sex and SHA) at the corresponding index date using indirect standardisation, producing estimates for annual rates of recalled referral that might be expected from THIN patients, based on Omnibus Survey responses (referred to as 'predicted referral rates'). Predicted referral rates were then compared graphically with the actual referral rates documented in THIN patients' medical records.

The small number of people questioned by the Omnibus Survey makes it difficult to produce meaningful comparisons of recorded and recalled referral in subgroups of the population defined by sex and age group, so this analysis was not undertaken. However, as in previous analyses, the variation in recording between practices was assessed.

3.5.3. Results

Figure 3.3 shows the proportion of patients aged 16 and above registered in THIN each year with a record of having being referred to a stop smoking service in the previous 12 months, alongside predicted referral rates.

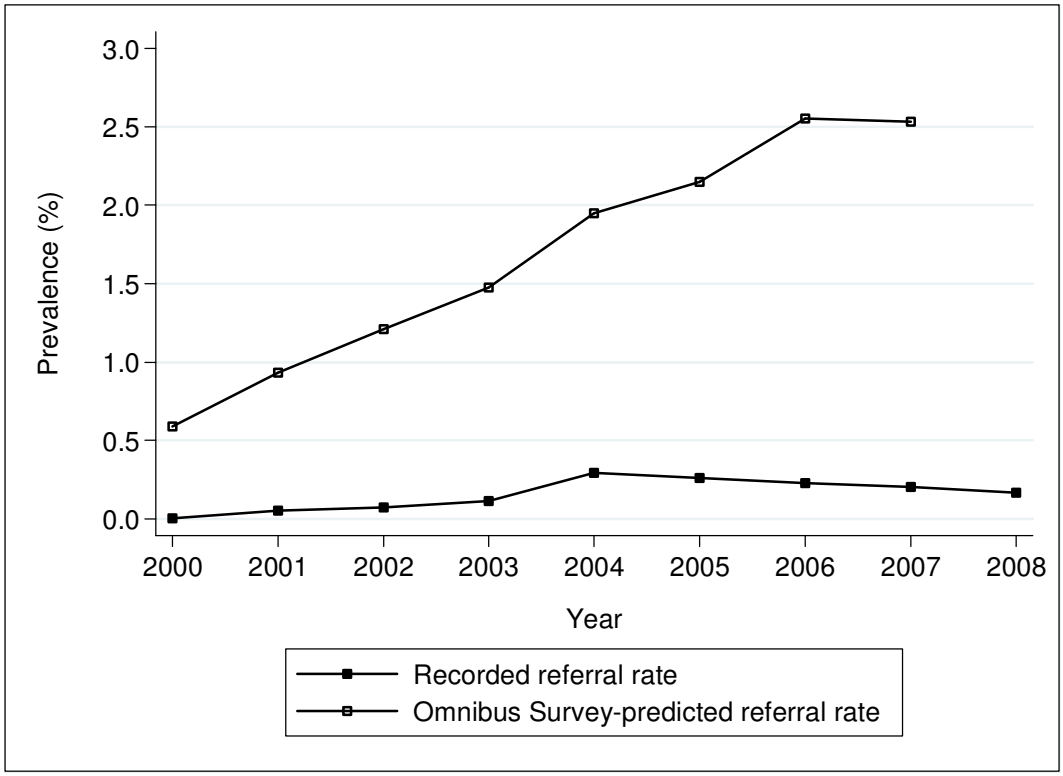


Figure 3.3 The proportion of THIN patients aged 16+ with recorded referral and predicted referral rates

The proportion of patients with a referral to a smoking cessation service recorded in their THIN records has remained relatively low across the study period, peaking at 0.3% of patients in the year up to 1st November 2004. The largest increase in recorded referral was seen between 2003 and 2004, and since 2004 the proportion has declined marginally each year.

The proportion of patients predicted to recall referral increased steadily between 2000 and 2006, though appears to have since levelled out. In each year there is a large difference between the proportion of THIN patients with referral recorded in their notes, and the proportion of patients predicted to recall referral based on the results of the Omnibus Survey.

There is again variation between practices in the extent of agreement between rates of recorded and recalled referral. In 2007, several practices had no patients recorded as having been referred to a smoking cessation service, and at the other

end of the spectrum the rate of recorded referral in another practice was 113.8% of the predicted referral rate (interquartile range 0.0-6.6%).

3.5.4. Discussion and conclusions

To my knowledge this is the first study to compare, at a population–level, referrals to smoking cessation services recorded in medical records with patients' recall of referral reported in large surveys.

Again, some of the longitudinal changes in the proportion of patients recalling referral to a cessation service, or having this documented in their medical records, may be due to changes in population smoking prevalence. Given the difficulty in identifying current smokers in THIN in the early years of the study period, as demonstrated in Section 2.5, this study compares rates of recording and recall in all patients.

As noted earlier, the large difference between the expected and recorded prevalence figures may reflect the nature of the question asked in the Omnibus Survey. Respondents were asked whether they had been referred *or self-referred* to a stop smoking service, and there is no way to distinguish between these means of referral. The Read Codes used in THIN will only identify referrals by a member of the primary healthcare team and thus comparing THIN and Omnibus Survey data is not comparing like with like.

The difference between self-reported and recorded referral rates may also reflect that fact that there are no financial incentives in the QOF for GPs to record that they have referred smokers to other sources of help, and so many patients may indeed be referred but this not be documented in their medical records. Additionally, if GPs are referring patients to cessation support available within

their own practice this may not be considered a referral to a specialist cessation service nor recorded as such.

In conclusion, this study shows if anything a small decrease in the proportion of patients who have a referral to a smoking cessation service recorded in their medical records since 2004, and this change may confound assessment of changes in the rate of referral at the time smokefree legislation was introduced. The method used to assess whether there was a change in the rate of referral recording at the time smokefree legislation was introduced must be able to account for this underlying trend. In addition, the discrepancy between recorded and recalled referrals at the time the smoking ban was enacted will make it difficult to be certain that any observed changes in recording truly reflect a change in the number of smokers being referred for cessation support.

3.6. ARE SMOKING CESSATION INTERVENTIONS ONLY RECORDED IN THE NOTES OF PATIENTS ALSO DOCUMENTED AS SMOKERS?

3.6.1. Introduction

A previous paper investigating the impact of the QOF on rates of recording of cessation advice and prescribing of smoking cessation medications based its analysis on rates of interventions recorded in the notes of patients who were also identified as smokers at that point in time[85]. However, Section 2.4 showed that historically many patients had no mention of smoking status in their notes, and Section 2.5 suggests that the ability to identify current smokers was poor before 2006. Analysing intervention rates only in patients recorded as current smokers may exclude patients who were not recorded as a current smoker at a particular point in time but had a cessation intervention recorded in their notes. This may lead to misunderstanding the rate at which smoking cessation interventions are

delivered, as well as any changes in the intervention rate associated with the introduction of smokefree legislation.

This study compares the rate of recording of cessation advice, referral to stop smoking services, and prescribing of smoking cessation medications in patients in THIN according to whether or not they are identified as a current smoker at the point in time intervention was recorded.

3.6.2. Methods

For each month from January 2000 to July 2009, all patients from the THIN dataset who were aged 16+ and registered with a practice in the UK for at least one day in the month were identified. Patients were classified as either smokers or non-smokers each month, based on the most recent smoking status Read Code in their medical records prior to the first day of each month. The combined time smokers, non-smokers and all patients spent registered in THIN each month was calculated, measured in person-months.

Read Codes were used to identify patients with at least one record of cessation advice or referral to a cessation service in their notes in each month. Similarly, Multilex drug codes were used to identify patients with one or more prescriptions for NRT, bupropion or varenicline recorded in their notes each month (see Appendix 8.10 for drug codes).

Monthly rates of recording of cessation advice, referral to a cessation service and prescribing of all smoking cessation medications were calculated separately for smokers, non-smokers and all patients, expressed as the number of patients with a record in that month per 100,000 person-months of follow-up time. The rate of

recording of each intervention in smokers, non-smokers and all patients was compared graphically.

3.6.3. Results

Figure 3.4 shows monthly rates of recording of cessation advice in all patients aged 16+ in THIN, as well as in patients recorded as smokers and patients not recorded as smokers.

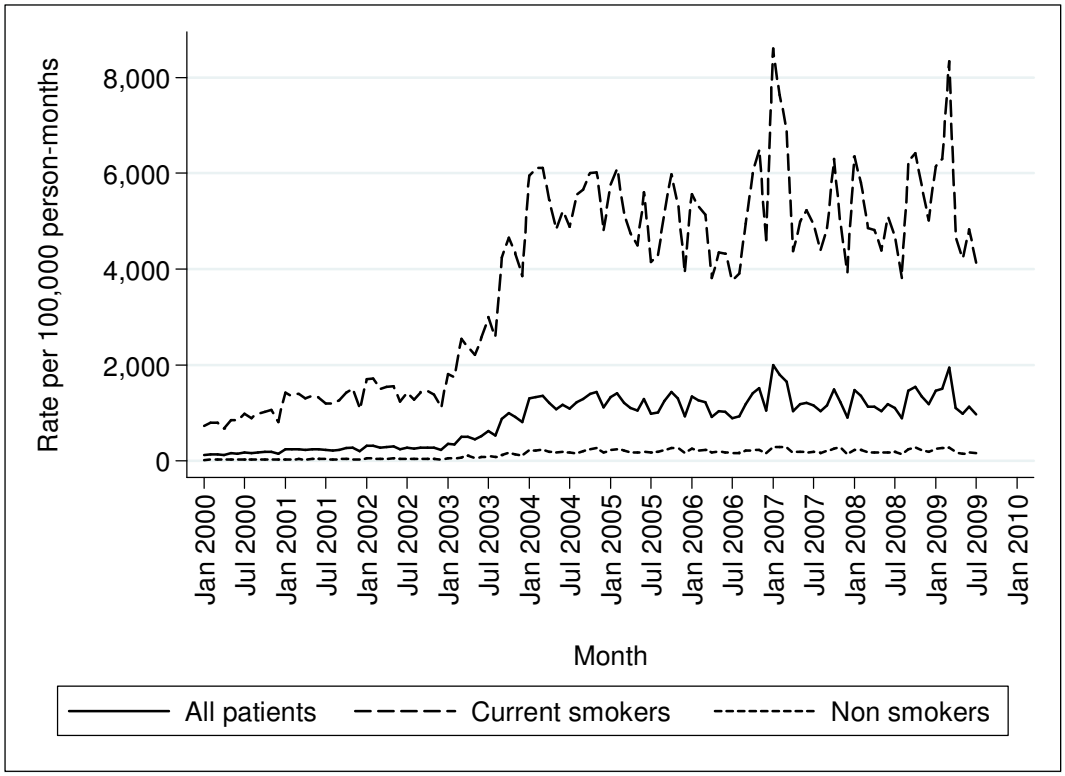


Figure 3.4 Rates of recording of cessation advice in all patients, smokers and non-smokers

As Figure 3.4 shows, some patients who are not recorded as smokers still have a record of cessation advice in their medical records. However, the rate of recording of advice in non-smokers is very low; across the study period, each month an average of just 139 non-smokers have a record of advice per 100,000 person-months, compared to 3,744 smokers.

Figure 3.5 shows monthly rates of recording of referrals to smoking cessation services in all patients, smokers and non-smokers.

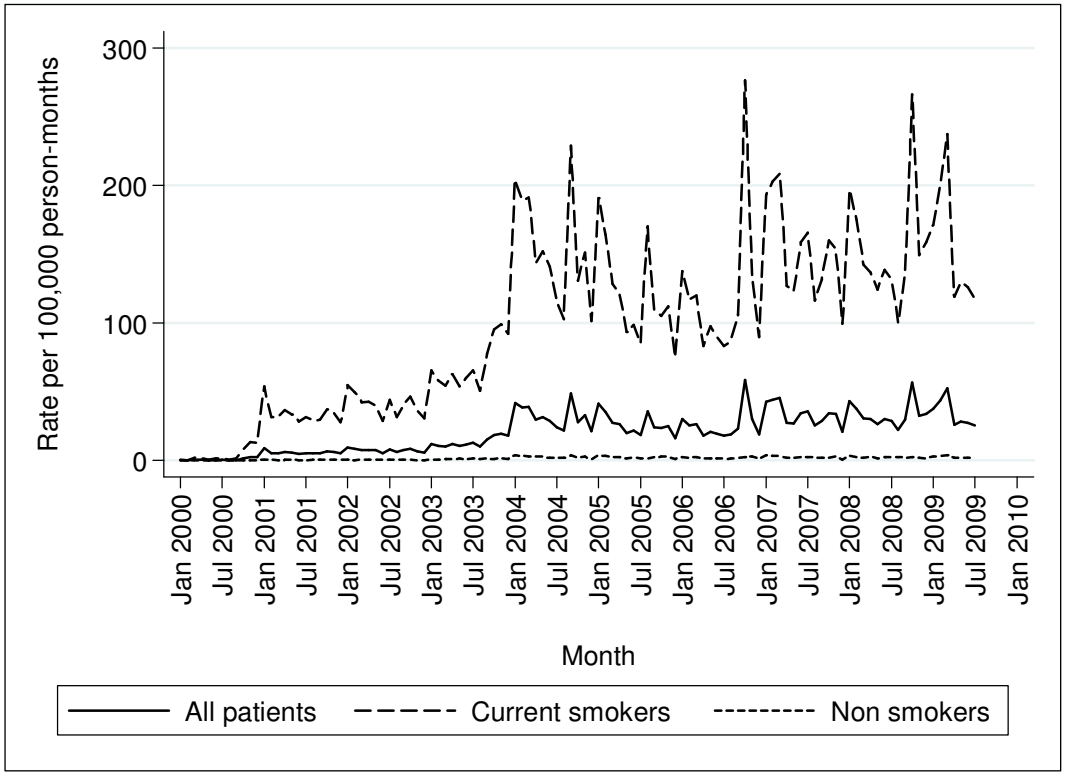


Figure 3.5 Rates of recording of referral to smoking cessation services in all patients, smokers and non-smokers

As Figure 3.5 shows, again some patients who are not recorded as smokers still have a record of referral to a cessation service in their medical records, though the rate of recording is again low. Across the study period, each month an average of just 1 non-smoker has a record of referral per 100,000 person-months, compared to 98 smokers.

Figure 3.6 shows monthly rates of prescribing of all smoking cessation medications in all patients, smokers and non-smokers.

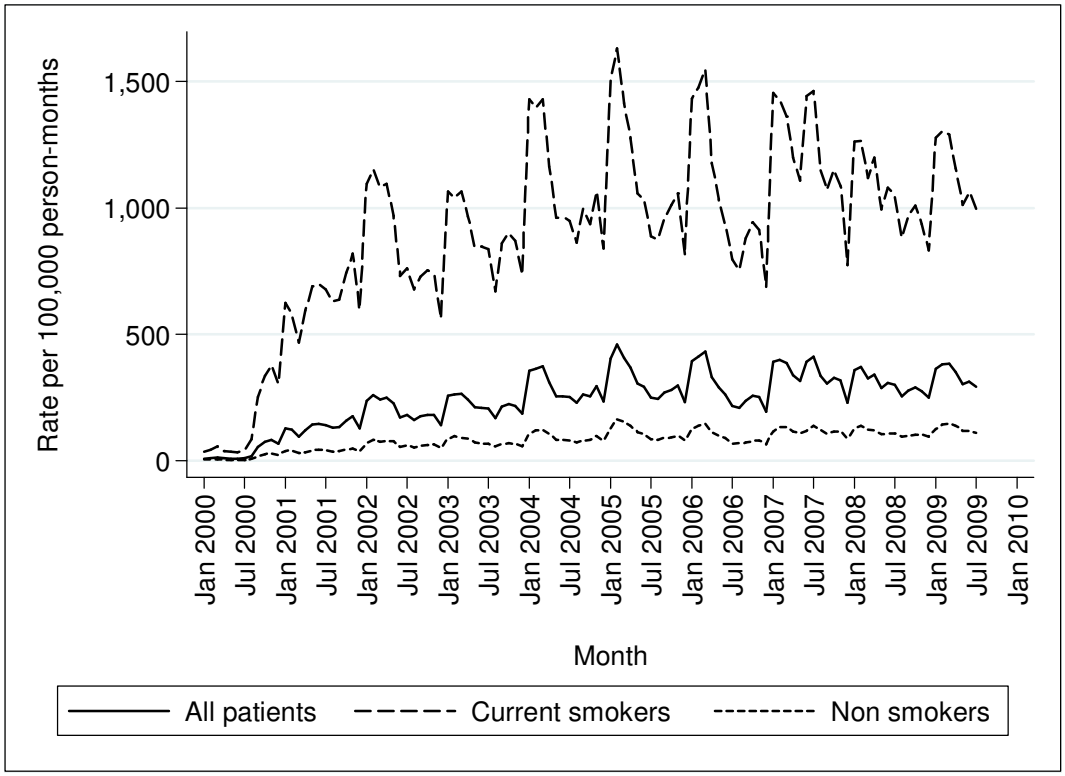


Figure 3.6 Rates of prescribing of all smoking cessation medications in all patients, current smokers and non-current smokers

As was seen in the recording of advice and referral, some patients who are not recorded as smokers still have a prescription for a smoking cessation medication recorded in their medical records. Across the study period, each month an average of 83 non-smokers have a prescription recorded in their notes per 100,000 person-months, compared to 913 smokers.

The pattern of prescribing appears to be similar in patients identified as smokers and non-smokers – in both groups prescribing shows an increasing trend in the first half of the study period before levelling off or perhaps decreasing slightly from 2005 onwards. Peaks in prescribing are seen at the same time in smokers and non-smokers.

3.6.4. Discussion and conclusions

The results presented in this section show that smoking cessation interventions are sometimes recorded in the medical records of patients in THIN who are not also documented as a smoker. Rates of recording of interventions in non-smokers are generally low, particularly in the case of recording of cessation advice and referral of smokers to smoking cessation services.

Analysis of rates of interventions recorded in the notes of current smokers may fail to give a complete picture of the pattern of recording as well as any changes in underlying trends associated with the introduction of smokefree legislation. Therefore, it may be worthwhile assessing and comparing the impact of smokefree legislation on rates of interventions recorded in both smokers and all patients.

3.7. CHAPTER CONCLUSIONS

The three studies undertaken in this chapter have highlighted several features of the recording of smoking cessation interventions in THIN which must be taken into account when using the data to investigate the impact of smokefree legislation on the management of smoking in primary care.

Figure 3.1 demonstrated substantial increases in the rate of recording of cessation advice, particularly between 2003 and 2005, and less dramatic secular trends are also seen in the recording of referral of smokers to cessation services (Figure 3.3) and prescribing of smoking cessation mediations (Figure 3.6). The method used to assess the impact of smokefree legislation on the rate at which primary health care professionals intervene with smokers must be able to take account of these underlying trends. In addition, Figure 3.4, Figure 3.5 and Figure 3.6 illustrate distinct monthly variation in the rate of recording of smoking cessation

interventions, and again the method used to assess the impact of smokefree legislation on the rate at which primary health care professionals intervene with smokers must be able to take account of this variation.

It remains unclear whether the rates of recording of cessation advice and referral of smokers to specialist cessation services are a true reflection of the rate at which GPs intervene with smokers. The improvements in the recording of smoking status shown in the previous chapter, and the comparability between rates of prescribing of smoking cessation medications in THIN and dispensing rates[130], suggest these measures may be the most robust outcome variables with which to assess the impact of the introduction of smokefree legislation on the management of smoking in primary care. Despite the limitations discussed already in the methods used to validate the advice and referral data in THIN, changes in these outcome variables at the time smokefree legislation was introduced will still be investigated. However, it should be noted that any changes in the recording of advice or referral may not reflect true changes in the rate at which GPs intervene with smokers.

Variations in the proportion of patients with recorded cessation advice and referral to a specialist cessation service, as well as variations between the recorded and recalled intervention rates, are seen in different population subgroups. As was suggested at the end of the previous chapter, it may be worthwhile investigating the impact of smokefree legislation on rates of intervention delivery individually by subgroup to take these underlying differences into account. The variation observed between practices means again that conclusions drawn using THIN about the impact of smokefree legislation on the management of smoking in primary care may not be generalisable to primary care throughout the UK.

Finally, analysis of rates of interventions recorded in the notes of smokers only may fail to give a complete picture of the pattern of recording as well as any changes in underlying trends associated with the introduction of smokefree legislation. As a result, the method used to assess the impact of smokefree legislation on the rate at which primary health care professionals intervene with smokers must be able to compare rates of the recording of interventions in all patients as well as just those recorded as smokers at a given point in time.

Having investigated the quality of smoking status recording in THIN in Chapter 2, and several issues surrounding the recording of smoking cessation interventions in this chapter, the following section of this thesis outlines the methods that will be used to investigate the impact of smokefree legislation on the management of smoking in primary care.

4. THE USE OF INTERRUPTED TIME SERIES ANALYSIS TO ASSESS THE IMPACT OF SMOKEFREE LEGISLATION ON THE MANAGMENT OF SMOKING IN PRIMARY CARE: OUTLINE OF METHODS

4.1. INTRODUCTION

The previous chapters investigating the quality of the smoking information recorded in THIN demonstrated temporal and seasonal trends in the rates of recording of smoking status and cessation interventions which must be taken into account when assessing the impact of smokefree legislation on the management of smoking in primary care. An analytical approach known as *interrupted time series analysis* is most appropriate to assess whether there was a statistically significant change in an outcome variable over and above any long-term trends at the time a policy intervention, such as smokefree legislation, is introduced. Therefore, this chapter will detail the interrupted time series analysis methods which will be used in Chapters 5 and 6 to assess whether the data recorded in THIN suggest that the introduction of smokefree legislation in the UK had an effect on the management of smoking in primary care.

There are several approaches to interrupted time series analysis, but, to my knowledge, there is no authoritative review of the methods available describing which approach should be used in a particular situation. Additionally, there is no published literature assessing whether the results of an interrupted time series analysis are sensitive to the method used and the choices which the data analyst must make during the analysis process.

This chapter first provides an overview of the different approaches to interrupted time series analysis, before concluding which is the most appropriate to use in this research using data from THIN to assess the impact of smokefree legislation on the management of smoking in primary care. Then, one example, that of prescribing of nicotine replacement therapy (NRT), will be used to explain the stages involved in carrying out an interrupted time series analysis to assess the impact of a policy change on an outcome variable. This will include the description of an automated procedure written for the Stata[134], the data management and statistical software used for the analyses presented in this thesis, which aids the analysis process. Finally, the results of several sensitivity analyses are presented which assess the implications of choices made during the data analysis process.

4.2. WHAT IS A TIME SERIES?

As introduced in Section 1.8.3, time series are encountered across many subject areas and consist of data collected on an individual or phenomenon at multiple, ordered, points in time. These measurements are usually taken at equally-spaced intervals, ranging from fractions of a second in an ECG trace of cardiac electrical activity, to monthly, yearly, or perhaps even less-frequently collected data.

Time series are often described as stochastic, non-deterministic, realisations of an underlying data-generating process, meaning that the values of a series at each point in time are determined by both predictable and random elements (in contrast, a deterministic process is driven by entirely predictable forces)[135]. The essence of time series analysis is to model the underlying stochastic process which best represents a particular time series.

One illustrative example of a time series will be used throughout this chapter to explain the principles of time series analysis and the methods used in this thesis

to assess the impact of smokefree legislation on the management of smoking in primary care. The time series in Figure 4.1 shows monthly rates of prescribing of NRT in THIN practices in England amongst smokers aged 16+. The series starts in April 2001, the month when NRT was first made available on NHS prescription. Appendix 8.11 lists the commands which can be used to analyse a time series in Stata and reproduce the figures presented in this chapter.

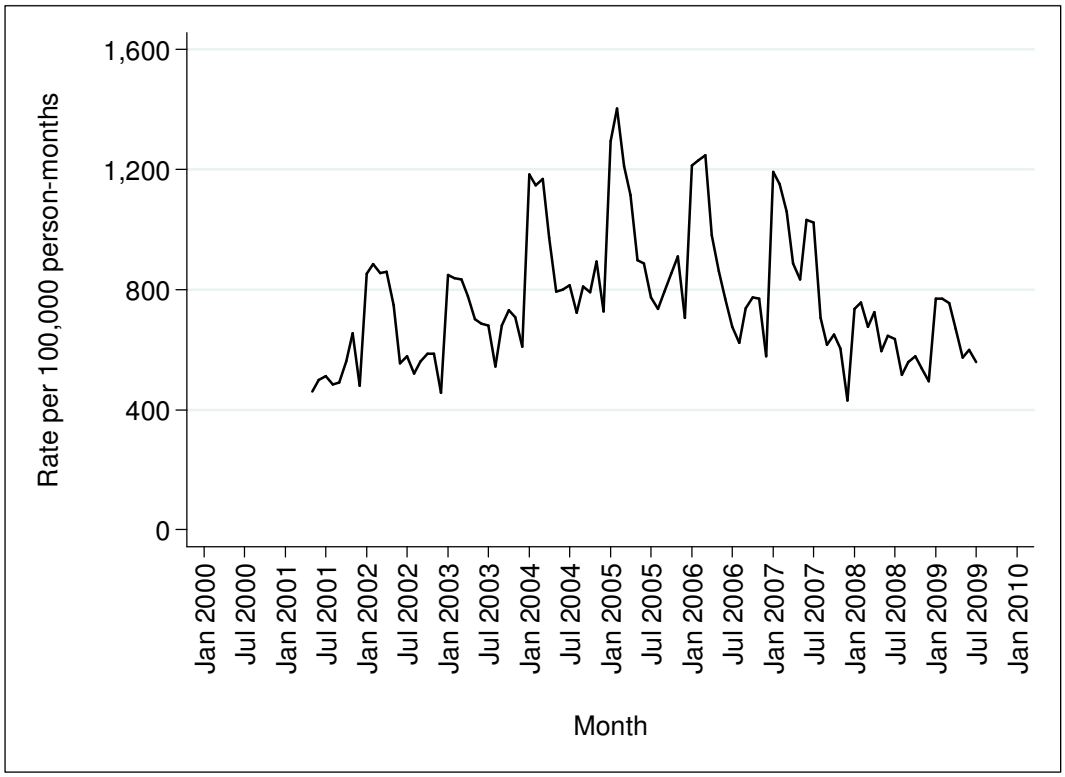


Figure 4.1 A time series showing monthly rates of prescribing of NRT in current smokers aged 16+ in THIN practices in England

4.2.1. Autocorrelation

Figure 4.1 illustrates a fundamental, defining feature of time series data – observations at neighbouring points in time are related to each other. The series does not fluctuate randomly from one month to the next, but the magnitude of the observation in one month is usually close to that in the previous month. In the parlance of time series analysis, the data are said to be autocorrelated, or to exhibit serial dependency. The average autocorrelation between pairs of data

points at successive lags (or intervals) across the whole of a time series can be represented graphically in the form of an autocorrelation function, or ACF, as shown in Figure 4.2. The average autocorrelation between each data point across the whole of the time series and the data point one month previously (i.e. at a lag of 1) is high, with a correlation coefficient of 0.695 (as with all correlation coefficients, the autocorrelation can range from -1, indicating perfect negative autocorrelation, to +1, indicating perfect positive autocorrelation).

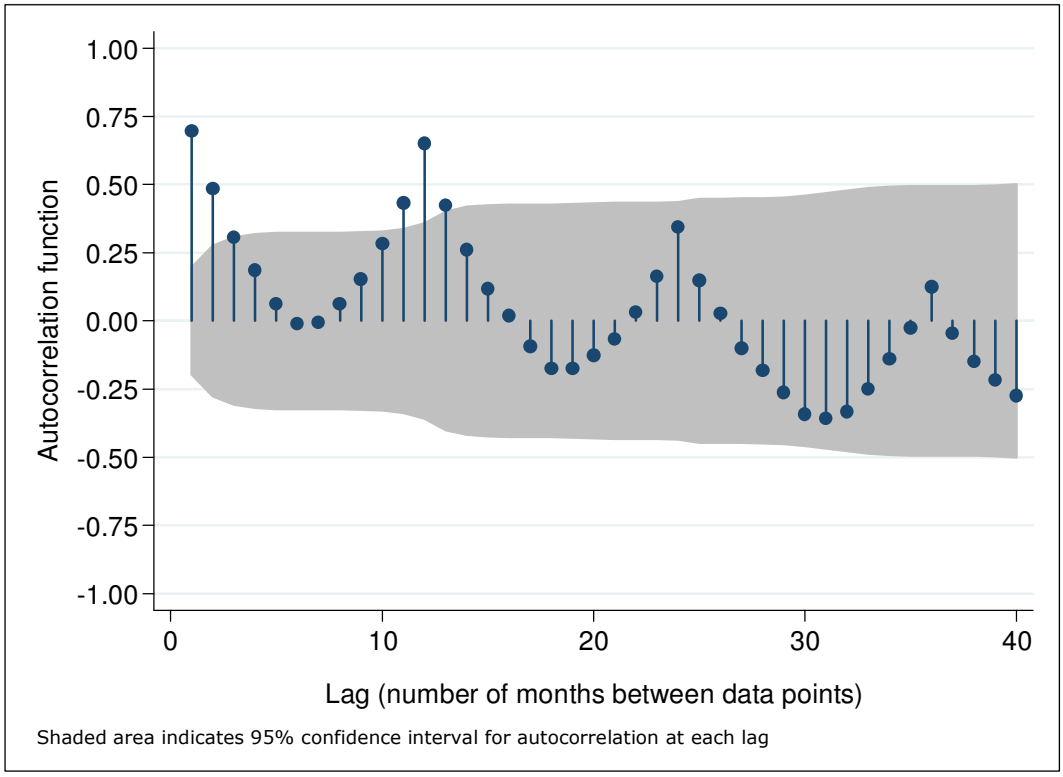


Figure 4.2 The autocorrelation function (ACF) of the illustrative time series

The increase in the degree of autocorrelation at lags 12 and 24 compared to the lags either side point to the presence of seasonal autocorrelation in the series – in monthly data such as this, the value of the series at one point in time is correlated with that 12 and 24 months previously. Many time series from the social sciences contain an element of seasonality[136], whereby the level of a series varies over the course of a year and the annual pattern of behaviour is repeated from one year to

the next. The implications of seasonality for time series analysis will be discussed shortly.

The shaded area in Figure 4.2 indicates 95% confidence intervals for the autocorrelation between data points at each lag, with the variance of each autocorrelation calculated as the inverse of the total sample size (in this case, 100 data points)[135]. Autocorrelations which extend outside of the shaded area of the ACF indicate correlation at that lag greater than would be expected by chance alone.

It is the autocorrelation present in a time series which demands specific analytical techniques and renders more traditional approaches to analysis inappropriate. Time series data violate the assumption of independence central to linear regression, and autocorrelation makes it difficult to assess whether any observed change in the pattern of a time series is significant and attributable to an intervention, or whether it is simply within the bounds of the 'normal behaviour' of the series[137].

If autocorrelation between data points is ignored, the standard errors of parameter estimates calculated through linear regression will be biased – positive autocorrelation decreases the apparent variability in the data resulting in lower standard errors, and negative autocorrelation increases the apparent variability producing higher standard errors[138]. The standard errors of point estimates may be inflated or deflated by up to 50% and the t-statistic by as much as 400%[136]. Thus, when assessing the effect of an intervention on a time series there is a strong chance of making either a type one error, rejecting a null hypothesis which is in fact true, or a type two error, failing to reject a null hypothesis which is in fact false. Therefore, the aim of the analytical techniques which will be outlined in this chapter is to model, and thereby statistically control, the autocorrelation in a

time series to enable accurate assessment of the impact of an intervention on a series[136].

4.3. OUTLINE OF METHODS USED TO ANALYSE TIME SERIES

As noted in Section 1.8.3, in recent years there has been an increase in the number of articles in the published literature which analyse time series data to assess the impact of an intervention on the phenomenon under investigation. Such analysis is described as 'interrupted time series analysis', with the point in time at which the intervention was introduced marking an interruption to the series. Broadly speaking, interrupted time series analyses employ one of two main approaches to analysing such data, using either a regression framework, or a class of mathematical models known as Autoregressive Integrated Moving Average (ARIMA) models.

4.3.1. Segmented regression

Using the most simple regression approach, a time series is divided into at least two segments with a break point between segments at the moment in time the intervention whose impact the analyst wishes to assess was introduced. Linear regression is then used to model the data in each segment of the series, with the regression line in each segment being allowed to exhibit a different level and trend if appropriate. The parameters of the fitted segmented regression model are then assessed to determine whether the level and/or the slope of the series changed significantly after the introduction of the intervention[97].

Figure 4.3 illustrates the fitting of a segmented regression model to the exemplar dataset to assess whether there was a permanent change in the level or slope of the prescribing series after the introduction of smokefree legislation. In order to

capture some of the non-linear trend in the series before the introduction of smokefree legislation in July 2007, the pre-intervention series has been divided into two segments with the break point in April 2004, the month the Quality and Outcomes Framework (QOF) was introduced.

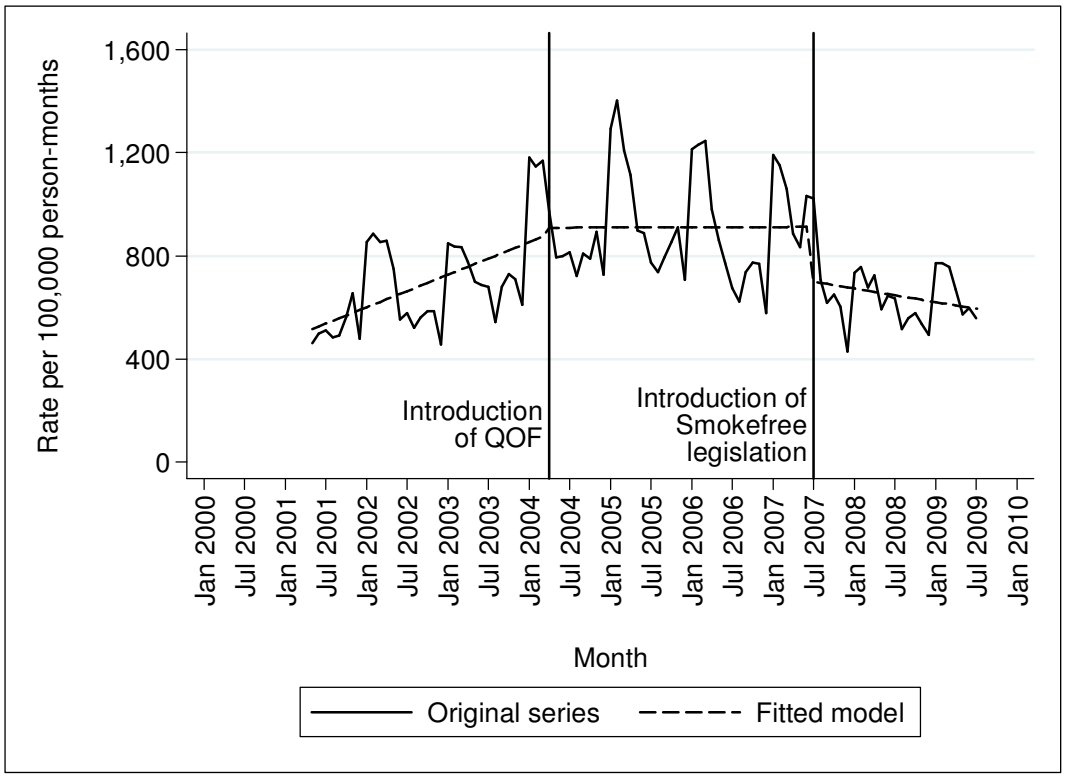


Figure 4.3 Illustration of a segmented regression model

The segmented regression model shown in Figure 4.3 assumes the data satisfy the independence assumption central to linear regression, though, as shown in Figure 4.2, it is clear there is significant autocorrelation present in the data. Drawing the ACF of the residuals from the segmented regression model (the difference between the observed values of the series and the values predicted by the regression model) allows the time series analyst to assess whether any autocorrelation has been adequately incorporated into the segmented regression model, or whether further steps must be taken to deal with any remaining serial dependency. The ACF of the residuals from the segmented regression model, shown in Figure 4.4, reveals significant autocorrelation at lags 1, 5, 6, 7, 12 and

24, suggesting the model has not adequately dealt with the autocorrelation present in the series and that this segmented regression model is invalid. In addition, the segmented regression model fits a linear trend through the data in each segment which is arguably not appropriate in this case, further invalidating the technique.

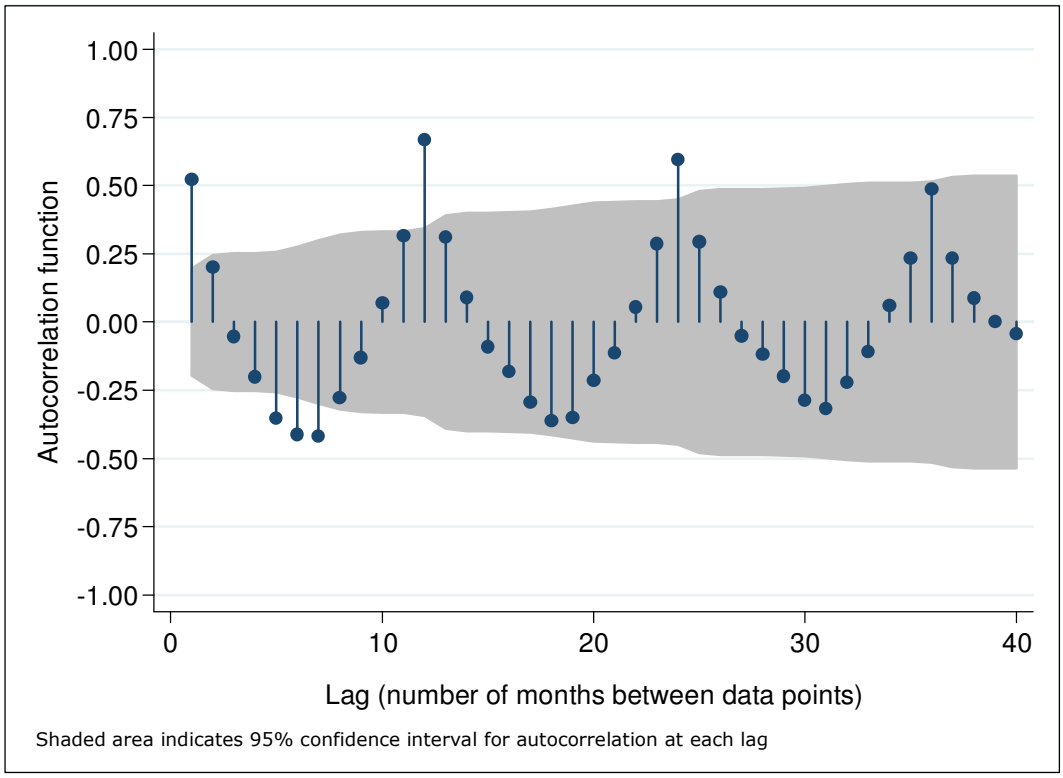


Figure 4.4 The ACF of residuals from the segmented regression model

A modified form of segmented regression, known as Prais-Winsten regression, allows the time series analyst to incorporate autocorrelation at lag 1 into a model (though again assumes a linear trend through each segment). However, within a simple regression framework it is not possible to incorporate autocorrelation at other lags into the model.

As suggested previously, the significant autocorrelation at lags 12 and 24 in the model residuals is indicative of a seasonal pattern in the monthly time series data. Some authors have dealt with the presence of seasonality in a time series by

attempting to estimate the seasonal component of the series, remove its effects from the data and then model the de-seasonalised series[139]. A common method used to estimate the seasonal component of a time series is to compute the 12-month centred moving average of the series, calculate the ratio of the original series to the moving average series for each month, and then compute the average of these ratios for each month of the year across the series[140]. Figure 4.5 shows the seasonal component for the exemplar series, calculated in this manner.

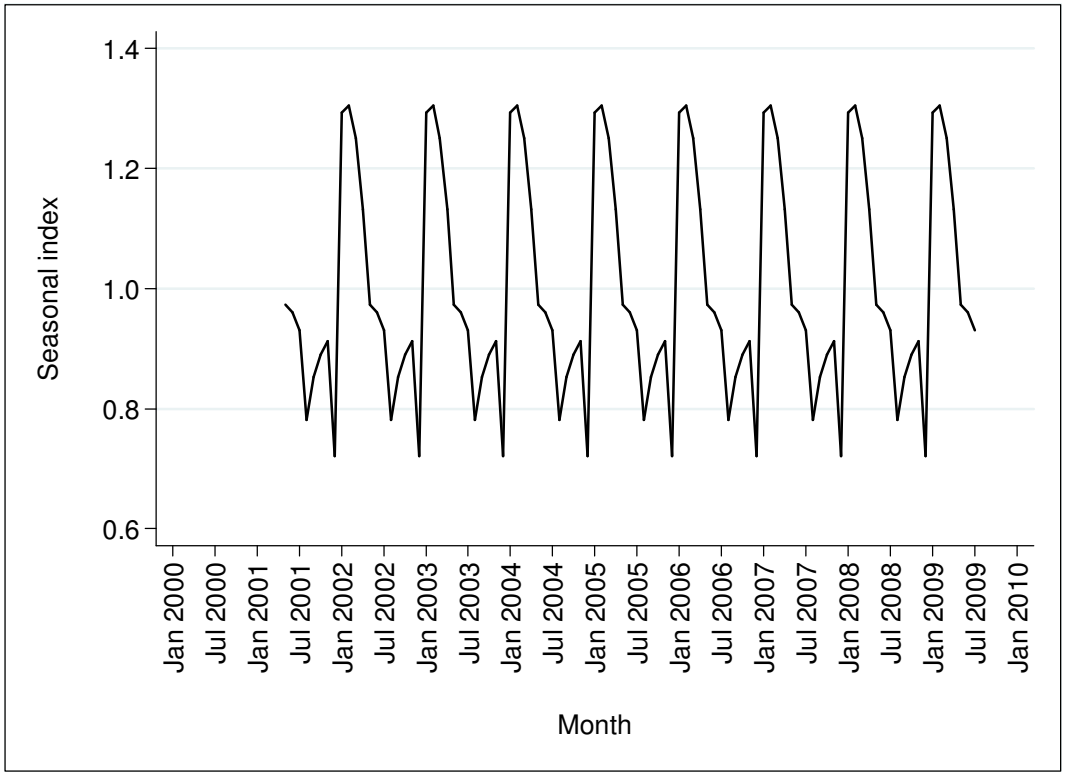


Figure 4.5 The seasonal component of the exemplar series

Figure 4.5 demonstrates peaks and troughs in rates of prescribing of NRT over the course of each year. The highest prescribing rates are seen in January, February and March each year, with troughs in prescribing occurring in August and December. Peaks in prescribing may perhaps be associated with more people visiting the doctor with respiratory conditions over the winter months and smokers being offered support to quit, or more smokers visiting their surgery for cessation support at New Year[141] or, in March, on national No Smoking Day[142]. The troughs

in prescribing may perhaps be attributable to holiday periods with fewer people visiting their GP, with some compensatory increased prescribing being seen in the months following these holiday periods.

Having estimated the seasonal component of a time series, its effects may be removed from the series by dividing the value of the series in each month by the appropriate seasonal index. However, the time series analyst should be extremely cautious in undertaking such an activity as, although in theory this should remove all of the seasonality present in a series, a seasonal pattern may still remain[143]. The decomposition approach assumes the seasonal effect is entirely deterministic (i.e. that it has no stochastic, random component) and is constant from one year to the next over the entire course of the series. However, this assumption may not be valid, particularly in long series where the seasonal component may change over time[140]. As Figure 4.6 shows, the pattern of prescribing in the exemplar series differs between years, and so assuming a constant seasonal effect over the entire course of the series is not appropriate.

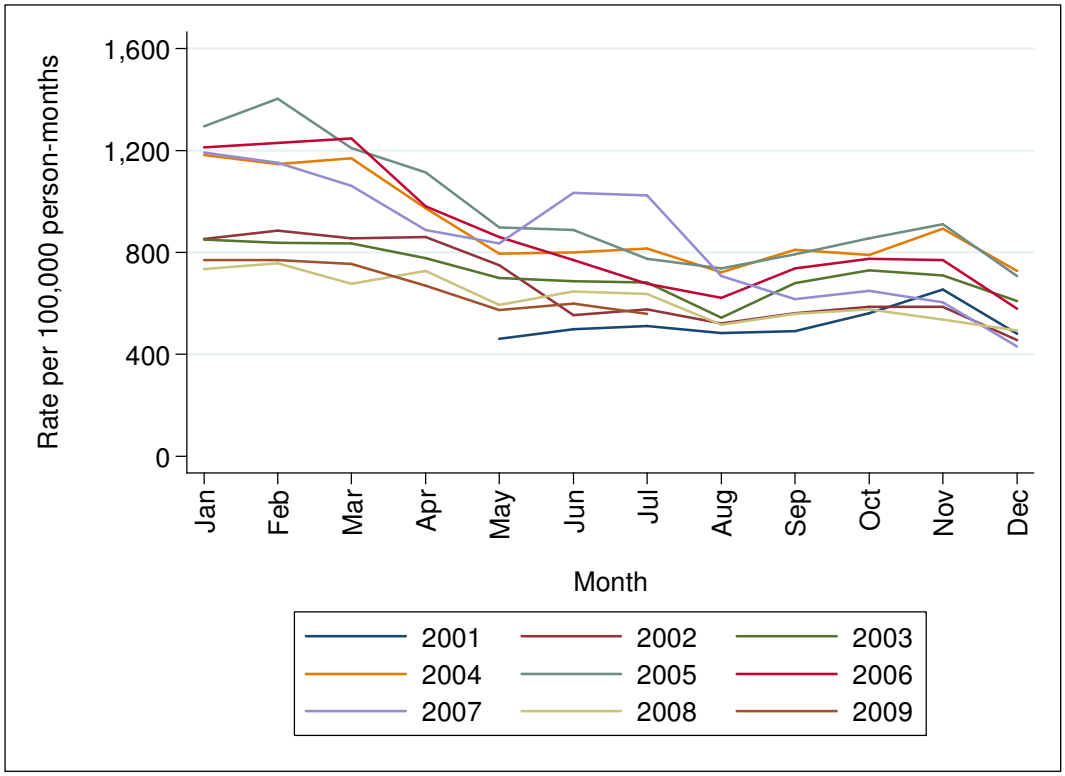


Figure 4.6 Varying annual patterns in the rate of prescribing

Some authors have incorporated seasonal effects into segmented regression models using dummy variables to represent each season of the year. Again, however, this assumes a deterministic seasonal effect, constant over the entire span of the time series. In addition, modelling seasonality using dummy variables can result in over-parameterisation of a model, particularly in the case of monthly data where 11 degrees of freedom may be needed[144].

It is expected that all of the series to be analysed in this thesis will contain a substantial seasonal component and, therefore, in the absence of an adequate way to remove all the seasonality from a series or incorporate it into a regression framework using dummy variables, segmented regression of the form demonstrated above will not be pursued further as a means of data analysis as it is unlikely to be able to model such data with complex seasonal patterns and autocorrelation.

4.3.2. Extensions to linear segmented regression

Within the last 20 years, generalised additive models (GAMs) have been developed as an extension to linear segmented regression, and allow the relationship between a time series and several explanatory variables to be modelled using non-parametric smooth terms (such as spline functions) or non-linear terms such as polynomial or exponential functions[145]. Any seasonality in a time series can be incorporated into a GAM using a smooth function rather than dummy variables. A recent extension to the GAM, the generalised additive mixed model (GAMM)[146], allows the incorporation of autocorrelated error terms into a model. Such an approach has been used recently to model the impact of the introduction of smokefree legislation on hospital admissions for myocardial infarction in England, accounting for temperature, flu rates and the week of the year[147]. Exploratory analysis suggests that GAMMs give similar results to the

Autoregressive Integrated Moving Average (ARIMA) model which will be discussed shortly, though are more complex and computationally intensive to fit. Therefore, these models will not be further explored; instead the ARIMA class of models will now be introduced, which also provide a means of modelling univariate time series and dealing with complex patterns of seasonality and autocorrelation.

4.3.3. Autoregressive Integrated Moving Average (ARIMA) models

ARIMA methods provide a powerful modelling tool capable of incorporating the complex patterns of seasonality and autocorrelation likely to be evident in THIN data. There is no 'one' ARIMA model, rather a class of models which afford great flexibility when modelling time series of many different phenomena. The individual elements of the ARIMA class of models date back over 80 years, but George Box and Gwilym Jenkins are credited with combining these in 1976 into a comprehensive single class of model[148]; for this reason, the ARIMA approach to time series analysis is often described as the Box-Jenkins approach.

An ARIMA model is built empirically from time series data and attempts to model mathematically the stochastic data-generating process which gave rise to the series, rather than adopting the deterministic approach of segmented regression where the analyst attempts to fit a pre-specified model to the data[149]. The empirical model-building approach of ARIMA analysis means such time series models routinely have R^2 values (a measure of the adequacy of model fit) over 0.9, indicating excellent model fit[150].

ARIMA methods are capable of modelling complex seasonal patterns in a time series, particularly when such seasonality has a stochastic component. Indeed, ARIMA methods should not be used with series that have been adjusted to remove the seasonal component, as the non-seasonal and seasonal components

of the model are best estimated simultaneously[143]. The empirical ARIMA approach to modelling seasonality requires fewer terms to account for seasonality, with perhaps only one extra degree of freedom being required[144], another benefit of the ARIMA approach over segmented regression for modelling time series with a seasonal component.

Dummy variables can be included in an ARIMA model to assess whether the mathematical model which best describes the data is different in one part of a time series compared to another, such as, for example, after smokefree legislation was introduced compared to the pre-legislation period. In this instance, a statistically significant change in the structure of the ARIMA model between time periods would be taken as evidence that the introduction of smokefree legislation had a significant effect on the outcome variable being modelled.

Given the advantages of ARIMA modelling outlined above, this approach is the one that will be used to model THIN data and assess whether the introduction of smokefree legislation had a significant impact on the management of smoking in primary care. The following sections of this chapter explain in detail the mathematical basis of the ARIMA model and the stages involved in using such a model to assess the impact of an intervention on a time series.

4.4. OUTLINE OF THE STAGES IN ARIMA MODELLING

Figure 4.7 outlines the general stages involved in time series analysis using ARIMA models. As with any data analysis, a crucial first step is for the analyst to familiarize themselves with their data and undertake a process of data cleaning. The data are then split into pre-intervention and post-intervention series, and an iterative procedure used to identify an appropriate model from the ARIMA class

which adequately describes the data-generating process which gave rise to the pre-intervention series. This iterative process involves first tentatively identifying a potential model, estimating the model parameters, and then undertaking several diagnostic checks to ensure the selected model is indeed appropriate. If the tentative model fails one or more of the diagnostic checks, a second model from the ARIMA class is proposed, and the estimation and diagnosis procedure repeated.

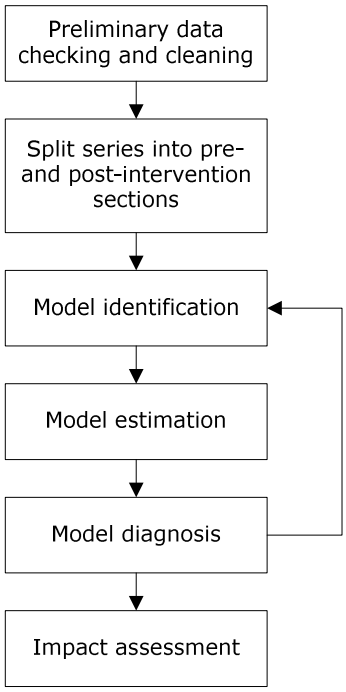


Figure 4.7 Stages involved in assessing the impact of an intervention on a time series

The iterative process of model identification, estimation and diagnosis is repeated until an ARIMA model is found which adequately describes the pre-intervention series and meets all diagnostic criteria. This selected model is then applied to the entire span of the time series, including the post-intervention data, and the analyst looks for evidence that the model does not fit the post-intervention series. If it does not fit, this is taken as evidence that the data-generating process changed significantly as a result of the introduction of the intervention, and

therefore that the intervention had a significant effect on the phenomenon under investigation.

The following sections of this chapter work though each of the stages of interrupted time series analysis using ARIMA models, using the exemplar series to assess whether the introduction of smokefree legislation had a significant impact on rates of prescribing of NRT amongst smokers in the THIN dataset.

4.5. PRELIMINARY DATA CHECKING AND CLEANING

The first, crucial, stage in undertaking any time series analysis is to draw and inspect a time plot of the whole length of the series, such as that shown in Figure 4.1. This section discusses a number of issues that must be addressed before starting the process of ARIMA model identification.

4.5.1. Are there any missing data?

ARIMA models demand an observation is recorded for each point in time across the entire span of the series, though observations can take a value of zero. Given the longitudinal nature of the THIN dataset, the exemplar series being analysed here does not contain any missing data, nor do any of the series analysed in this thesis. However, there are several approaches to dealing with missing data should such a situation arise, and the choice of method can have an impact on the outcome of an interrupted time series analysis. Generally, missing data points should not be replaced with values representing the global or local mean of the series, as this can produce inaccurate estimates of the autocorrelation present in the series[138]. Similarly, ignoring the time points with missing data and analysing the shorter series will also produce inaccurate estimates of the serial dependence present in a series[138]. A more desirable approach is to impute maximum likelihood

estimates for the missing data, which has been shown to produce accurate estimates of the autocorrelation present in a series even when 40% of data points are missing[138]. An accurate assessment of the autocorrelation present in a series is a necessary pre-requisite of assessing the impact of an intervention on the series, as discussed previously in Section 4.2.1.

4.5.2. Do any data points appear to be outliers?

Outliers in a series, perhaps caused by measurement error or the impact of an unknown event, can have the same implications for analysis as the presence of missing data, biasing estimates of the level and slope of a series as well as the ACF. There are no obvious outliers in the exemplar series, but outliers in a series can be treated in the same way as missing data and replaced using a suitable imputation method[135].

4.5.3. Is the temporal frequency of data collection appropriate?

Time series data can potentially be collected at one temporal frequency, such as daily, and then aggregated to give measures at another frequency, such as weekly, monthly, quarterly or yearly. It is important that the frequency of data collection and temporal aggregation of a time series is appropriate to allow the hypothesised effect of an intervention to be assessed[135]. For example, if an intervention is introduced which is expected to have an effect on a series for the duration of just a few months, data collected yearly may fail to detect the temporary effect of the intervention. This issue must be addressed when planning the collection of any time series data, where financial and resource limitations may play a part in determining how frequently data can be collected. An advantage of the THIN dataset is that it allows data to be aggregated over any time period from daily upwards. The literature reviewed earlier suggests that the

effects of smokefree legislation may be seen in the months leading up to, and immediately after, the introduction of the policy, but potentially are not sustained in the longer-term. As a result, data aggregated quarterly or yearly are unlikely to detect these complex patterns. There is a necessary trade-off between temporal frequency and the computational demands involved in analysing time series with more data points. Therefore, data aggregated monthly will form the primary series analysed in this thesis, though a sensitivity analysis will be undertaken in Section 4.12.2 to assess whether data aggregated weekly results in similar estimates of the effect of the introduction of smokefree legislation on the exemplar time series.

4.5.4. Is the series long enough?

Consideration must also be given to the length of a time series, though there are no accepted rules defining just how many data points are needed for time series analysis, and power calculation is difficult. A commonly-cited rule-of-thumb is that at least 50 data points are needed if an ARIMA model is to be fitted to a series, though simulation exercises suggest that three to five times this number may in fact be needed to determine whether the correct model has been chosen to represent a series[135].

The time series analysed in this thesis span the period from January 2000 (April 2001 in the case of the NRT prescribing illustrated here) to July 2009, yielding a total of at least 100 monthly observations. Importantly, the study period includes data for a two-year period after the introduction of smokefree legislation in England, and slightly longer in the rest of the UK where legislation was introduced earlier, allowing the detection of any temporary effects of smokefree legislation or assessment of whether any impacts have been sustained. In addition, if a series is expected to contain a seasonal component then both the pre- and post-

intervention data must span enough seasons to enable detection and modelling of the pattern[135]. More consideration will be paid to seasonality in time series later in this chapter.

4.5.5. Are there any threats to data validity?

When planning the collection of data for an interrupted time series analysis, or before analysing data which have already been collected, it is crucial to consider several aspects of data quality which may influence the internal and external validity of a study[151].

4.5.5.1. Instrumentation changes

Ideally, identical methods should be used to collect the time series data at each point in time - instrumentation changes may invalidate an interrupted time series analysis, particularly if the means of observing the outcome variable changes at the same time the intervention under assessment is introduced and causes a change in the series which is mistaken for the effect of the intervention[151]. In this thesis, the use of automated methods to extract rates of smoking cessation activity from the THIN dataset for each month means the method of calculation of the outcome variable from the raw THIN data is constant over time and thus there are no instrumentation changes to confound assessment of the impact of the introduction of smokefree legislation.

4.5.5.2. Changes in the composition of the study population

The observations at each point in time must be directly comparable and there should be no changes over time in the composition of the population being studied[151]. In this thesis, consistent data extraction methods have been used to ensure that the population each month in whom rates of recording of smoking

status and intervention delivery are calculated consists of all THIN patients (or smokers in the analysis of cessation interventions) alive, actively registered with a participating practice, and aged 16 or over. This definition necessarily allows patients to move into and out of the denominator population each month and, therefore, the structure of the population with respect to patient characteristics such as sex, socio-economic status and medical history may vary from one month to the next. Such variation may result in these factors acting as confounders in the interrupted time series analysis, making it impossible to assess whether any observed changes result from the introduction of an intervention. Restricting the denominator to the same group of patients who are aged 16+ and registered in THIN for the whole of the 10-year period studied here will not solve the potential confounding problem – over the course of the decade the average age of the denominator will increase by 10 years. The rate at which doctors intervene with smokers is known to vary by age[62], and so the potential for confounding remains. Additionally, the socio-economic and health status of this constant group of patients may still change over time. A sensitivity analysis is presented in Section 4.12.3 which assesses the potential degree of confounding caused by changes in denominator population characteristics over time.

4.5.5.3. The impact of extraneous events

When assessing the impact of an intervention on a time series it is important that any observed changes in a series can be attributed to the effect of that intervention only and not to other interventions or events which have had an effect on the series at the same time[151]. However, as shown in Figure 1.2 several tobacco control policies have been implemented in the UK over the past decade and the effects of some of these may confound the assessment of the impact of smokefree legislation on measures of clinical activity in primary care. The potential implications of this will be discussed in Section 4.12.4.

4.5.5.4. The impact of 'trading days'

In many series some of the variation over time may be the result of differences in the number of days in each time period – the monthly value of retail sales, for example, will be determined in part by the number of *trading days* in each month. Similarly, the monthly rates derived from the primary care data analysed in this thesis will be determined in part by the number of days each month that surgeries are open, which ranges from 18 to 23 days per month across the study period. Some of the relatively low rates of NRT prescribing in December compared to other months, as discussed previously, may be due, for example, to practices being open for fewer days in December. In order to remove this source of variation, crude monthly rates can be adjusted for the number of surgery days per month using the following formula[140]:

$$\text{Adjusted rate} = \frac{\text{Unadjusted rate x Number of surgery days in month}}{\text{Average number of surgery days across all months}}$$

The number of days practices were open in each month between January 2000 and July 2009 was determined, accounting for closure at weekends, Christmas and Easter, and other bank holidays. The number and timing of bank holidays differs between jurisdictions of the UK, and so the number of surgery days each month was calculated separately for England, Scotland, Wales and Northern Ireland.

Figure 4.8 shows the effect of this adjustment on the monthly rate of NRT prescribing. As can be seen, the adjustment increases the rate slightly in some months, and reduces it in others. Removing the effect of monthly variation in surgery days will now make it easier to detect and interpret other seasonal patterns in the series, and thus from this point forth all analyses and presented results will be based on adjusted data.

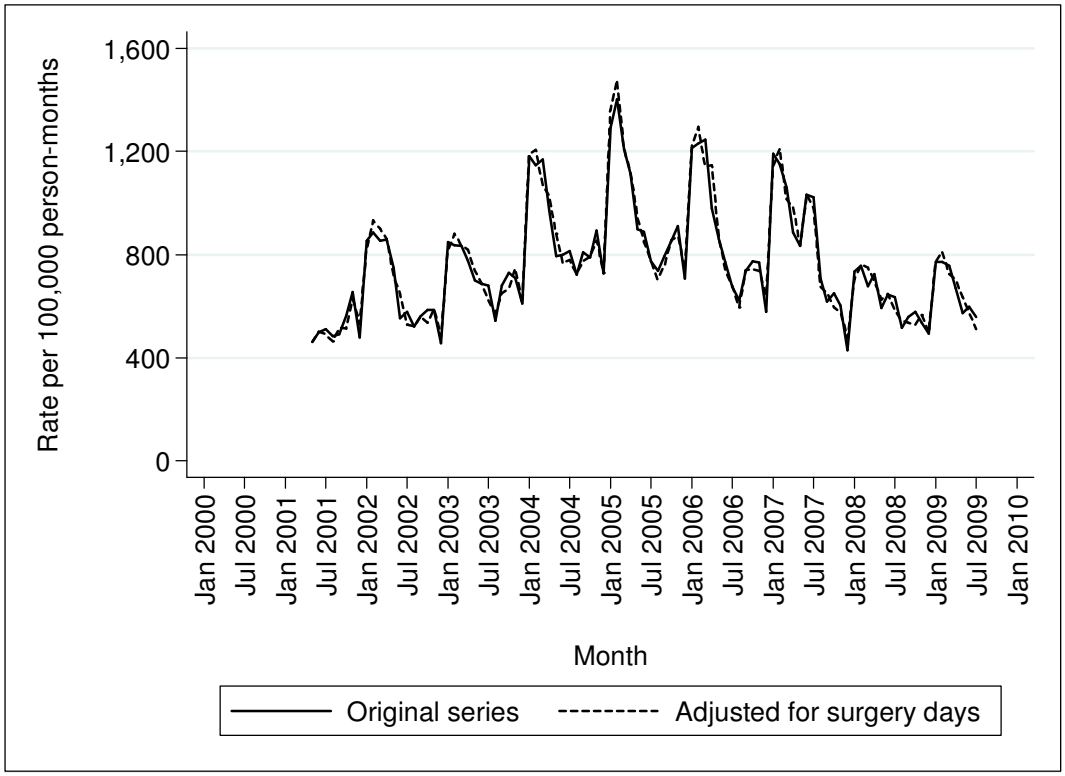


Figure 4.8 Monthly rates of prescribing in current smokers aged 16+ in THIN practices in England, showing adjustment for GP surgery days

4.6. MODEL IDENTIFICATION

4.6.1. Isolating the pre-intervention series

As noted previously, the essence of interrupted time series analysis using ARIMA methods is to fit an appropriate model to describe the data-generating process responsible for the pre-intervention data series, and then assess whether this process is altered by the introduction of the intervention. For this reason, identification of an appropriate ARIMA model is conventionally carried out on pre-intervention data only[135].

It is a requirement of interrupted time series analysis that the intervention is introduced at a single, known point in time, allowing the separation of the pre- and post-intervention data. Smokefree legislation was introduced in England on 1st July 2007, and Figure 4.9 identifies the rate of prescribing of NRT observed in

THIN practices in England, highlighting the point at which smokefree legislation was implemented.

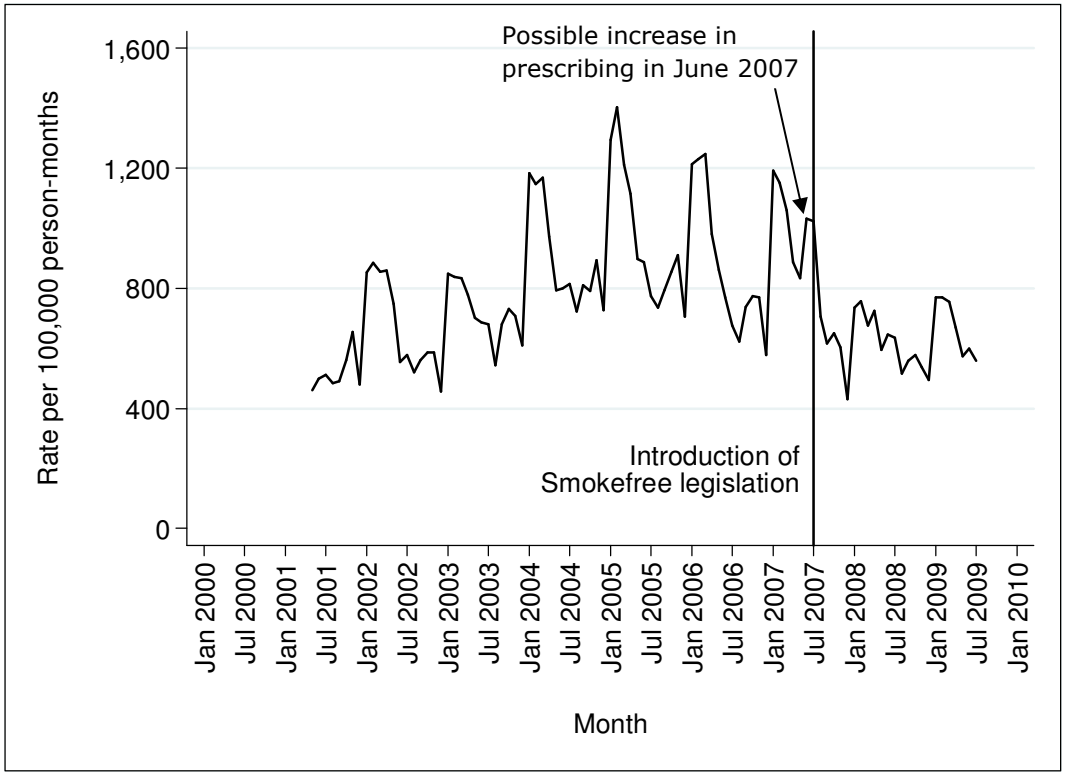


Figure 4.9 Time series highlighting the introduction of smokefree legislation

As the systematic review presented in Section 1.6 concludes, smokers may have attempted to quit in the months leading up to the introduction of smokefree legislation. It can be hypothesised that evidence in support of increased quitting activity may similarly be seen in THIN prescribing data. In order to test this hypothesis, and also to illustrate various aspects of ARIMA modelling and the implications of decisions made during the modelling process, this chapter will illustrate the use of interrupted time series analysis to assess whether there was a significant increase in the rate of prescribing of NRT to smokers in the month before the introduction of smokefree legislation in England, June 2007, and, if so, to quantify the magnitude of this effect. Visual inspection of Figure 4.9 suggests there may have been an increase in the rate of prescribing of NRT in June 2007, though it is difficult to be sure whether this is outside of the normal seasonal

pattern of prescribing. The method presented in the following sections will confirm whether indeed there was a statistically significant increase in NRT prescribing in June 2007, over and above the longer-term trend and seasonal pattern in the data.

Initially, therefore, the data will be separated into a pre-intervention series spanning the period from April 2001 to May 2007, and a post-intervention period spanning the period from June 2007 to July 2009. The modelling techniques outlined in the remainder of this chapter can be followed and adapted to assess changes in prescribing, or any other outcome variable, in any time period.

4.6.2. Achieving stationarity

In order to fit an ARIMA model to a time series dataset, the series must first be rendered stationary – the mean and variance of the data must be constant over time[135]. A series can be non-stationary as a result of several factors which can be identified from a time plot of the data and which will now be discussed in turn.

Outliers will change the mean level of the series in the region of the aberrant point and so the mean will not be constant over time. As noted previously, outliers should be treated as missing data and replaced with imputed values[135]. There are no obvious outliers in Figure 4.9.

As Figure 4.9 shows, there are slight differences in the variance of the series over time, with the magnitude of variation in the rate of prescribing from one month to the next being smaller at the start and end of the series compared to the middle section. In order to render the variance constant over time the series must be transformed – a log transformation is most commonly used. Even if the variability of a series does not change over time a log transformation may still be preferred –

a significant change of a given magnitude in a logged series is approximately equivalent to a percentage change in the unlogged data, perhaps a more intuitive way to present the results of ARIMA modelling.

Figure 4.10 shows the logged pre-intervention series; as can be seen, logging the data has rendered the variance at the start of the series similar to that in the middle part of the study period.

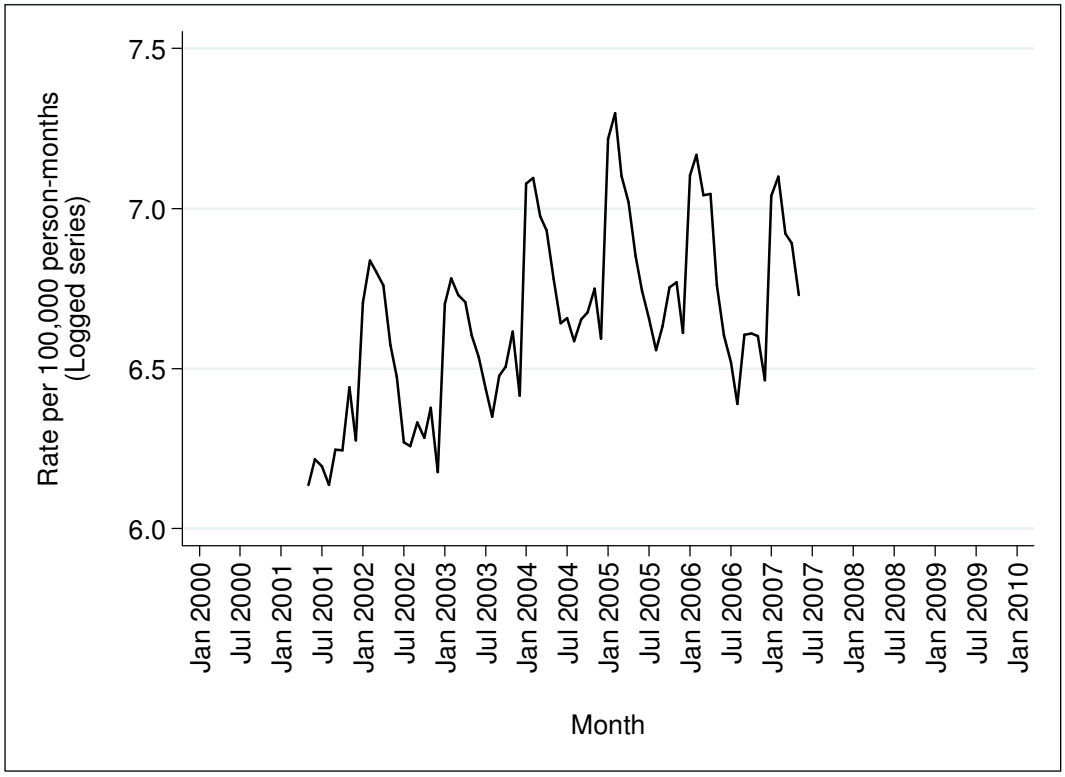


Figure 4.10 The logged pre-intervention series

The logged series shown in Figure 4.10 is still not stationary – there is a clear upwards trend in the data between 2001 and 2005 and thus the mean of the series is not constant over time. In order to remove the trend from a time series the data must be differenced – the value of the series at each point in time must be replaced by the value of the difference between that point and the data point in the preceding month, as shown for an excerpt of data in Table 4.1. Such a

difference cannot be calculated for the first value of the series, which is replaced with a missing value indicator.

Table 4.1 Illustration of differencing of the logged pre-intervention series

Month	Value of logged series	Differenced series
May 2001	6.14	-
Jun 2001	6.22	0.08
Jul 2001	6.19	-0.03
Aug 2001	6.14	-0.05
Sep 2001	6.25	0.11
Oct 2001	6.24	-0.01
Nov 2001	6.44	0.20
Dec 2001	6.28	-0.16
Jan 2002	6.71	0.43
Feb 2002	6.84	0.13
Mar 2002	6.80	-0.04
Apr 2002	6.76	-0.04

Having differenced the logged pre-intervention series, the ACF of this differenced series must then be re-drawn to ensure that all evidence of non-stationarity has been removed. Figure 4.11 shows a time plot of the logged, differenced pre-intervention series.

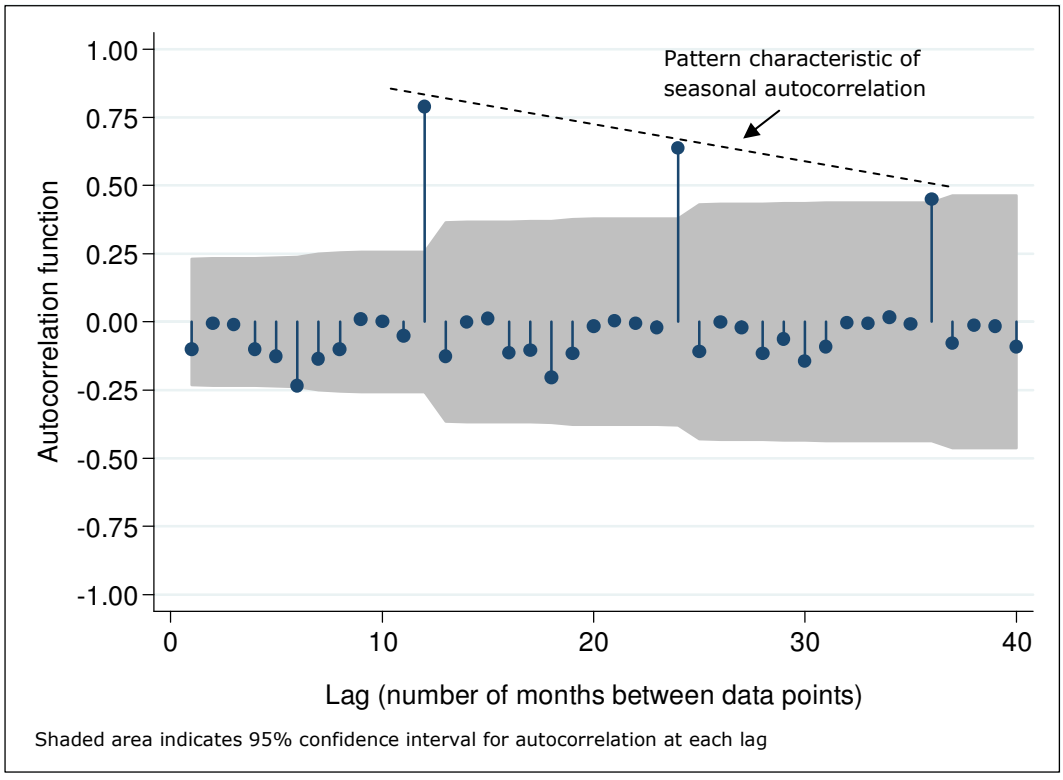


Figure 4.11 ACF of the logged, differenced pre-intervention series

Significant autocorrelation remains in the series at lags 12, 24 and 36. This pattern of gradually diminishing autocorrelation at multiples of the seasonal order of the series is indicative of seasonal non-stationarity in a series. The series must be seasonally differenced in order to render it seasonally stationary – in the case of monthly data the value of the series at each point in time must be replaced by the value of the difference between that point and the data point in the same month of the previous year. Such seasonal differencing necessarily replaces the series with missing values for the first 12 months, and these months cannot then be used to fit the ARIMA model and assess the impact of an intervention. This is one reason why it is important to have a long pre-intervention data series when using ARIMA modelling.

Figure 4.12 shows the ACF of the logged, first differenced and seasonally differenced pre-intervention series. There is no evidence of any remaining stationarity, either non-seasonal or seasonal in nature.

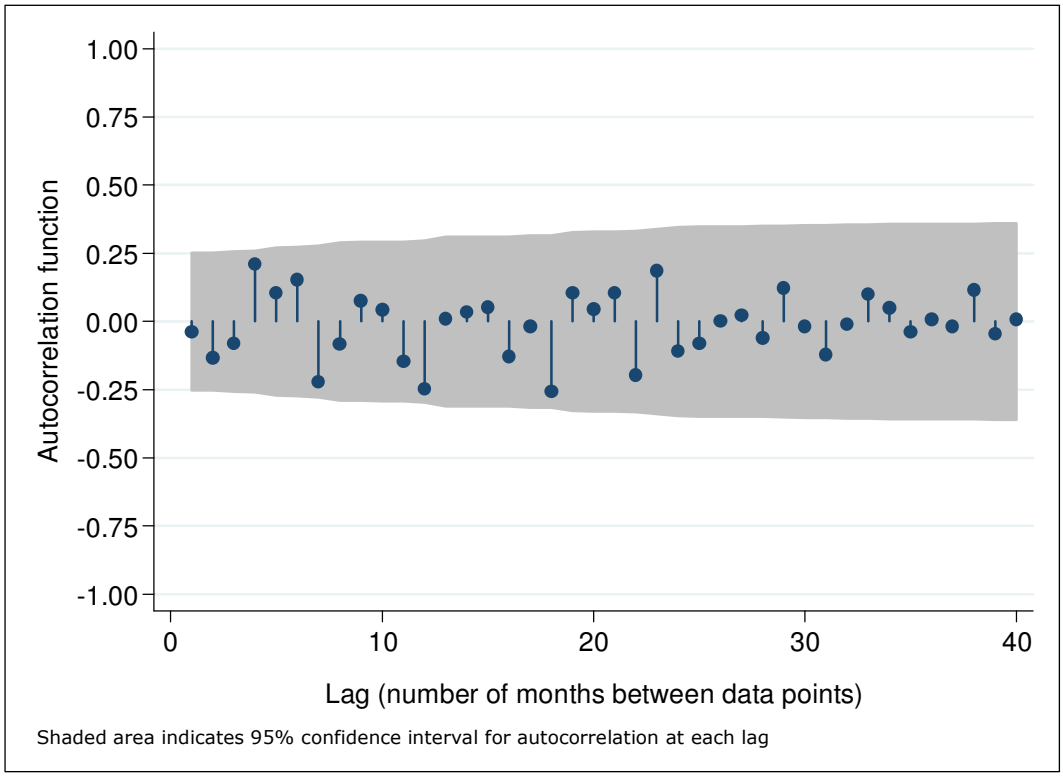


Figure 4.12 ACF of differenced and seasonally differenced logged pre-intervention series

As the time plot of the logged, first differenced and seasonally differenced pre-intervention series in Figure 4.13 shows, the trend has now been removed from the series and its variance is relatively constant over time. Occasionally it may be necessary to difference a series twice (i.e. compute the difference of an already-differenced series) in order to render the series stationary, though this is rarely necessary. The analyst can now be satisfied that the series has been rendered stationary and can proceed to the next stage of analysis, model identification.

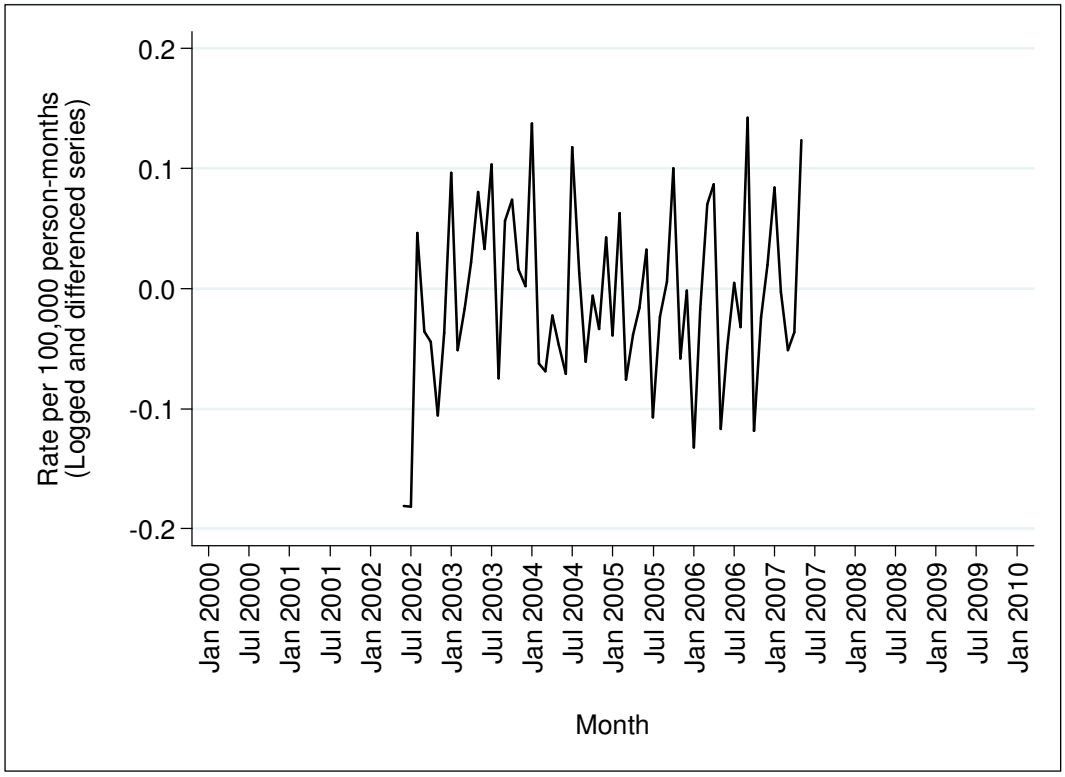


Figure 4.13 Time plot of differenced and seasonally differenced logged pre-intervention series

4.6.3. Identifying a tentative ARIMA model

Having rendered the pre-intervention series stationary, the next stage of an interrupted time series analysis is to identify what form the autocorrelation present in a series takes and to build a mathematical model to represent the data-generating process responsible for the series. There are two types of autocorrelation that may be present in a series – autoregressive and moving

average. This section details these in turn, and explains how the autocorrelation function (ACF) introduced already, and partial autocorrelation function (PACF), to be described shortly, can be used to assess whether a series contains such autocorrelation. Then, this knowledge will be used to determine the type of autocorrelation present in the exemplar series being used in this chapter to illustrate the principles of time series analysis.

4.6.3.1. Autoregressive autocorrelation

If autoregressive autocorrelation is present in a time series, the value of the series at a particular point in time is a function of the value of the series at an earlier point in time, plus an error component. In an autoregressive process of order one – AR(1) – the value of a series at one point in time (Y_t) is the sum of a fraction ($Ø_1$) of the value of the series at the immediately preceding point in time (Y_{t-1}) and an error component (e_t)[135]:

$$Y_t = Ø_1 Y_{t-1} + e_t$$

Similarly, in an AR(2) process the value of a series at any point in time is the sum of fractions of the values of the series at the two immediately preceding time points as well as an error component:

$$Y_t = Ø_1 Y_{t-1} + Ø_2 Y_{t-2} + e_t$$

Autoregressive processes produce characteristic patterns in the ACF of a stationary series. However, before considering these, it is necessary to introduce a related concept, the partial autocorrelation function (PACF). The PACF illustrates the autocorrelation present in a series at different lags having removed, or 'partialled out', the effect of autocorrelation at intermediate lags[135]. It is not always possible to distinguish between autoregressive processes of different

orders on the basis of the ACF alone, but the PACF provides additional information to allow the analyst to correctly identify the order of autoregressive autocorrelation present in a series. Figure 4.14 shows the characteristic patterns seen in the ACF and PACF of time series displaying autoregressive autocorrelation of different magnitudes.

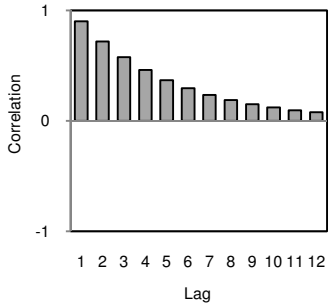
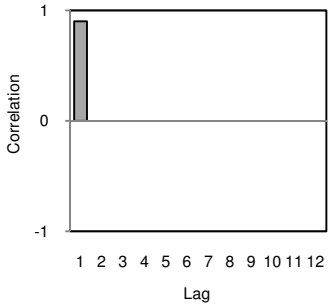
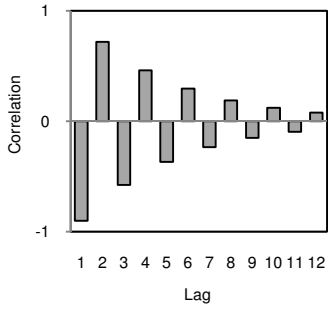
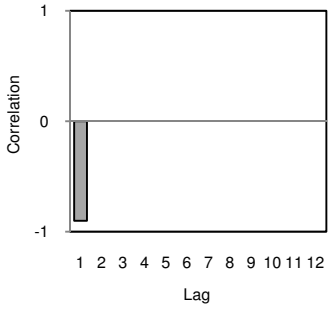
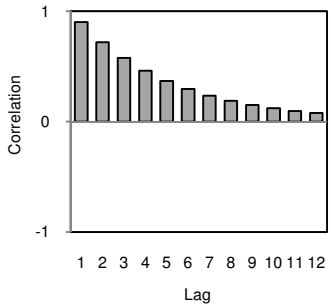
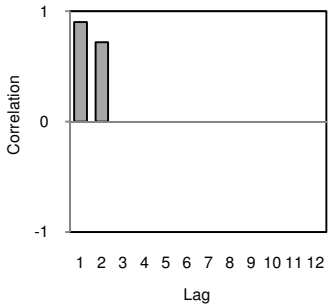
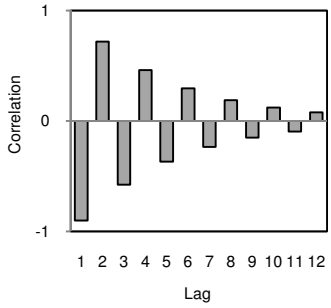
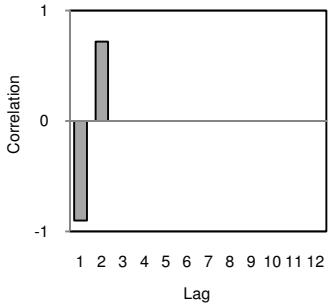
Order of autoregressive process	Value of AR parameter	ACF	PACF
AR(1)	$Ø_1 > 0$		
	$Ø_1 < 0$		
AR(2)	$Ø_1 > 0$ $Ø_2 > 0$		
	$Ø_1 < 0$ $Ø_2 > 0$		

Figure 4.14 Illustration of typical autocorrelation and partial autocorrelation functions of time series displaying autoregressive autocorrelation[135]

As Figure 4.14 shows, autoregressive processes typically produce ACFs with gradually-decaying autocorrelation at increasing lags, a pattern which is the same for AR(1) and AR(2) processes (and indeed all autoregressive processes regardless of order). Recourse to the PACF is needed to distinguish the order of an autoregressive process; the PACF will show significant autocorrelation at lags corresponding to the order of the process. For example, the ACF of an AR(1) process where the direction of autocorrelation is negative will show gradually-decaying autocorrelation alternating in sign, and the PACF will show significant negative autocorrelation at lag 1 only.

4.6.3.2. Moving average autocorrelation

If moving average autocorrelation is present in a time series, the value of the series at a particular point in time is a function of the error component (the difference between the observed value of the series and that estimated by the ARIMA model) from the series at an earlier point in time and an error component at the current time. In a moving average process of order one – MA(1) – the value of a series at one point in time (Y_t) is a function of a fraction (θ_1) of the error component of the series at the immediately preceding point in time (e_{t-1}) and an error component at the current point in time (e_t)[135]:

$$Y_t = e_t - \theta_1 e_{t-1}$$

Similarly, in an MA(2) process the value of a series at any point in time is a function of a fraction of the error component of the series at the two immediately preceding time points and an error component at the current point in time:

$$Y_t = e_t - \theta_1 e_{t-1} - \theta_2 e_{t-2}$$

Figure 4.15 shows the typical patterns seen in the ACF and PACF of stationary time series displaying moving average autocorrelation. As can be seen, the ACF is more helpful here in distinguishing between moving average processes of different orders. As Figure 4.15 shows, moving average processes typically produce PACFs with gradually-decaying autocorrelation at increasing lags, and ACFs with significant autocorrelation at lags corresponding to the order of the process.

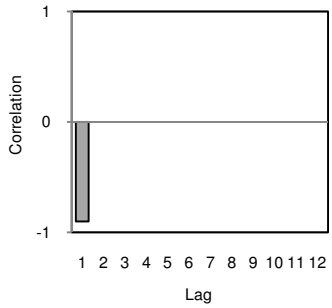
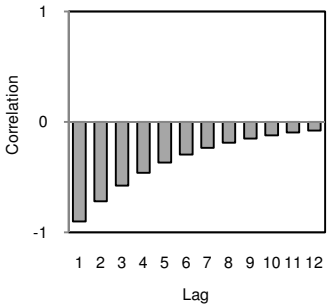
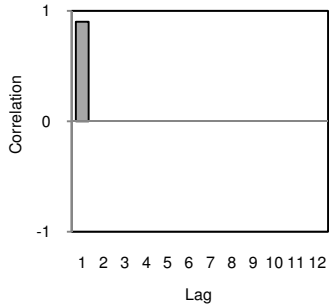
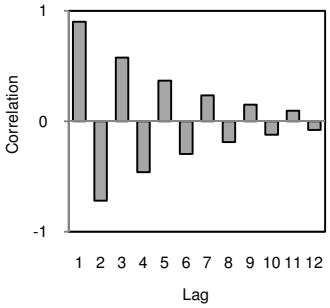
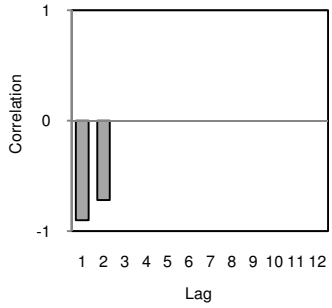
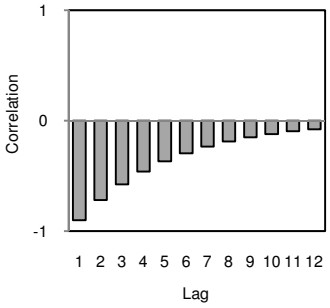
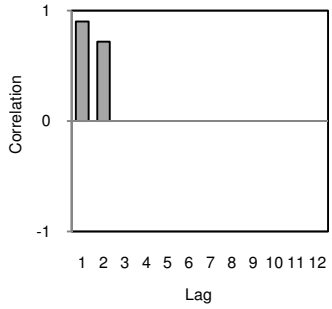
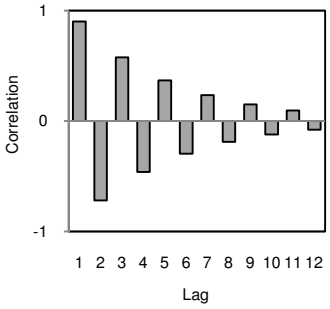
Order of moving average process	Value of MA parameter	ACF	PACF
MA(1)	$\theta_1 > 0$		
	$\theta_1 < 0$		
MA(2)	$\theta_1 > 0$ $\theta_2 > 0$		
	$\theta_1 < 0$ $\theta_2 < 0$		

Figure 4.15 Illustration of typical autocorrelation and partial autocorrelation functions of time series displaying moving average autocorrelation[135]

4.6.3.3. Mixed ARMA processes

It is possible that the data-generating process responsible for a time series is best represented by a mixed process combining both autoregressive and moving average autocorrelation. For example, a process combining autoregressive autocorrelation of order two with moving average correlation of order two may be represented by the following equation[135]:

$$Y_t = \emptyset_1 Y_{t-1} + \emptyset_2 Y_{t-2} + e_t - \theta_1 e_{t-1} - \theta_2 e_{t-2}$$

Figure 4.16 shows the typical patterns seen in the ACF and PACF of stationary time series displaying mixed autoregressive and moving average autocorrelation. As can be seen, both the ACF and PACF of a mixed process show gradually-decaying autocorrelation at increasing lags.

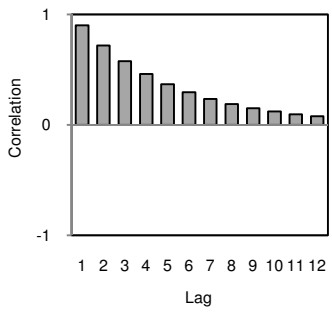
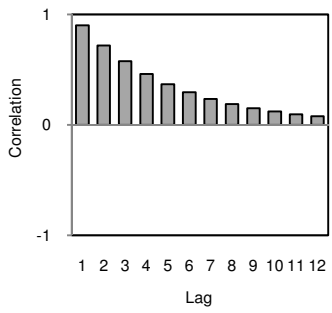
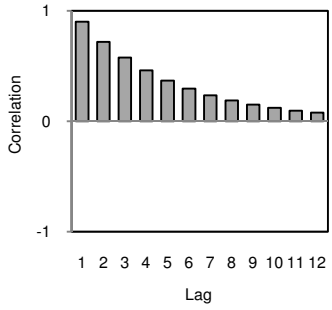
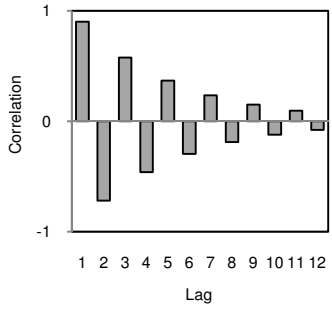
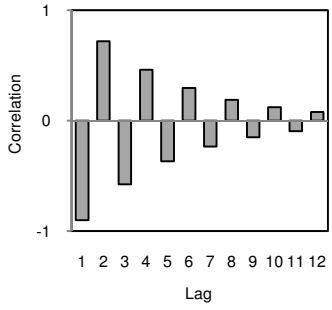
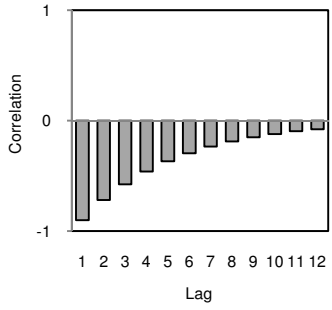
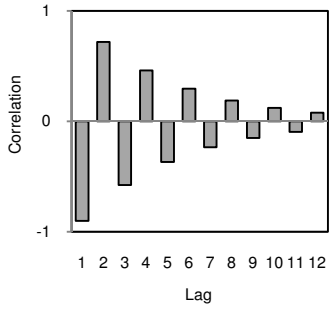
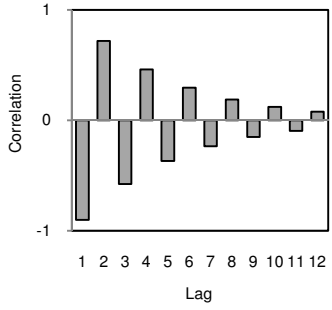
Order of autoregressive and moving average process	Value of AR (Ø) and MA (θ) parameter	ACF	PACF
ARMA(1,1)	$Ø_1 > 0$ $θ_1 > 0$		
	$Ø_1 > 0$ $θ_1 < 0$		
	$Ø_1 < 0$ $θ_1 > 0$		
	$Ø_1 < 0$ $θ_1 < 0$		

Figure 4.16 Illustration of typical autocorrelation and partial autocorrelation functions of time series displaying mixed autoregressive and moving average autocorrelation[135]

4.6.3.4. Seasonal autocorrelation

Time series can also display autoregressive and moving average autocorrelation at seasonal lags. Figure 4.17 and Figure 4.18 show the characteristic patterns seen in the ACF and PACF of stationary monthly time series displaying seasonal autoregressive or moving average autocorrelation.

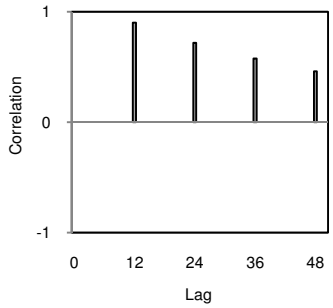
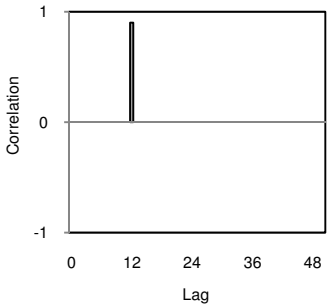
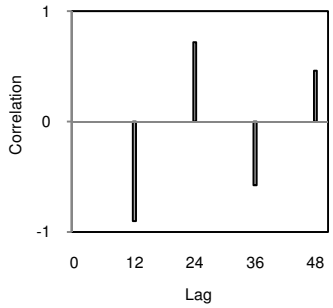
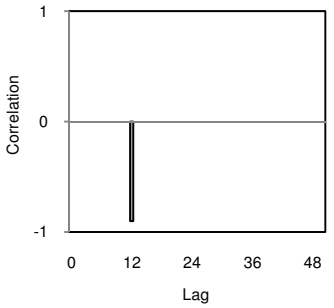
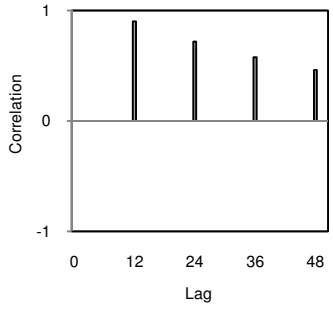
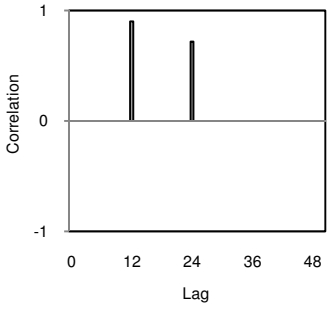
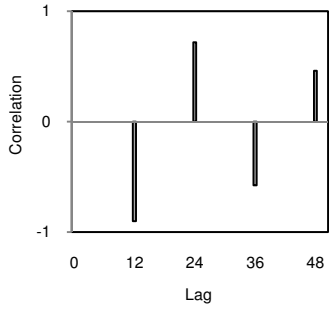
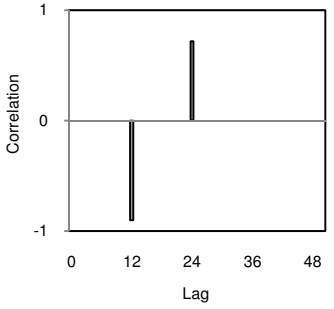
Order of autoregressive process	Value of AR parameter	ACF	PACF
$AR(1)_{12}$	$Ø_1 > 0$		
	$Ø_1 < 0$		
$AR(2)_{12}$	$Ø_1 > 0$ $Ø_2 > 0$		
	$Ø_1 < 0$ $Ø_2 > 0$		

Figure 4.17 Illustration of typical autocorrelation and partial autocorrelation functions of time series displaying seasonal autoregressive autocorrelation[150]

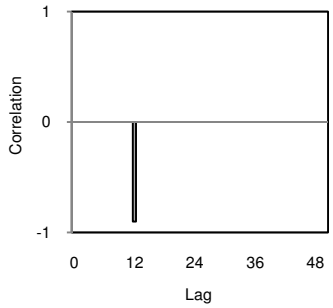
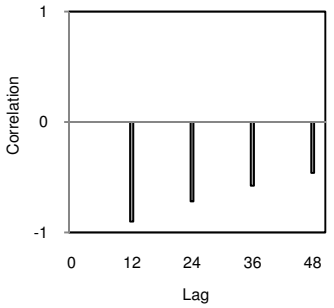
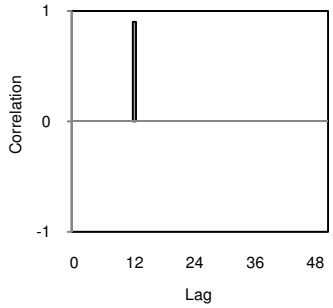
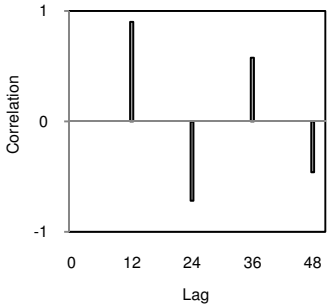
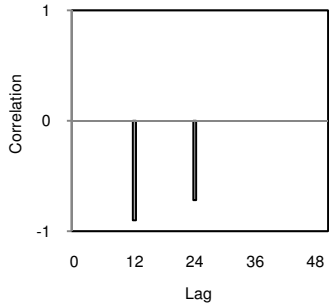
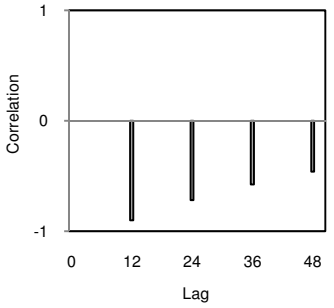
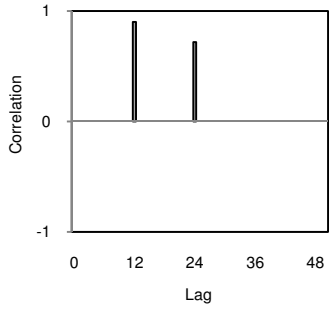
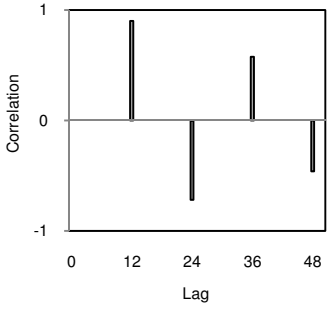
Order of moving average process	Value of MA parameter	ACF	PACF
$MA(1)_{12}$	$\theta_1 > 0$		
	$\theta_1 < 0$		
$MA(2)_{12}$	$\theta_1 > 0$ $\theta_2 > 0$		
	$\theta_1 < 0$ $\theta_2 < 0$		

Figure 4.18 Illustration of typical autocorrelation and partial autocorrelation functions of time series displaying seasonal moving average autocorrelation[150]

As Figure 4.17 shows, seasonal autoregressive processes typically produce ACFs with gradually-decaying autocorrelation at multiples of the number of seasons in a year. For data aggregated monthly this equates to autocorrelation at lags 12, 24, 36 and so on. In data aggregated quarterly, autocorrelation would be observed at lags 3, 6, 9, 12 and so on, and in data aggregated weekly at lags 52, 104, 156 and so on. For a seasonal autoregressive process the PACF will show significant

autocorrelation at multiples of the number of seasons in a year, with the absolute number of significant lags corresponding to the order of the process. As was seen in non-seasonal processes, the pattern in the ACF and PACF is reversed if seasonal moving autocorrelation is present in a series.

4.6.3.5. Mixed non-seasonal and seasonal autocorrelation

Finally, it is possible that a time series may be best represented by a model which combines elements of both non-seasonal and seasonal autocorrelation. Interaction between the non-seasonal and seasonal components of a model can produce 'satellite effects' in the ACF, making interpretation difficult[152]. Figure 4.19 shows two examples of how non-seasonal and seasonal moving average behaviour may interact to produce an ACF which displays satellite effects. As can be seen, the non-seasonal autocorrelation is reflected either side of the seasonal autocorrelation.

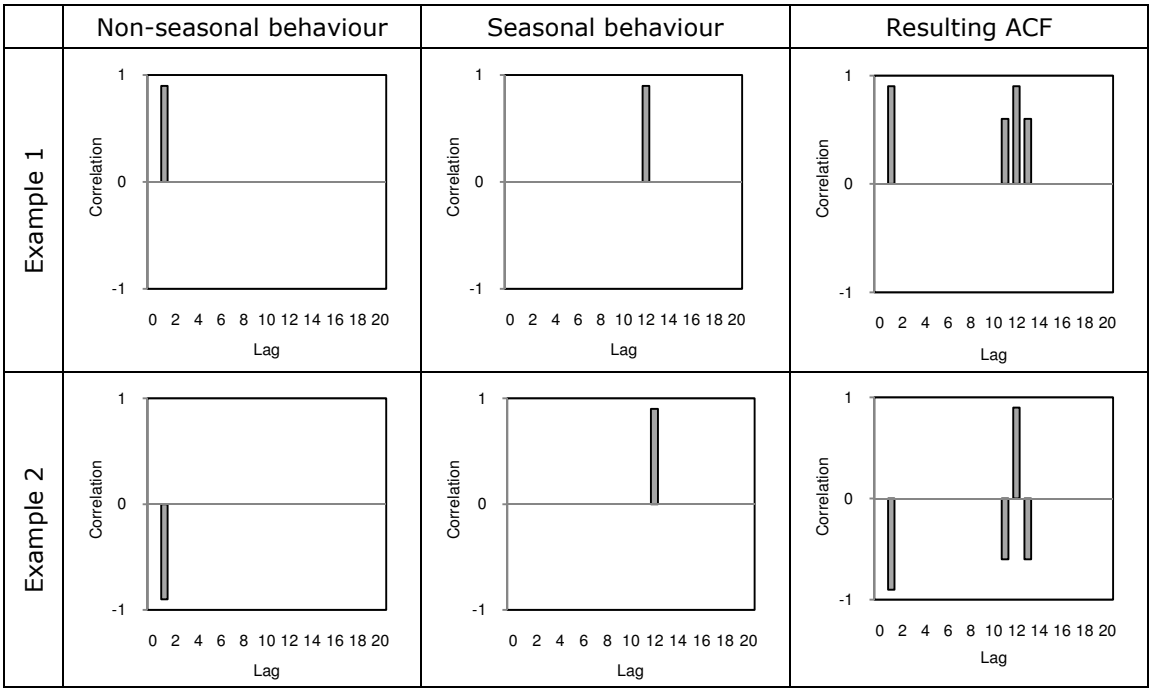


Figure 4.19 Illustration of the satellite effects produced in autocorrelation functions by interaction between non-seasonal and seasonal moving average components[152]

4.6.3.6. Identifying the autocorrelation present in the exemplar series

Having outlined the two types of autocorrelation that may be present in a time series, and shown how the ACF and PACF of the data can be used to identify their presence, it is now appropriate to examine the ACF and PACF of the stationary pre-intervention exemplar series, with the aim of tentatively suggesting the type of autocorrelation present in the data and building an ARIMA model to represent the data-generating process.

Figure 4.20 shows the ACF and PACF of the logged, first differenced and seasonally differenced pre-intervention series. This figure shows clearly that, unfortunately, autocorrelation functions are rarely as easy to interpret as the typical ACFs and PACFs in Figure 4.14 to Figure 4.19 suggest. However, it is worth bearing in mind that time series rarely contain autoregressive or moving average autocorrelation of an order higher than two[151]; in a re-analysis of 70 time series studies published in the academic literature, 80% of series could be satisfactorily represented by an AR(1) process[153]. Higher-order models can often be represented by mathematically-equivalent lower-order processes[135]; for example, an MA(2) process can almost always be adequately modelled using an AR(1) model[150]. In addition, it is likely that only a very small minority of time series will be best represented by a mixed model – only a few series in a thousand according to one estimate[136]. Therefore, a mixed model should not be adopted until more simple models involving just autoregressive or moving average parameters have been ruled out.

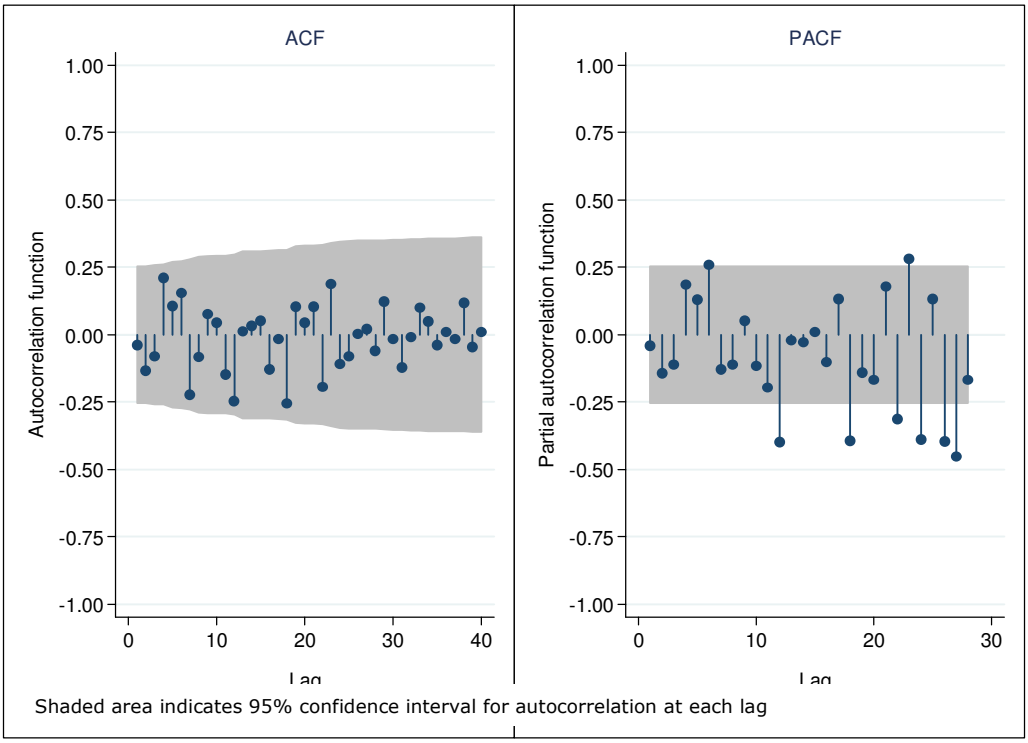
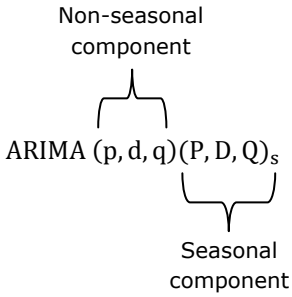


Figure 4.20 The autocorrelation and partial autocorrelation function of the logged, first differenced and seasonally differenced pre-intervention series

The significant autocorrelation at lags 12 and 24 in the PACF in Figure 4.20 hints at the presence of seasonal autoregressive autocorrelation of order two in the stationary series. It is not immediately obvious how to interpret the other significant autocorrelations in the PACF – there is, for example, unlikely to be non-seasonal autoregressive autocorrelation of order six in the series, despite the significant autocorrelation at lag six in the PACF. The suggestion of seasonal autoregressive autocorrelation of order two does, however, provide a starting point for model identification and estimation.

An ARIMA model is conventionally described using the general syntax:



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)

In Section 4.6.2 it was shown that the exemplar time series must be both first differenced and seasonally differenced into order to render it stationary; therefore, in this example, both d and D are equal to one. Having tentatively identified the existence of seasonal autoregressive autocorrelation of order two in the stationary series, the ARIMA model which potentially represents the pre-intervention section of the exemplar time series can be written as:

$$\text{ARIMA } (0,1,0)(2,1,0)_{12}$$

This specification provides a starting point for model identification. As discussed previously, model identification is an iterative process, with models being suggested, estimated, evaluated and refined until the most appropriate model is

found. The following sections detail the stages involved in estimating and evaluating an ARIMA model.

4.7. MODEL ESTIMATION

Having identified a tentative ARIMA model to describe the pre-intervention series, the 'arima' command in Stata can be used to estimate the values of the autoregressive and moving average parameters in the model.

Stata uses maximum likelihood estimation (MLE) to select values for the model parameters which maximise the likelihood of the observed result[125], returning point estimates along with a 95% confidence interval and Wald p-value. Table 4.2 shows parameter estimates returned when an ARIMA(0,1,0)$(2,1,0)_{12}$ model is fitted to the logged pre-intervention series.

Table 4.2 Parameter estimates for ARIMA(0,1,0)$(2,1,0)_{12}$ model

Parameter	Estimate	95% confidence interval	Wald p-value
$AR(1)_{12}$	-0.416	-0.061 to -0.771	0.022
$AR(2)_{12}$	-0.285	-0.025 to -0.554	0.032

These parameter estimates can be substituted into the general formula for an autoregressive ARMA process described previously to show the mathematical process which describes the logged, pre-intervention time series:

$$Y_t = -0.416\, Y_{t-12} + -0.285\, Y_{t-24} + e_t$$

Once a model has been estimated, the next step is to carry out various diagnostic tests to assess the model's adequacy and, if necessary, find a more appropriate model to describe the series.

4.8. MODEL DIAGNOSIS

As with other statistical modelling techniques, the aim of ARIMA model identification is to select the most parsimonious model, containing as few parameters as possible, which adequately represents the data[154]. This section outlines several checks that should be undertaken to ensure a selected model is parsimonious and appropriate. Attention will be paid to the statistical significance of the autoregressive and moving average parameters, restrictions on the magnitude of these parameters and features of the model residuals.

4.8.1. Are all the model parameters statistically significant?

Guided by the principle of parsimony, no autoregressive or moving average parameters should be included in the final ARIMA model if they are not statistically significant at the 5% significance level. As can be seen in Table 4.2, the two autoregressive parameters are both statistically significant, suggesting that the tentative model selected may be an appropriate one to describe the data. On this criterion of parameter significance alone the ARIMA$(0,1,0)(2,1,0)_{12}$ model can be accepted. However, other diagnostic tests for model adequacy must also be carried out before finally accepting a particular model.

4.8.2. Do the model parameters lie within the bounds of stationarity and invertibility?

In order for a model to be selected as an appropriate representation of a data-generating process, the values of the autoregressive and moving average parameters must fall within certain bounds, known as the bounds of stationarity and invertibility. These bounds apply to both the non-seasonal and seasonal

model parameters. These bounds of stationarity for AR(1) and AR(2) processes, and bounds of invertibility for MA(1) and MA(2) processes are shown in Table 4.3.

Table 4.3 Bounds of stationarity and invertibility for model parameters

	Bounds of stationarity for autoregressive parameters	Bounds of invertibility for moving average parameters
Order 1	$-1 < Ø_1 < 1$	$-1 < \theta_1 < 1$
Order 2	$-1 < Ø_2 < 1$ $Ø_1 + Ø_2 < 1$ $Ø_2 - Ø_1 < 1$	$-1 < \theta_2 < 1$ $\theta_1 + \theta_2 < 1$ $\theta_2 - \theta_1 < 1$

Ø = autoregressive autocorrelation parameter; θ = moving average autocorrelation parameter

The autoregressive parameters estimated in Table 4.2 fall within the bounds of stationarity, and therefore the ARIMA$(0,1,0)(2,1,0)_{12}$ model passes this diagnostic test. Parameter estimates close to, or outside of, the bounds of stationarity and/or invertibility may suggest that the time series has not been rendered stationary before fitting the ARIMA model, and the model estimating procedure may fail to converge to estimates of the parameters. If this occurs it is advisable to re-check whether the series has indeed been rendered stationary through non-seasonal and/or seasonal differencing prior to model fitting.

4.8.3. Are any of the model parameters collinear?

Again following the guiding principle of parsimony, parameter estimates in a selected model should not be collinear. Table 4.4 shows the extent of collinearity between the $AR(1)_{12}$ and $AR(2)_{12}$ parameters included in the estimated model.

Table 4.4 Collinearity between model parameters

	$AR(1)_{12}$	$AR(2)_{12}$
$AR(1)_{12}$	1	-
$AR(2)_{12}$	-0.365	1

The time series literature does not contain any specific guidance on the extent of correlation between parameter estimates that the analyst should be concerned about. However, a correlation coefficient of more than 0.8 is sometimes taken to indicate very high collinearity[155] and would suggest a need for one of the collinear parameters to be removed from the model. In this instance collinearity between model parameters does not appear to be a problem.

4.8.4. Are the model residuals normally distributed?

Figure 4.21 shows the frequency distribution of the residuals from the ARIMA$(0,1,0)(2,1,0)_{12}$ model, standardised to have a mean of zero and a standard deviation of one. This standardisation makes it easier to detect outliers – any residuals with an absolute value greater than three are worthy of further investigation[140]. The histogram is overlaid with a normal distribution with the same mean and standard deviation as the residuals.

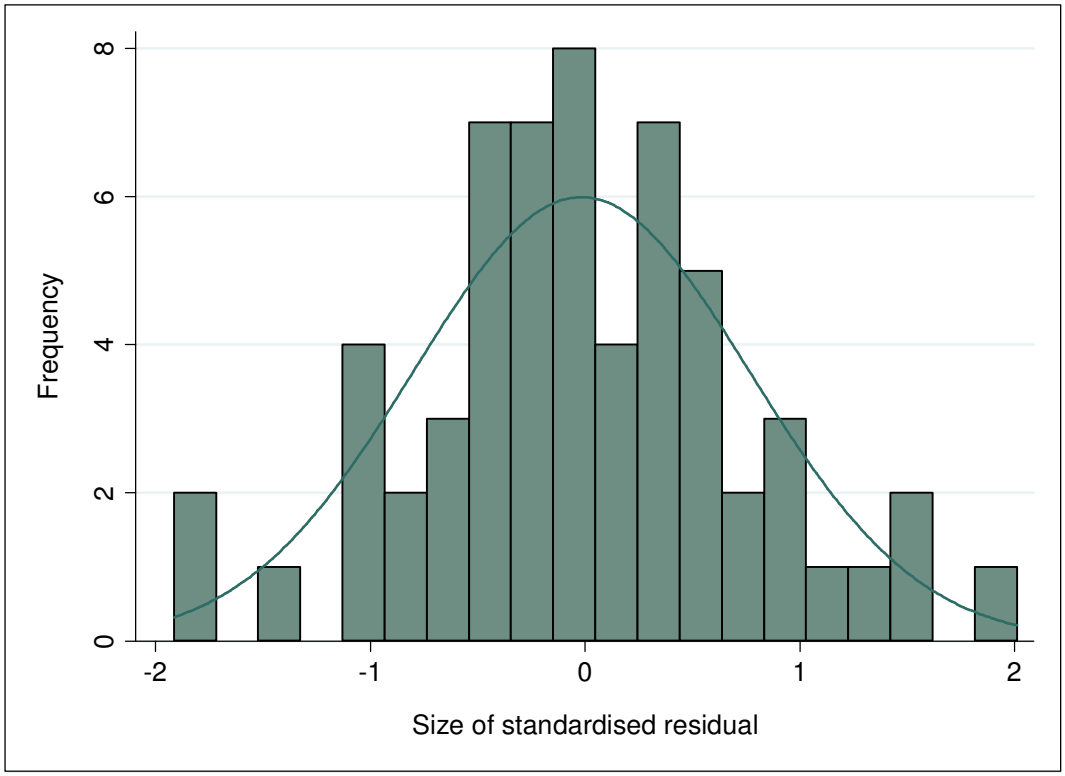


Figure 4.21 Histogram of model residuals

An adequately-fitting ARIMA model will have residuals which are normally-distributed with no obvious outliers. It appears that the ARIMA$(0,1,0)(2,1,0)_{12}$ model produces residuals which meet this diagnostic criterion.

4.8.5. Is the variance of the model residuals constant over time?

Figure 4.22 shows the standardised model residuals plotted over time. In an appropriate ARIMA model the variance of the residuals will be relatively constant over time, and this does appear to be the case for the ARIMA$(0,1,0)(2,1,0)_{12}$ model.

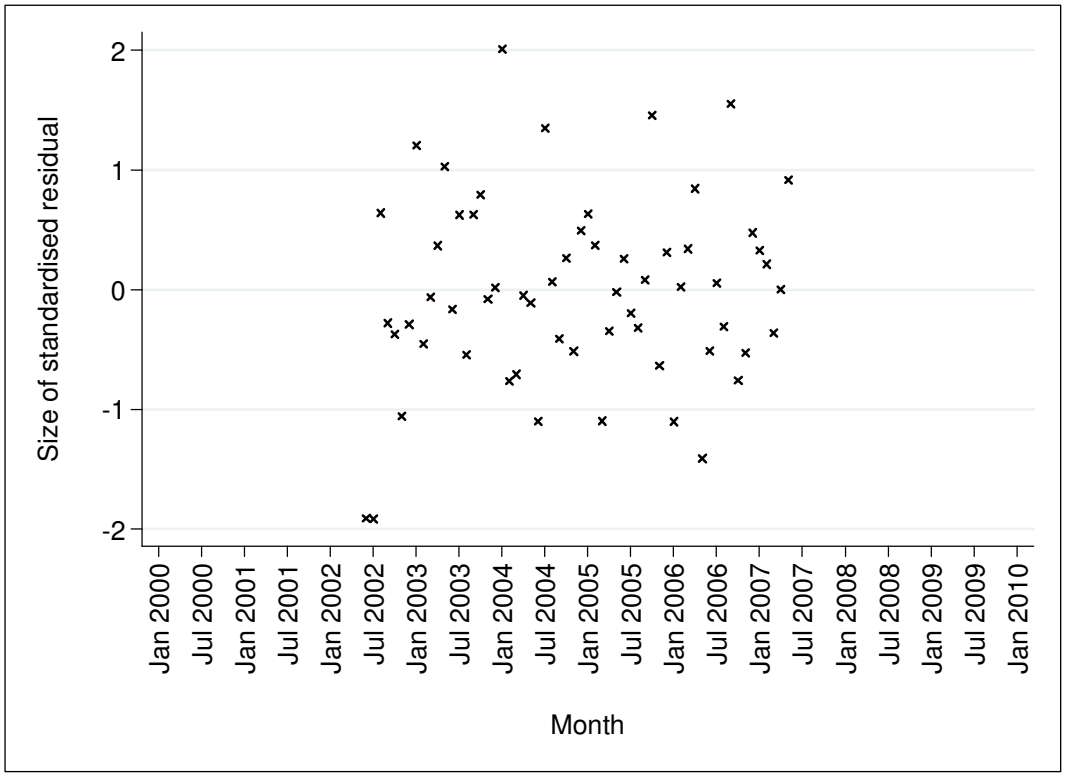


Figure 4.22 Scatter plot of model residuals over time

4.8.6. Are the residuals random and independent?

Finally, the model residuals must be random and independent, resembling, in parlance borrowed from the field of engineering, a white noise process. The easiest way to assess this requirement is to plot an ACF of the model residuals, as shown in Figure 4.23.

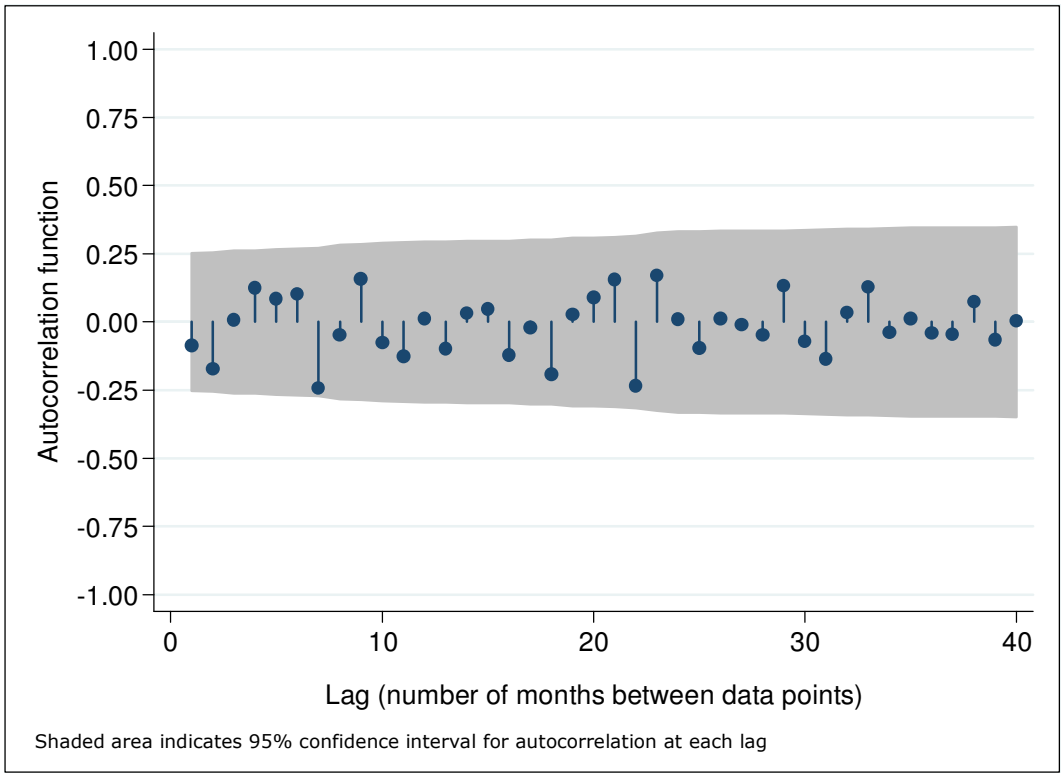


Figure 4.23 ACF of residuals from the ARIMA(0,1,0)(2,1,0)12 model

If the ACF shows no significant autocorrelation between residuals at any lag then the residuals are confirmed as random and independent, a white noise process, as is the case in Figure 4.23. However, an ACF may contain one or two significant autocorrelations purely by chance, and autocorrelation at higher lags is difficult to interpret, particularly in short time series, given the few pairs of observations which can be formed at high lags[144]. Therefore, a portmanteau test, the Ljung-Box Q test, can be carried out to assess whether the whole ACF up to a certain lag (lag

20 is most frequently used) is indicative of a white noise process[140]. The Ljung-Box Q statistic is calculated as follows:

$$Q = n(n+2)\sum_{k=1}^{h}(n-k)^{-1}\,{r_k}^2$$

where n = number of observations in series

h = maximum lag to be tested (commonly 20)

r_k = autocorrelation at lag k

If the residual ACF is a white noise process, the Ljung-Box Q statistic follows a chi-squared distribution with (h-m) degrees of freedom, where m is the number of parameters in the ARIMA model fitted to the series[140]. Therefore, the null hypothesis of a white noise process can be rejected if the value of Q is larger than the critical value of the chi-squared distribution at the 5% significance level.

The Ljung-Box Q test on the model residuals up to lag 20 shown in Figure 4.23 yields a Q statistic of 18.79, which when tested against a chi-squared distribution using 18 degrees of freedom yields a p-value of 0.600, confirming that the residual ACF is indeed a white noise process.

The diagnostic tests presented here suggest that an ARIMA$(0,1,0)(2,1,0)_{12}$ model is a good representation of the logged pre-intervention data series. However, this model contains two parameters, and, in the light of the ambiguous PACF in Figure 4.20, it may be that the series can also be represented by a simpler model containing just one parameter. When a model tentatively chosen to represent a time series fails one or more diagnostic tests, or if the analyst suspects a more parsimonious model may be possible, the next step is to suggest an alternative ARIMA model and to repeat the model estimation procedure and diagnostic tests.

4.9. IDENTIFYING AN ALTERNATIVE ARIMA MODEL

As the work presented thus far alludes to, identifying an appropriate ARIMA model to represent a pre-intervention series is an extremely time-consuming task, and it may not be immediately clear which of the class of ARIMA models is the best starting point for model identification. The time-consuming nature of model identification will be further amplified when many series are to be analysed, as is the case in this thesis which aims to assess the impact of smokefree legislation in subgroups of the population defined by categories such as age, sex and social class. The model chosen to represent rates of prescribing of smoking cessation medications in all smokers in England may not be the same, for example, as the model that best describes the time series of rates of prescribing in women and men separately. An automated procedure to help identify the most appropriate ARIMA model to represent a series is highly desirable.

4.9.1. Automating the ARIMA model identification procedure

In order to help identify the best ARIMA model to describe a time series I have written a procedure in Stata (the 'arimaintervention' command) that, when told whether a time series requires a log transformation and/or differencing to render it stationary, fits several different ARIMA models to the pre-intervention data, systematically working through combinations of non-seasonal and seasonal autoregressive and moving average parameters of order zero, one and two. As noted previously, it is very unlikely that a series will best be represented by a model containing either autoregressive or moving average autocorrelation above order two, justifying the upper limit of two placed on the parameters in the models tested. For each model that is fitted, the automated procedure assesses whether the model estimation procedure converged to produce parameter estimates, assesses whether all parameters are statistically significant and fall

within the bounds of stationarity and invertibility, and uses a Ljung-Box Q test to judge whether the residuals are a white noise process. In addition, the procedure highlights the absolute magnitude of the largest standardised residual to allow detection of possible outliers and computes two estimates of model fit, R^2 and the AIC, which will be discussed shortly. Further details regarding the specification of this automated procedure are presented in Appendix 8.12.

Table 4.5 illustrates the output from this automated procedure applied to the pre-intervention portion of the exemplar series, indicating, of the 81 different ARIMA models estimated in total, which pass the diagnostic tests of model adequacy and can, therefore, be considered as potential representations of the pre-intervention series.

As Table 4.5 shows, four models meet all parameter diagnostic criteria and produce residuals which resemble a white noise process, suggesting they may adequately represent the data generating process behind the pre-intervention time series - ARIMA$(0,1,0)(0,1,0)_{12}$, ARIMA$(0,1,0)(1,1,0)_{12}$, ARIMA$(0,1,0)(2,1,0)_{12}$ and ARIMA$(0,1,0)(0,1,1)_{12}$. The absolute magnitude of the largest standardised residual for each of these models does not suggest there are any major residual outliers which might have allowed the selection of one model over the others as the best representation of the pre-intervention series. As can be seen, the R^2 values indicating model fit are high for all models – over 0.90. However, R^2 values are rarely used by time series analysts as measures of model fit or to choose one model over another. The value of R^2 necessarily improves as more parameters are added to the ARIMA model, though the principle of parsimony suggests a contradictory need to choose the model with the fewest possible terms to model a time series[143]. Similarly, one model cannot be chosen over another on the basis of its sum of squared errors or likelihood, as the values of these can also be improved by increasing the number of terms in the model[140].

Table 4.5 Comparison of the adequacy of different ARIMA models

Model (pdqPDQ)	Did the model estimating procedure converge?	Are all parameters statistically significant?	Are all AR parameters within the bounds of stationarity?	Are all MA parameters within the bounds of invertibility?	Are the residuals a white noise process?	R^2	Model AIC	Largest standardised residual	Possible model?
010010	✓	✓	✓	✓	✓	2.33	-141.28	0.923	✓
110010	✓		✓	✓	✓	2.41	-139.34	0.923	
210010	✓		✓	✓	✓	2.45	-138.68	0.924	
011010	✓		✓	✓	✓	2.44	-139.37	0.923	
111010	✓	✓	✓		✓	2.38	-137.83	0.925	
211010	✓		✓	✓	✓	2.44	-136.86	0.924	
012010	✓		✓	✓	✓	2.46	-138.29	0.924	
112010	✓		✓	✓	✓	2.45	-136.31	0.924	
212010	✓				✓	2.95	-142.50	0.932	
010110	✓	✓	✓	✓	✓	2.53	-144.53	0.928	✓
110110	✓		✓	✓	✓	2.58	-142.84	0.929	
210110	✓		✓	✓	✓	2.60	-141.72	0.930	
011110	✓		✓	✓	✓	2.64	-142.94	0.929	
111110	✓		✓	✓	✓	2.65	-141.23	0.929	
211110	✓		✓	✓	✓	2.60	-139.82	0.930	
012110	✓		✓	✓	✓	2.61	-141.57	0.929	
112110	✓		✓	✓	✓	2.61	-139.57	0.929	
212110	✓	✓			✓	3.05	-146.10	0.937	
010210	✓	✓	✓	✓	✓	2.59	-145.33	0.932	✓
110210	✓		✓	✓	✓	2.61	-143.61	0.932	
210210	✓		✓	✓	✓	2.64	-143.23	0.934	
011210	✓		✓	✓	✓	2.70	-143.75	0.932	
111210	✓		✓	✓	✓	2.71	-142.14	0.932	
211210	✓		✓	✓	✓	2.63	-141.26	0.934	
012210	✓		✓	✓	✓	2.65	-142.84	0.933	
112210	✓		✓	✓	✓	2.64	-140.89	0.933	
212210	✓		✓		✓	2.76	-146.10	0.938	
010011	✓	✓	✓	✓	✓	2.68	-146.90	0.931	✓
110011	✓		✓	✓	✓	2.70	-145.27	0.931	
210011	✓		✓	✓	✓	2.71	-144.54	0.933	
011011	✓		✓	✓	✓	2.71	-145.43	0.931	
111011	✓		✓	✓	✓	2.74	-143.76	0.932	
211011	✓		✓	✓	✓	2.72	-142.56	0.933	
012011	✓		✓	✓	✓	2.74	-144.26	0.933	
112011	✓		✓	✓	✓	2.73	-142.29	0.933	
212011	✓	✓			✓	3.09	-148.14	0.940	
010111	✓		✓	✓	✓	2.65	-145.01	0.932	
110111	✓		✓	✓	✓	2.67	-143.32	0.932	
210111	✓		✓	✓	✓	2.68	-142.71	0.933	
011111	✓		✓	✓	✓	2.69	-143.47	0.932	
111111	✓		✓	✓	✓	2.72	-141.82	0.932	
211111	✓		✓	✓	✓	2.69	-140.74	0.933	
012111	✓		✓	✓	✓	2.71	-142.38	0.933	
112111	✓		✓	✓	✓	2.71	-140.41	0.933	
212111	✓		✓		✓	2.67	-144.19	0.937	
010211	✓		✓	✓	✓	2.61	-143.66	0.932	
110211	✓		✓	✓	✓	2.64	-141.97	0.932	
210211	✓		✓	✓	✓	2.65	-141.61	0.934	
011211	✓		✓	✓	✓	2.72	-142.14	0.932	
111211	✓		✓	✓	✓	2.72	-140.51	0.933	
211211	✓		✓	✓	✓	2.65	-139.63	0.934	
012211	✓		✓	✓	✓	2.68	-141.21	0.934	
112211	✓		✓	✓	✓	2.67	-139.28	0.934	
212211	✓		✓		✓	2.75	-144.31	0.938	
010012	✓		✓	✓	✓	2.63	-145.07	0.932	
110012	✓		✓	✓	✓	2.66	-143.35	0.932	
210012	✓		✓	✓	✓	2.65	-142.83	0.934	
011012	✓		✓	✓	✓	2.69	-143.49	0.932	
111012	✓		✓	✓	✓	2.70	-141.85	0.932	
211012	✓		✓	✓	✓	2.67	-140.86	0.934	
012012	✓		✓	✓	✓	2.69	-142.47	0.933	
112012	✓		✓	✓	✓	2.69	-140.50	0.933	
212012			✓		✓	3.02	-145.49	0.938	
010112	✓		✓	✓	✓	2.62	-143.16	0.932	
110112	✓		✓	✓	✓	2.65	-141.44	0.932	
210112	✓		✓	✓	✓	2.65	-140.97	0.934	
011112	✓		✓	✓	✓	2.69	-141.57	0.932	
111112	✓				✓	2.73	-140.98	0.932	
211112	✓		✓	✓	✓	2.66	-139.01	0.934	
012112	✓		✓	✓	✓	2.69	-140.59	0.933	
112112	✓		✓	✓	✓	2.68	-138.63	0.933	
212112			✓		✓	3.10	-145.00	0.939	
010212	✓		✓		✓	2.59	-142.97	0.933	
110212	✓		✓		✓	2.73	-141.60	0.933	
210212	✓		✓		✓	2.76	-140.91	0.935	
011212	✓		✓		✓	2.83	-141.86	0.933	
111212	✓		✓		✓	2.81	-140.11	0.934	
211212	✓		✓		✓	2.77	-138.94	0.935	
012212	✓		✓		✓	2.71	-140.53	0.934	
112212	✓		✓		✓	2.75	-138.77	0.935	
212212	✓		✓		✓	2.77	-142.42	0.938	

The solution traditionally employed by time series analysts is to compute a measure of model fit which penalises the likelihood for each additional parameter included in a model. *Akaike's Information Criterion* (AIC) is the most frequently used measure, and is calculated as follows[140]:

$$\mathrm{AIC} = 2\mathrm{k} - 2\ln(\mathrm{L})$$

where k = number of autoregressive and moving average parameters in model

L = likelihood of estimated model

Models with a smaller AIC (taking negative signs into account) are preferred over models with a larger AIC. Of the four ARIMA models identified as potentially adequate, ARIMA$(0,1,0)(0,1,1)_{12}$ has the lowest AIC (-146.90) and so this model will be selected as the most appropriate model to represent the pre-intervention data series. Generally the model with the lowest AIC will have residuals that resemble a white noise process. However, on occasion it might be necessary, and is acceptable, to select a model with a slightly higher AIC but no residual outliers[140]. Should the exploration of model adequacy fail to identify any ARIMA models which adequately represent a series it is recommended that the series is checked again for outliers and to ensure the correct differencing transformation has been applied to render the series stationary. Additionally, the p-values estimated for the autoregressive and moving average parameters should be checked – a model with a parameter which is only marginally non-significant can acceptably be used to model a series.

The selected ARIMA$(0,1,0)(0,1,1)_{12}$ model produces an estimate for the one seasonal moving average parameter as shown in Table 4.6. As can be seen, this model parameter is highly statistically significant and falls within the bounds of

invertibility. As there is only one parameter in this model it is not necessary to undertake a check for collinearity of parameters.

Table 4.6 Parameter estimates for ARIMA(0,1,0)(0,1,1)$_{12}$ model

Parameter	Estimate	95% confidence interval	Wald p-value
MA(1)$_{12}$	-0.513	-0.851 to -0.177	0.003

Having identified an ARIMA model to represent the pre-intervention time series, the impact of an intervention on this series can now be assessed.

4.10. IMPACT ASSESSMENT

In Section 4.9 the ARIMA(0,1,0)(0,1,1)$_{12}$ model was selected as the best model from the ARIMA class to represent the pre-intervention time series. This model can now be applied to the whole time series, including the post-intervention data, and an assessment made as to whether there was a statistically significant increase in the rate of prescribing of NRT in smokers in THIN in England in June 2007.

The introduction of an intervention is a deterministic event with no stochastic component, and so can be modelled in an interrupted time series analysis using a dummy variable[135]. If the pre-intervention ARIMA(p,d,q)(P,D,Q)$_s$ model is represented as N_t, the impact assessment model can be written as:

$$Y_t = f(I_t) + N_t$$

In the above equation, f(I_t), is a function representing the intervention component of the model[136]. This dummy variable can take several forms depending upon the impact the intervention is expected to have on the series, and prior to undertaking

any interrupted time series analysis one should review any existing literature and theory to formulate a hypothesis describing the expected effect[135].

The most simple effect of the introduction of an intervention is to cause an immediate, permanent increase or decrease in the level of the time series (often referred to as a step change), as illustrated in Figure 4.24.

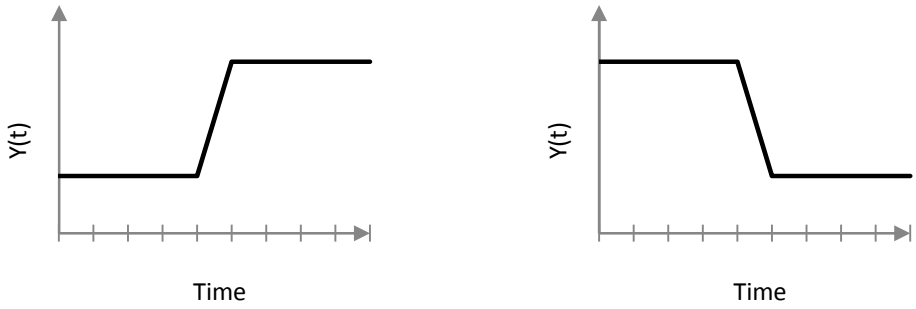


Figure 4.24 Illustration of a step change in a time series

To assess whether the introduction of an intervention caused a step change in a time series, a dummy variable must be generated which takes the value 0 for all points in time before the introduction of the intervention, and the value 1 for all points in time at and after the introduction of the intervention.

Another simple effect of the introduction of an intervention may be to cause a sudden but temporary change in the level of the series at that point in time, referred to in the time series literature as a pulse and illustrated in Figure 4.25.

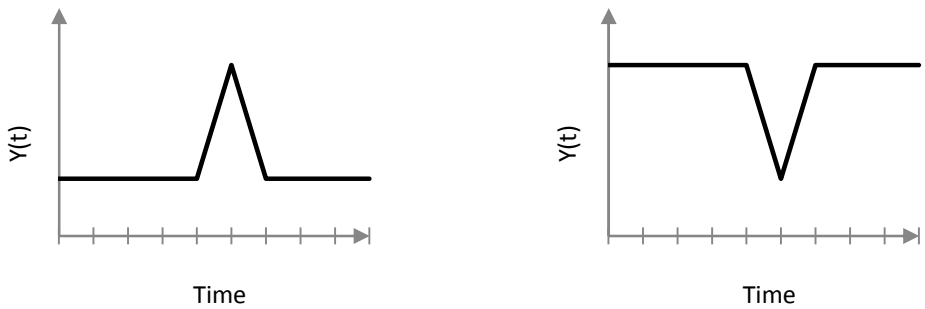


Figure 4.25 Illustration of a pulse effect in a time series

A pulse may modelled to last just one time period, such as a month, or more than one period, spanning several months, using a dummy variable which takes the value 0 for all points in time before and after the intervention period, and the value 1 during the intervention period.

As discussed in Section 4.6.1, this chapter seeks to illustrate the use of interrupted time series analysis by assessing whether there was a significant change in the rate of prescribing of NRT amongst smokers in June 2007 and, if so, to quantify the magnitude of this change. This equates to testing for a pulse effect in June 2007.

In the model identification procedure documented above, an ARIMA model was chosen which best represented the log-transformed pre-intervention series. In assessing the impact of smokefree legislation on the series, the impact assessment model must be applied to the whole span of the series, including the post-intervention data, again once this has been log-transformed.

Table 4.7 shows the parameter estimate for a pulse effect in June 2007 obtained when an impact assessment model is estimated including a dummy variable coded as 1 in June 2007 and 0 in all other months.

Table 4.7 Modelling the effect of SFL

Change in prescribing in June 2007	95% confidence interval	Wald p-value
0.175	0.111 to 0.240	<0.001

The interrupted time series analysis suggests that there was a statistically significant increase in the rate of prescribing of NRT of 0.175 units on the logarithmic scale in June 2007 (equivalent to an increase of 17.5% in the original series).

In this example, the ARIMA model detected a statistically significant change in the outcome variable during the intervention period. However, if an interrupted time series analysis indicates there was no statistically significant change in an outcome variable during an intervention period it may be because the ARIMA model had a low probability of rejecting the null hypothesis of no significant change even if this hypothesis was false.

The following section presents a method to assess the power of an ARIMA model to detect a change of a given magnitude in a time series.

4.11. ESTIMATING THE STATISTICAL POWER OF AN INTERRUPTED TIME SERIES ANALYSIS

Prior to starting data collection, many study designers undertake a power calculation to quantify the sample size needed to detect a specified effect size with a given level of statistical power. A power of 80% is often considered appropriate[156]. Such a calculation requires an estimate to be made of the effect size likely to be observed and the level of variance likely to exist in the data, estimates which may be difficult to make, particularly if there is no existing literature in the subject area as is the case with the work presented in this thesis. An alternative to this prospective power analysis is to compute a retrospective indication of the power of a study to detect a significant effect, using the variance observed in the sample to calculate the minimum effect size that could be detected with a statistical power of 80%[157].

Very few interrupted time series analyses published to date discuss the power of the analytical methods used, and it is only within the last five years that methods have been developed for computing the power of interrupted time series analysis carried out using ARIMA models[158]. The equation below shows the formula which

can be used to calculate the power of an ARIMA model to detect an effect size of magnitude δ[158]:

$$\Pi(\delta) = \Phi\left(-Z_{1-\alpha/2} - \delta/\widehat{se}(\delta)\right) + 1 - \Phi\left(Z_{1-\alpha/2} - \delta/\widehat{se}(\delta)\right)$$

where Φ = the cumulative distribution of the standard normal distribution

$Z_{1-\alpha/2}$ = the upper 1-α/2 quantile of the standard normal distribution

δ = effect size

$\widehat{se}(\delta)$ = standard error of effect size derived from ARIMA model

This equation can be solved for incremental values of δ in order to draw a power curve depicting the power of the ARIMA model to detect effect sizes of different magnitudes given the degree of variance observed in the time series. From this power curve, the minimum effect size which can be detected with 80% power can be determined.

The standard error for the estimate of a pulsatile increase in the rate of prescribing of NRT in June 2007 is 0.033. Substituting this value into the equation above, the power curve shown in Figure 4.26 can be drawn. This power curve suggests that the minimum effect size which the ARIMA model can detect with 80% power, given the degree of variation in the data, is a pulse of 0.092 in the logged series (equivalent to a 9.2% change in the unlogged data). The effect size actually estimated by the ARIMA model was a pulse of 0.175 in the logged series, larger than this minimum detectible effect, and hence there was a probability greater than 80% that the ARIMA model would detect as statistically significant the 17.5% change in NRT prescribing.

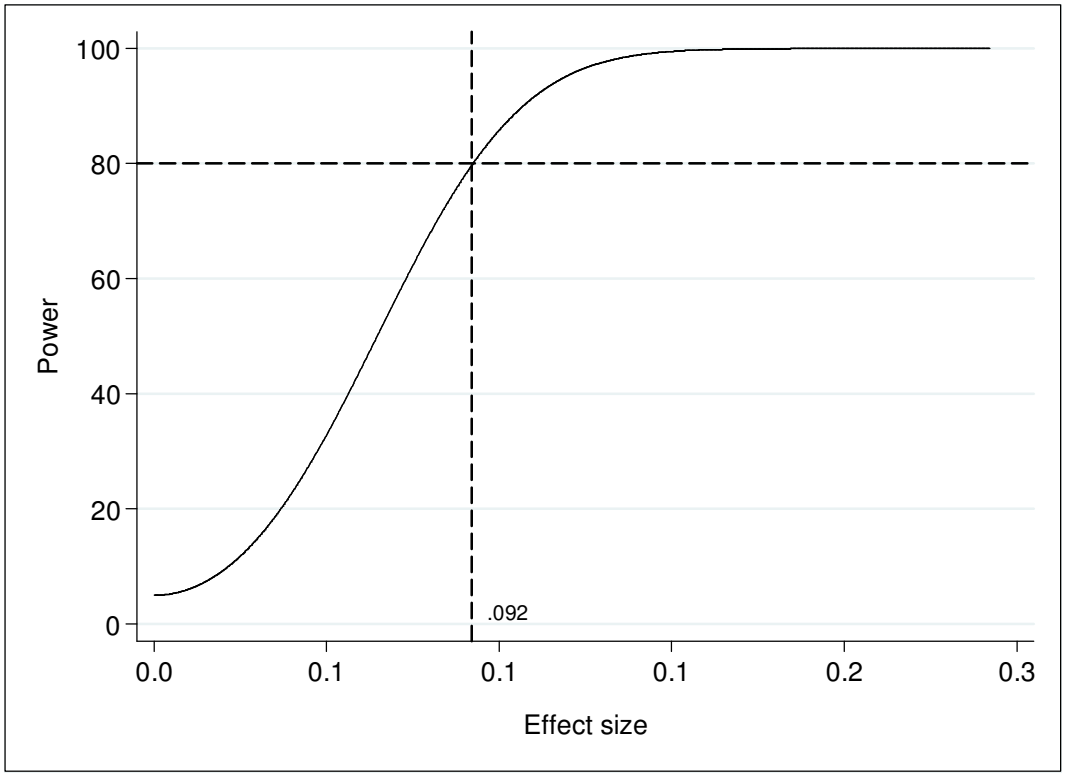


Figure 4.26 Power curve showing the minimum effect size which can be detected with 80% power

This chapter to this point has outlined the principles of ARIMA modelling and the use of interrupted time series analysis to assess the impact of an intervention on a series. In the following section, various sensitivity analyses will be presented which evaluate the impacts of ARIMA model misspecification and potential confounding on the conclusions reached regarding the impact of an intervention on a time series.

4.12. SENSITIVITY ANALYSES

4.12.1. The effects of model misspecification

As shown previously, interrupted time series using ARIMA modelling requires the identification of an appropriate model from the ARIMA class which best represents the pre-intervention data series. This can be a very-consuming process and,

unless automated methods such as that developed here are used to narrow down the number of potential models, an element of judgement is required in interpreting the series ACF and PACF at each iteration of the model selection process. It is possible that this element of subjectivity may lead different analysts to select different ARIMA models to represent the same data series. The use of different models to represent the pre-intervention data generating process may ultimately lead to different conclusions regarding the impact of an intervention on the series.

The 'arimaintervention' command described earlier will also, for each ARIMA model estimated, calculate the magnitude of change in the outcome variable in the intervention period, along with 95% confidence intervals and a Wald p-value for the parameter. The results can then be scanned visually to assess whether the choice of model influences the magnitude and statistical significance of the change in the outcome variable estimated in the intervention period.

In order to assess the impact of model misspecification, Table 4.8 shows the parameter estimates and p-values generated from different ARIMA models for the change in the rate of prescribing of NRT to smokers in June 2007.

Shaded boxes in Table 4.8 indicate models which fit all diagnostic criteria and, before selection of the model with the lowest AIC, could potentially be used to represent the pre-intervention series. As can be seen, even if the non-seasonal and seasonal differencing components are misspecified a number of ARIMA models still pass all diagnostic tests and could potentially be used to model the series.

Table 4.8 Estimates of the change in the rate of NRT prescribing in June 2007 in different ARIMA models (point estimates and p-values)*

Model (pqPQ)	Both first order and seasonal differencing		Neither first order nor seasonal differencing		First order differencing only		Seasonal differencing only	
	Point estimate	(p-value)	Point estimate	(p-value)	Point estimate	(p-value)	Point estimate	(p-value)
0000	0.380	(<0.001)	0.338	(0.215)	0.214	0.255	0.343	(0.076)
1000	0.351	(0.847)	0.141	(0.499)	0.195	(0.972)	0.171	(<0.001)
2000	0.311	(0.080)	0.139	(0.495)	0.194	(0.969)	0.136	(<0.001)
0100	0.342	(0.655)	0.112	(0.536)	0.192	(0.961)	0.099	(0.087)
1100	0.334	(0.372)	0.139	(0.496)	0.008	(0.956)	0.126	(<0.001)
2100	0.312	(0.087)	0.221	(0.283)	0.000	(0.999)	0.136	(<0.001)
0200	0.323	(0.156)	0.110	(0.532)	0.194	(0.969)	0.087	(0.052)
1200	0.299	(0.004)	0.148	(0.451)	0.253	(0.951)	0.128	(<0.001)
2200	0.211	(0.005)	0.160	(0.297)	0.073	(0.677)	0.127	(<0.001)
0010	0.291	(0.001)	0.404	(0.382)	0.273	(<0.001)	0.426	(0.290)
1010	0.287	(0.001)	0.120	(<0.001)	0.266	(<0.001)	0.139	(<0.001)
2010	0.276	(0.001)	0.095	(<0.001)	0.259	(<0.001)	0.126	(<0.001)
0110	0.286	(0.001)	0.092	(0.015)	0.262	(<0.001)	0.103	(0.076)
1110	0.281	(0.002)	0.091	(<0.001)	0.263	(0.001)	0.122	(<0.001)
2110	0.278	(0.001)	0.091	(<0.001)	0.248	(0.001)	0.121	(<0.001)
0210	0.275	(0.001)	0.067	(0.032)	0.259	(<0.001)	0.085	(0.057)
1210	0.260	(<0.001)	0.091	(<0.001)	0.262	(<0.001)	0.121	(<0.001)
2210	0.259	(<0.001)	0.090	(<0.001)	0.285	(0.004)	0.121	(<0.001)
0020	0.236	(<0.001)	0.406	(0.423)	0.298	(<0.001)	0.425	(0.299)
1020	0.232	(<0.001)	0.127	(<0.001)	0.295	(<0.001)	0.125	(<0.001)
2020	0.209	(<0.001)	0.112	(<0.001)	0.307	(<0.001)	0.115	(<0.001)
0120	0.229	(<0.001)	0.096	(0.005)	0.295	(<0.001)	0.113	(0.062)
1120	0.231	(<0.001)	0.110	(<0.001)	0.306	(<0.001)	0.109	(<0.001)
2120	0.213	(<0.001)	0.109	(<0.001)	0.287	(<0.001)	0.107	(<0.001)
0220	0.207	(<0.001)	0.066	(0.030)	0.305	(<0.001)	0.082	(0.058)
1220	0.211	(<0.001)	0.108	(<0.001)	0.311	(<0.001)	0.107	(<0.001)
2220	0.251	(<0.001)	0.109	(<0.001)	0.293	(<0.001)	0.107	(<0.001)
0001	0.175	(<0.001)	0.376	(0.104)	0.283	(0.170)	0.422	(0.321)
1001	0.176	(<0.001)	0.150	(0.007)	0.283	(0.171)	0.070	(0.003)
2001	0.171	(<0.001)	0.135	(0.011)	0.269	(0.127)	0.070	(0.004)
0101	0.176	(<0.001)	0.157	(0.003)	0.283	(0.171)	0.103	(0.074)
1101	0.170	(<0.001)	0.135	(0.010)	0.242	(0.030)	0.069	(0.005)
2101	0.172	(<0.001)	0.159	(0.004)	0.232	(0.040)	0.068	(0.006)
0201	0.167	(<0.001)	0.110	(0.022)	0.268	(0.127)	0.084	(0.058)
1201	0.146	(<0.001)	0.135	(0.011)	0.231	(0.024)	0.068	(0.006)
2201	0.148	(<0.001)	0.135	(0.010)	0.276	(0.030)	0.068	(0.006)
0011	0.175	(<0.001)	0.407	(0.384)	0.288	(0.004)	0.426	(0.294)
1011	0.174	(<0.001)	0.127	(<0.001)	0.287	(0.004)	0.076	(0.002)
2011	0.164	(<0.001)	0.118	(<0.001)	0.290	(0.005)	0.068	(0.005)
0111	0.173	(<0.001)	0.096	(0.005)	0.286	(0.004)	0.103	(0.071)
1111	0.183	(<0.001)	0.116	(<0.001)	0.283	(0.017)	0.065	(0.008)
2111	0.170	(<0.001)	0.134	(<0.001)	0.372	(<0.001)	0.067	(0.006)
0211	0.161	(<0.001)	0.066	(0.031)	0.286	(0.004)	0.052	(0.150)
1211	0.168	(<0.001)	0.111	(<0.001)	0.351	(0.016)	0.065	(0.008)
2211	0.148	(<0.001)	0.112	(<0.001)	0.258	(<0.001)	0.065	(0.009)
0021	0.169	(<0.001)	0.403	(0.491)	0.275	(0.018)	0.418	(0.333)
1021	0.166	(<0.001)	0.122	(<0.001)	0.272	(0.019)	0.074	(0.003)
2021	0.154	(<0.001)	0.106	(<0.001)	0.307	(<0.001)	0.065	(0.009)
0121	0.165	(<0.001)	0.094	(0.008)	0.296	(<0.001)	0.096	(0.030)
1121	0.159	(<0.001)	0.102	(<0.001)	0.291	(0.029)	0.061	(0.014)
2121	0.164	(<0.001)	0.102	(<0.001)	0.275	(0.010)	0.088	(0.011)
0221	0.152	(<0.001)	0.065	(0.040)	0.268	(0.016)	0.045	(0.161)
1221	0.138	(<0.001)	0.099	(<0.001)	0.295	(0.029)	0.063	(0.011)
2221	0.146	(<0.001)	0.100	(<0.001)	0.229	(0.005)	0.063	(0.015)
0002	0.175	(<0.001)	0.343	(0.560)	0.268	(0.229)	0.414	(0.214)
1002	0.173	(<0.001)	0.092	(0.018)	0.272	(0.225)	0.076	(0.002)
2002	0.162	(<0.001)	0.073	(0.038)	0.278	(0.201)	0.067	(0.008)
0102	0.172	(<0.001)	0.063	(0.173)	0.272	(0.226)	0.106	(0.005)
1102	0.183	(<0.001)	0.074	(0.036)	0.237	(0.065)	0.063	(0.011)
2102	0.169	(<0.001)	0.080	(0.026)	0.219	(0.052)	0.067	(0.007)
0202	0.160	(<0.001)	0.061	(0.110)	0.278	(0.200)	0.045	(0.188)
1202	0.167	(<0.001)	0.166	(<0.001)	0.266	(0.084)	0.065	(0.009)
2202	0.137	(<0.001)	0.077	(0.034)	0.229	(0.054)	0.064	(0.027)
0012	0.169	(<0.001)	0.368	(0.455)	0.273	(0.029)	0.402	(0.240)
1012	0.171	(<0.001)	0.122	(<0.001)	0.269	(0.027)	0.075	(0.004)
2012	0.159	(<0.001)	0.106	(<0.001)	0.268	(0.025)	0.067	(0.012)
0112	0.170	(<0.001)	0.084	(0.024)	0.287	(0.006)	0.098	(0.034)
1112	0.182	(<0.001)	0.101	(<0.001)	0.289	(0.062)	0.063	(0.016)
2112	0.167	(<0.001)	0.100	(<0.001)	0.261	(0.014)	0.128	(<0.001)
0212	0.157	(<0.001)	0.068	(0.024)	0.263	(0.017)	0.050	(0.153)
1212	0.140	(<0.001)	0.097	(<0.001)	0.293	(0.067)	0.065	(0.013)
2212	0.167	(<0.001)	0.100	(<0.001)	0.280	(0.003)	0.065	(0.019)
0022	0.174	(<0.001)	0.376	(0.480)	0.277	(0.023)	0.333	(0.010)
1022	0.152	(<0.001)	0.122	(<0.001)	0.273	(0.025)	0.061	(0.030)
2022	0.153	(<0.001)	0.118	(0.004))	0.274	(0.028)	0.067	(0.037)
0122	0.171	(<0.001)	0.086	(0.028)	0.291	(0.020)	0.099	(0.033)
1122	0.181	(<0.001)	0.101	(<0.001)	0.285	(0.015)	0.045	(0.113)
2122	0.171	(<0.001)	0.113	(<0.001)	0.284	(0.010)	0.051	(0.087)
0222	0.156	(<0.001)	0.070	(0.023)	0.282	(0.027)	0.020	(0.484)
1222	0.162	(<0.001)	0.103	(<0.001)	0.278	(0.012)	0.049	(0.102)
2222	0.155	(<0.001)	0.102	(<0.001)	0.451	(<0.001)	0.070	(0.005)

*Shaded boxes indicate models meeting all diagnostic criteria for model fit

There are large variations in the magnitude of change in the rate of prescribing in June 2007 estimated by the various ARIMA models, though the majority of models produce statistically significant estimates for an increase in the rate of prescribing. Several models produce non-statistically significant estimates of the change in NRT prescribing in June 2007, including the ARIMA$(1,0,0)(0,0,0)_{12}$ model which passes all diagnostic tests for model adequacy.

The results presented in Table 4.8 suggest that care must be taken when selecting an ARIMA model to represent a time series as the use of different models may ultimately lead to different conclusions being drawn about the effect of an intervention on the phenomenon under investigation.

An important early stage in the ARIMA modelling procedure is to correctly identify the order of non-seasonal and seasonal differencing required to render a series stationary. There is a growing body of literature devoted to developing statistical methods which can identify whether a time series needs to be non-seasonally or seasonally differenced to induce stationarity, using what are called unit root tests, rather than relying on visual inspection of the series ACF. However, the most frequently used of these tests, the Dickey-Fuller test for non-seasonal non-stationarity, is acknowledged to have poor power properties[159] and its use has been labelled 'misguided'[160]. There are no tests available for use in Stata to assess whether a time series needs to be seasonally differenced to remove seasonal non-stationarity. As a result, the work presented in this thesis relies on visual assessment of the ACF to determine whether the series needs to be non-seasonally or seasonally differenced to induce stationarity.

The potential effects of model misspecification lend further weight to using an automated procedure to identify the most appropriate model to represent the data-generating process behind a pre-intervention time series, selecting the

model which passes all diagnostic tests and has the lowest AIC. In this thesis, a large number of population subgroups will be analysed to assess whether the introduction of smokefree legislation had a differential impact in different groups of patients. Applying the same automated procedure to each analysis will remove the element of subjectivity involved in identifying an ARIMA model and ensure that all results are generated using the same methodological procedure and are, therefore, comparable.

4.12.2. Choice of temporal aggregation

As noted earlier, a choice must be made early in the study design process about the degree of temporal aggregation (e.g. data collected weekly, monthly or yearly) most appropriate to detect the impact of the introduction of an intervention, bearing in mind the increased computational demands that come with analysing longer time series. Thus far, all analyses have been based on data aggregated monthly, and this section assesses whether different conclusions about the impact of smokefree legislation may be generated using data aggregated weekly.

Figure 4.27 compares the shapes of the time series produced when the rate of prescribing of NRT in smokers in THIN is aggregated weekly and monthly. Both series have been appropriately adjusted to account for variations in the number of days general practices were open in each time period. Even after this adjustment there is a particularly large amount of variation in the weekly time series – the last week of the year in many years has a particularly low rate of recording, as well as other weeks seemingly randomly distributed throughout the series.

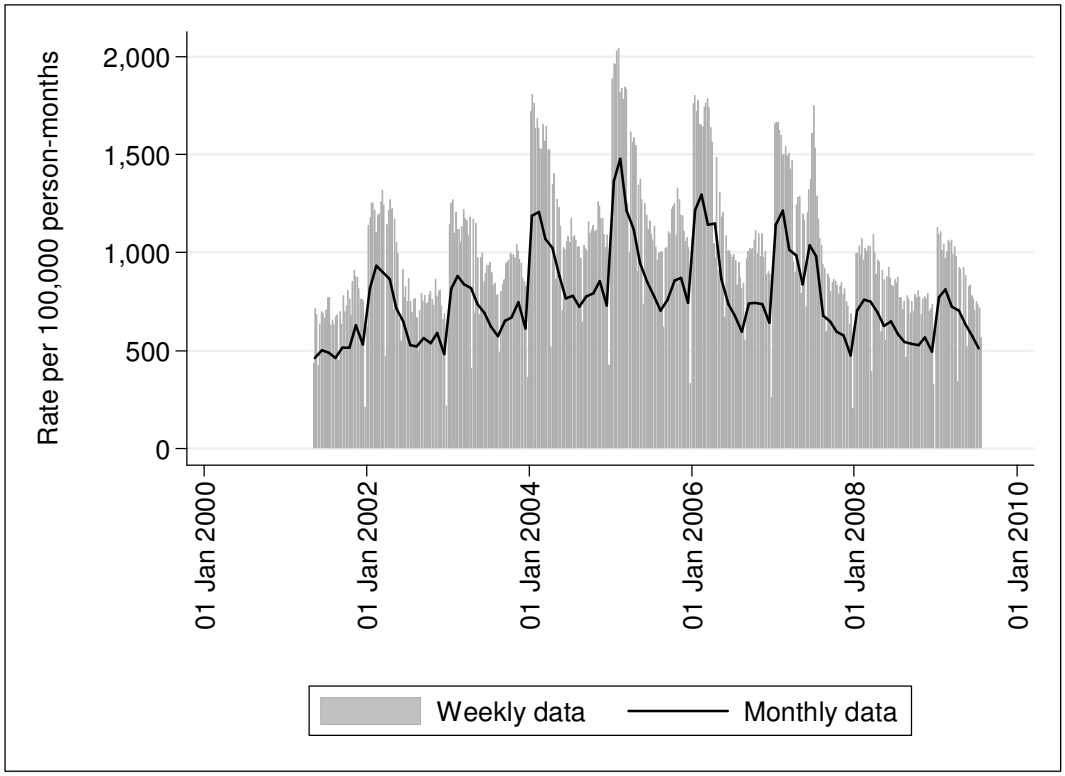


Figure 4.27 A comparison of weekly and monthly rates of NRT prescribing

The very low rate of prescribing in some weeks of the year makes it impossible to adequately fit an ARIMA model to the weekly series – the model with significant and acceptable parameters and with the lowest AIC produces severely non-normally distributed residuals, an outlier of 6.55 in magnitude and an R^2 value of only 0.517. The inability to fit an ARIMA model to the weekly series means it is impossible to assess the impact of the introduction of an intervention on the weekly rate of prescribing of NRT. The majority of the time series analysed in this thesis show similar patterns when aggregated weekly, and, given a lack of the computing power necessary to model multiple weekly series, all analyses presented in the following chapters will be based on monthly data.

4.12.3. Confounding due to changes in the study population over time

As mentioned in Section 4.5.5.2, the observations at each point in time in a series must be directly comparable and there should be no changes over time in the

composition of the population being studied[151]. In particular, there should be no change in the composition of the study population at the same time as the introduction of an intervention, such as smokefree legislation. However, in practice this is very difficult to achieve. In the work presented in this thesis it is desirable to use as many THIN patients' data as possible, though defining the denominator population each month as all patients aged 16+ necessarily allows the structure of the population by characteristics such as sex to change over time. Similarly, restricting the denominator each month to the same group of patients who are registered in THIN throughout the whole of the study period may introduce confounding by age group – the population will become on average ten years older over the decade. This section assesses the potential degree of confounding by time-varying characteristics of the denominator population.

The results presented thus far are based on rates of NRT prescribing in a denominator population of all patients aged 16+ registered in THIN each month. Figure 4.28 shows how the structure of the monthly denominator population changes over time with respect to sex and age group.

As Figure 4.28 shows, there are only small changes over time in the proportion of the denominator who are male, as well as the proportion in different age groups, and so these factors are unlikely to act as major confounders when assessing the impact of the introduction of smokefree legislation on a time series.

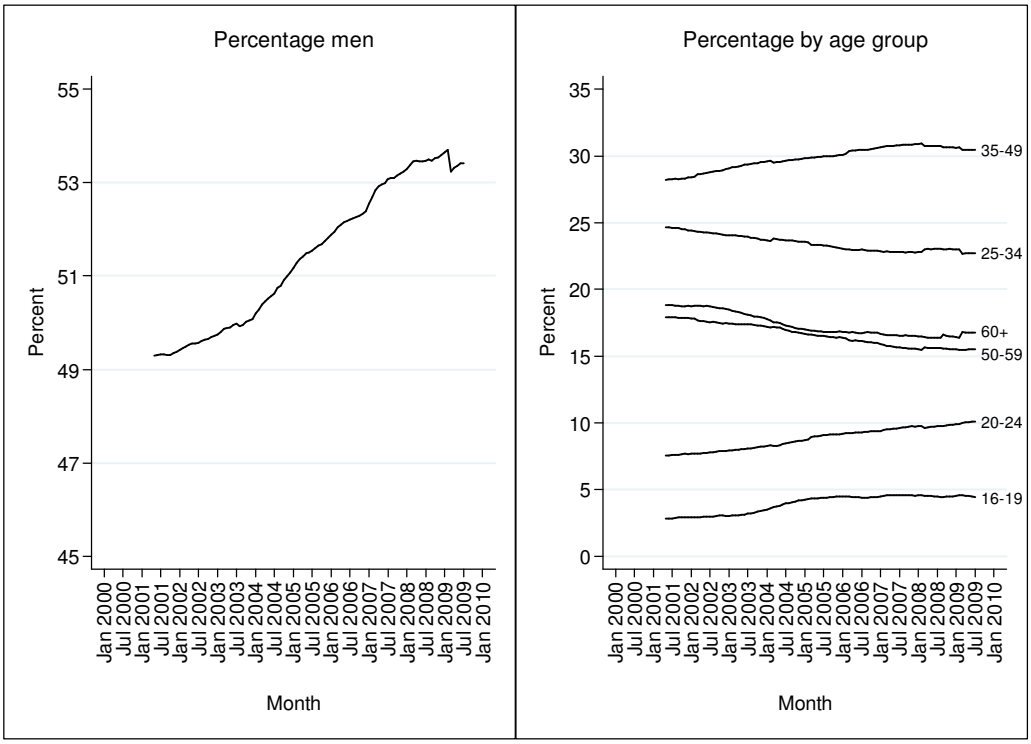


Figure 4.28 Changes in the sex and age group structure of the denominator population over time

Figure 4.29 shows changes over time in the proportion of the denominator from different regions of the UK and in different quintiles of the Townsend Index of Deprivation. There are some changes over time in the regional distribution of THIN patients, most notably a decline in the proportion from the Eastern region, caused by practices entering and leaving THIN as well as individual patients joining and leaving THIN practices. There are only very small changes over time in the proportion of patients in each quintile of the Townsend Index of Deprivation. Again, the relative stability of these variables over time mean these factors are unlikely to act as major confounders when assessing the impact of the introduction of smokefree legislation on a time series.

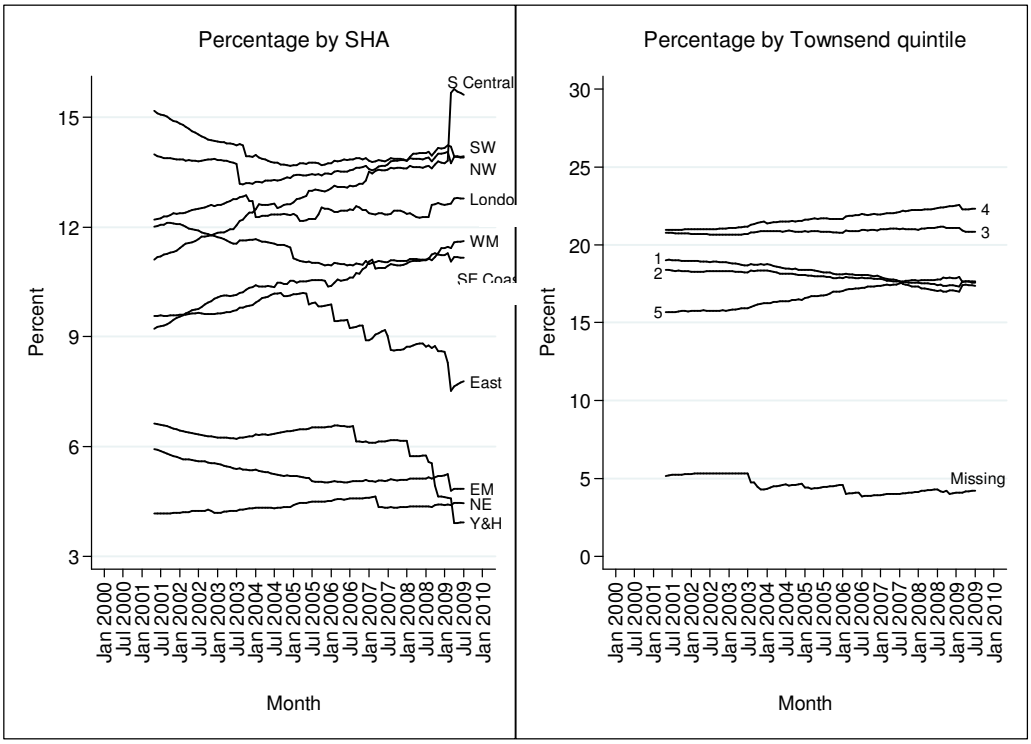


Figure 4.29 Changes in the regional and social class structure of the denominator over time

As discussed in Chapter 2, the recording of patient smoking status has improved over time – fewer patients have no mention of smoking in their medical records, and the proportion of patients recorded as current smokers has approached national estimates of smoking prevalence. Changes in recorded smoking prevalence amongst THIN patients may act as a confounder in any interrupted time series analysis – for example, an increase in the rate of prescribing of NRT may simply be the result of an increase in smoking prevalence amongst the denominator population. In addition, Figure 3.6 showed that prescriptions for smoking cessation medications are also recorded in the notes of patients who are not recorded as current smokers. To assess whether these data recording practices confound the assessment of the impact of smokefree legislation on prescribing, Table 4.9 presents the estimated change in prescribing in June 2007 in all patients, in those recorded as current smokers, and in those not recorded as current smokers.

Table 4.9 The change in NRT prescribing in June 2007 in all patients, and those recorded and not recorded as current smokers

Study population	ARIMA model	Change in prescribing in June 2007	95% CI	Wald p-value
All patients	$(0,1,0)(0,1,1)_{12}$	0.153	0.085 to 0.221	<0.001
Current smokers	$(0,1,0)(0,1,1)_{12}$	0.175	0.111 to 0.240	<0.001
Non-current smokers	$(0,1,0)(0,1,1)_{12}$	0.111	-0.035 to 0.257	0.136

As the estimates for the change in prescribing in June 2007 presented in Table 4.9 show, the estimated magnitude of increase was similar in all patients compared to an analysis restricted to just those patients recorded as current smokers, suggesting changing data recording habits do not confound assessment of the impact of smokefree legislation. There was no significant increase in prescribing in patients not recorded in their notes as current smokers. The direction of effect estimated in non-current smokers suggests there may have been an increase in prescribing in this group, though it failed to reach statistical significance. Application of the power calculation described in Section 4.11 suggests that the ARIMA model was only powered to detect a 20.8% change in prescribing in June 2007 in non-current smokers (an effect of 0.208 in the logged series).

4.12.4. Attribution of changes in a time series to the effect of an intervention

As noted in Section 4.5.5.3, when assessing the impact of an intervention on a time series it is important that the intervention was introduced independently of other changes which may also have an impact on the series. However, the introduction of smokefree legislation in the UK is just one of a raft of tobacco control measures introduced over the last few years. In December 2006 a new smoking-cessation medication, varenicline (Champix), was licensed for use in the UK and made available on NHS prescription, and in July 2007 the National Institute for Health and Clinical Excellence (NICE) published guidelines

recommending the use of varenicline as a clinically effective and cost-effective pharmacotherapy to assist smokers who wish to quit[161]. There is conflicting evidence about the impact of the introduction and subsequent endorsement of varenicline, with studies suggesting both that varenicline prescribing cannibalised that of NRT[162] and conversely that it had no effect on NRT prescribing rates[163]. It is also conceivable that the availability of a new smoking cessation intervention provided a stimulus for increased smoking cessation activity in primary care, prompting health care professionals to offer smokers a prescription for NRT. The magnitude of the increase in prescribing of NRT in June 2007 identified in this chapter may, therefore, be influenced by the impact of the introduction of varenicline.

Perhaps the most significant event to have occurred in primary care during the last decade was the introduction of the QOF, and Chapters 2 and 3 discussed the impact this had on rates of recording of patient smoking status, cessation advice and referral of patients to specialist cessation services. Accounting for the effect of the QOF in an interrupted time series analysis to assess the impact of smokefree legislation is difficult as it is not clear what form of dummy variable could be included in an impact assessment model to represent the increased electronic recording of smoking-related information seen as a result of the policy. Perhaps the best way to remove the effect of the QOF from assessment of the impact of smokefree legislation is to model the time series of data from the post-QOF period only. However, the exclusion of several years' data from the pre-intervention time series seriously affects the ability to identify and model the underlying data-generating process, and in many cases it becomes impossible to fit an ARIMA model to the pre-intervention series and hence to assess the impact of the introduction of an intervention on that series. For this reason, the results presented in the following chapter are based on the analysis of the entire span of available data, though a sensitivity analysis is undertaken to assess the impact of

analysing a shorter time series to account for the potential confounding effect of the QOF when assessing the impact of smokefree legislation on rates of recording of patients' smoking status and the offer of cessation advice and referral to a specialist cessation service.

4.13. CONCLUSIONS

This chapter has outlined the main approaches to interrupted time series analysis, concluding that the framework of the ARIMA model offers the most appropriate means to model the complex time trends and seasonal patterns seen in smoking-related data recorded in THIN. The mathematical basis of the ARIMA model has been described, and a step-by-step guide to identifying and fitting an ARIMA model to assess the impact of an intervention on a time series has been provided.

As noted, this model identification process is a complex, time-consuming procedure, and the development of the 'arimaintervention' command allows several ARIMA models to be estimated and their adequacy to be assessed. In addition, the command allows the analyst to judge whether the selection of different ARIMA models to describe a time series ultimately leads to different conclusions regarding the impact of an intervention on the outcome under investigation.

The sensitivity analyses presented in this chapter show how many of the choices which must be made during the ARIMA modelling process may have an impact on the conclusions reached about the effectiveness of an intervention. Caution is, therefore, warranted when interpreting the results of the growing number of time series analyses presented in the public health literature. It is recommended that, when writing up the results of a time series analysis for publication, the analyst

should consider undertaking and describing the results of similar sensitivity analyses to those presented here to be confident in their conclusions.

The following chapter uses the techniques explained here to assess the impact of smokefree legislation on rates of recording of patients' smoking status and the delivery of smoking cessation interventions in each jurisdiction of the UK, and Chapter 6 assesses whether any effect of smokefree legislation varied between subgroups of the population.

5. DID THE INTRODUCTION OF SMOKEFREE LEGISLATION HAVE AN IMPACT ON THE MANAGEMENT OF SMOKING IN PRIMARY CARE?

5.1. INTRODUCTION

The literature reviewed in Section 1.6 suggests that the introduction of smokefree legislation may increase quitting activity and reduce daily cigarette consumption amongst heavier smokers, though perhaps not translate into reduced population smoking prevalence. There is a lack of research examining the pathways by which the introduction of smokefree legislation might exert an impact on smoking behaviour. Similarly, it is not known whether other tobacco control policies or interventions could, when introduced alongside smokefree legislation, ensure that as many smokers as possible succeed in quitting.

As noted previously, health care professionals working in primary care have at their disposal a range of smoking cessation interventions proven to increase the likelihood of a smoker quitting. The introduction of smokefree legislation may prompt smokers to seek cessation support from primary care, or prompt health care professionals to offer support even if this is not directly solicited by their patients. No studies to date have investigated rates of clinical activity related to smoking cessation in primary care at the time smokefree legislation was introduced. If there was no change in rates of delivery of cessation advice to smokers, prescription of pharmacological cessation aids, or referral of smokers for cessation support, this could suggest opportunities were missed to increase the impact of smoking bans. When smokefree legislation is introduced, simultaneous improvements in the provision of cessation support to smokers through primary

care could be one way of maximising the number of smokers who attempt to quit and who remain permanently abstinent.

This chapter uses the time series methods explained previously to investigate whether there were changes in rates of smoking-related clinical activity in THIN practices that may be associated with the introduction of smokefree legislation. The analysis is in part hypothesis-driven, assessing whether changes in cessation activity comparable with those reported by other authors are evident in THIN. In addition, given the short pre- and post-legislation data collection periods used in several of the studies reviewed in Section 1.6, this chapter utilises the longitudinal nature of the THIN dataset to explore just how long before the introduction of smokefree legislation any changes in clinical activity may become evident, and how long after a law is enacted they may persist.

5.2. METHODS

5.2.1. Extraction of time series from THIN

5.2.1.1. Rates of ascertainment of smoking status

For each month from January 2000 to July 2009 all patients were identified from the THIN dataset who were aged 16 or over and registered with a practice for at least one day of the month. Section 2.4 showed that a majority of new patients registering with a GP will have their smoking status recorded soon after registration, and this may confound assessment of changes in the rate of recording at the time smokefree legislation was introduced. Therefore, patients who registered with a practice within the previous three months were excluded from this analysis. Given that some patients registered or deregistered with a

practice part-way through each month, the combined time all eligible patients spent registered in THIN each month was calculated, measured in person-months.

All records of smoking status, identified by relevant Read Codes (see Appendix 8.2), entered into patients' notes on or after their registration date were extracted from THIN. The number of patients with at least one record of their smoking status documented in their medical notes each month was calculated.

Monthly rates of ascertainment of patients' smoking status were calculated separately for each jurisdiction of the UK, expressed as the number of patients with a record of smoking status in that month per 100,000 person-months.

5.2.1.2. Rates of recording of smoking status interventions

Patients registered in THIN each month from January 2000 to July 2009 were identified as detailed above and current smokers identified as those patients whose most recent smoking status Read Code in their medical records prior to the first day of each month classified them as such. The combined time all current smokers spent registered in THIN each month was calculated, again measured in person-months.

Relevant Read Codes were used to identify current smokers with at least one record of cessation advice or referral to a cessation service in their notes in each month (see Appendices 8.8 and 8.9 for Read Codes). Similarly, Multilex drug codes were used to identify current smokers with one or more prescriptions for NRT, bupropion or varenicline recorded in their notes each month (see Appendix 8.10).

Monthly rates of recording of cessation advice, referral to a cessation service and prescribing of NRT, bupropion, varenicline, or any of these medications, were calculated separately for each jurisdiction of the UK, expressed as the number of smokers with a record of an intervention being given in that month per 100,000 person-months of follow-up time.

5.2.2. ARIMA modelling

The extracted time series were modelled to assess the impact of the introduction of smokefree legislation, following the ARIMA procedure outlined in Chapter 4. First, the time plot and autocorrelation function (ACF) of each series was examined to identify whether differencing was needed to render the series stationary. Then, the 'arimaintervention' command developed for the purposes of this thesis (see Section 4.9.1 and Appendix 8.12) was used to fit a number of different ARIMA models to each series. The output from this command was assessed to choose the particular model from the ARIMA class which most appropriately described the stationary pre-intervention time series.

Dummy variables were included in the interrupted time series models to assess the impact of smokefree legislation on each series, and, as suggested previously, the output of the arimaintervention command was assessed to ensure that any conclusions drawn about the statistical significance of changes to the series were robust to the choice of ARIMA model. Several intervention effects were modelled for each outcome variable, based upon hypotheses generated from the existing literature about the potential changes in smoking–related clinical activity that may be seen in primary care and also to allow exploration of the timing and duration of any changes. These intervention effects are illustrated in Figure 5.1 with respect to the date legislation was introduced in England. Previous research has suggested that the introduction of smokefree legislation in England in July 2007 may have

brought forward to the start of the year quit attempts that would have been made later in 2007[46]. Therefore, a pulse effect was modelled in the first quarter of the year in which smokefree legislation was introduced to assess whether the ban increased smoking-related clinical activity at New Year and national No Smoking Day. Secondly, pulse effects lasting one, two, three, six and nine months before and after the introduction of legislation were modelled to assess whether rates of clinical activity changed before the smoking ban, and if so how long before, as well as how long any changes lasted. Finally, a permanent step change was modelled to assess whether there were abrupt, sustained changes in the outcome measures after the introduction of smokefree legislation.

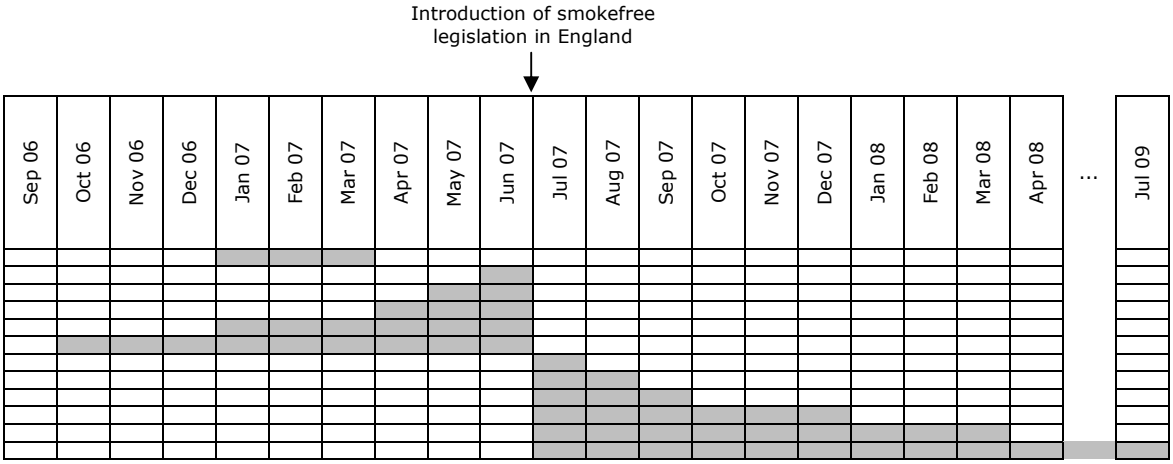


Figure 5.1 Diagram to illustrate intervention effects modelled in the first quarter of the year in which smokefree legislation was introduced, pulses 1, 2, 3, 6, and 9 months before and after legislation, and a permanent step change

To enable the expression of results as more intuitive percentage changes in the original outcome variable, all time series were logged before ARIMA model identification and impact assessment, even if logging was not necessary to stabilise the variance of the data. The estimates of percentage change in the original series are presented alongside their 95% confidence intervals and Wald p-values.

5.2.3. Sensitivity analyses

Section 3.6 showed that some patients have a record of cessation advice, referral to a cessation service, or a prescription for a stop smoking medication in their medical notes even if they are not recorded at that point in time as a current smoker. Though their numbers are small, and the ratio of recording in current to non-current smokers has remained fairly stable over time, the results of time series analysis of rates of recording of smoking cessation interventions in only patients identified as smokers may be biased. Thus, a sensitivity analysis was undertaken modelling the impact of smokefree legislation on rates of recording of advice, referral and prescribing in all patients. The results of this sensitivity analysis are presented in Appendix 8.13 though discussed in the current chapter.

Initially, the time series were modelled using all available data, from January 2000 (or, in the case of medication prescribing, the first month these were made available on NHS prescription) to July 2009. However, Section 4.12.4 considered whether the increased recording of patients' smoking status, cessation advice and referral in the run-up to the introduction of the QOF may confound assessment of the impact of smokefree legislation on the rates of recording of clinical activity in primary care. Analysis of a shorter time series including data from April 2004 only was proposed as a means to remove any confounding effect of the QOF.
Therefore, the time series of rates of recording of patients' smoking status, cessation advice and referral were additionally modelled using only data recorded from April 2004 onwards. These results are presented in Appendix 8.14.

5.3. RESULTS

5.3.1. Ascertainment of patients' smoking status

Figure 5.2 shows monthly rates of recording of smoking status in THIN in each of the four jurisdictions of the UK. Vertical lines indicate the data collected in the month immediately after the introduction of smokefree legislation (July 2007 in England, April 2006 in Scotland, April 2007 in Wales and May 2007 in Northern Ireland).

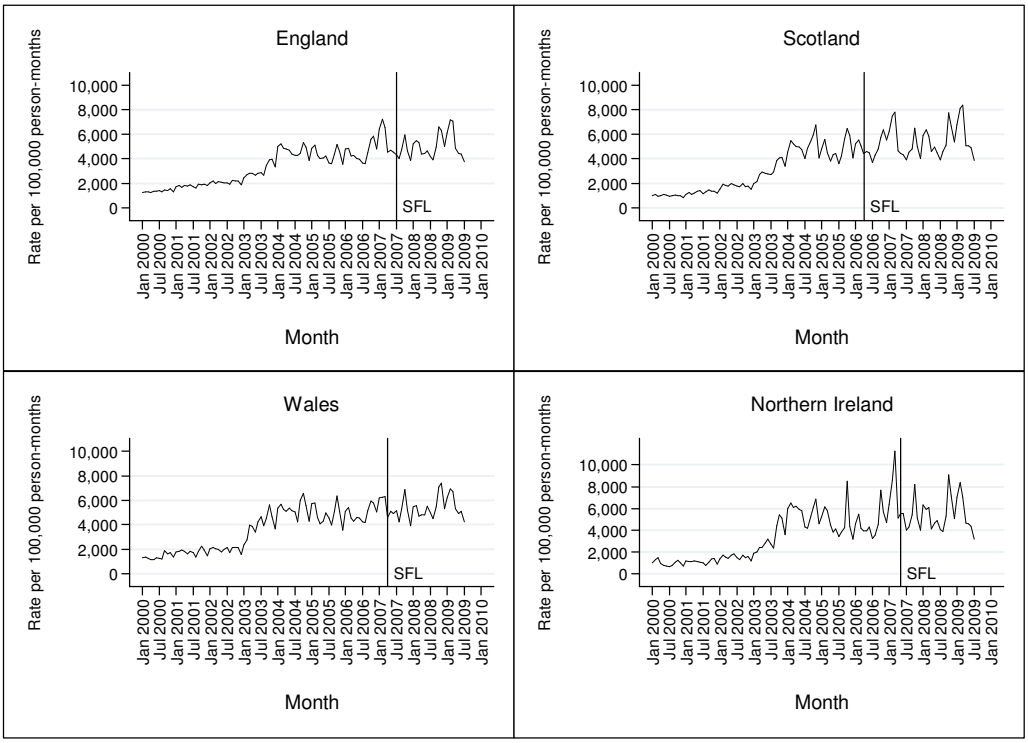


Figure 5.2 Rates of recording of patients' smoking status in THIN (vertical line indicates the introduction of smokefree legislation - SFL)

In all countries rates of recording are initially low, increasing only slightly between January 2000 and the end of 2002. The rate of recording begins to increase more rapidly at the start of 2003, and this faster improvement is sustained to the end of 2003 when all series reach a plateau. There is variation in the rate of recording from one month to the next in each country, though it is hard to tell whether this

variation forms a regular seasonal pattern. The magnitude of the monthly variation is similar in England, Scotland and Wales, though the month-to-month variation in Northern Ireland is much larger. Given this monthly variation it is difficult to judge visually whether there are any changes in the rate of recording around the introduction of smokefree legislation outside of the normal behaviour of the series.

Table 5.1 shows the results of the ARIMA modelling assessing the impact of the introduction of smokefree legislation on monthly rates of recording of smoking status, expressed as percentage changes in each of the time periods studied. Figures in bold print highlight statistically significant results, a convention which will be used in all tables of results presented from this point forward.

Table 5.1 Time series analysis of changes in recording of patient smoking status

	England			**Scotland**		
Intervention effect	Estimate (%)	95% CI (%)	P-value	Estimate (%)	95% CI (%)	P-value
Q1 of SFL year	4.3	-12.4 to 21.0	0.611	0.9	-16.5 to 18.3	0.920
1 month before	-0.5	-36.3 to 35.3	0.978	7.2	-31.3 to 45.7	0.714
2 months before	1.8	-15.2 to 18.8	0.836	1.0	-18.8 to 20.7	0.925
3 months before	**-9.4**	**-5.3 to -13.6**	**<0.001**	0.9	-16.5 to 18.3	0.920
6 months before	-2.5	-7.4 to 2.3	0.305	1.9	-6.9 to 10.6	0.677
9 months before	0.0	-4.9 to 4.9	0.990	1.3	-6.3 to 8.9	0.741
1 month after	-0.8	-34.5 to 33.0	0.965	**-24.8**	**-14.5 to -35.1**	**<0.001**
2 months after	-2.8	-24.4 to 18.8	0.798	**-13.6**	**-1.3 to -25.9**	**0.030**
3 months after	-1.7	-21.0 to 17.6	0.863	-9.7	-22.9 to 3.5	0.148
6 months after	-2.1	-7.7 to 3.4	0.448	-6.9	-19.4 to 5.6	0.281
9 months after	-0.6	-5.4 to 4.3	0.824	-0.9	-7.6 to 5.9	0.799
Step change	-0.8	-3.3 to 1.7	0.525	-0.6	-3.1 to 1.8	0.617

	Wales			**Northern Ireland**		
Intervention effect	Estimate (%)	95% CI (%)	P-value	Estimate (%)	95% CI (%)	P-value
Q1 of SFL year	-4.4	-16.3 to 7.5	0.469	2.8	-7.8 to 13.4	0.603
1 month before	0.1	-20.0 to 20.3	0.989	**-39.1**	**-17.7 to -60.4**	**<0.001**
2 months before	-0.6	-18.2 to 17.0	0.945	**-14.7**	**-3.6 to -25.7**	**0.009**
3 months before	-4.4	-16.3 to 7.5	0.469	-8.1	-16.9 to 0.6	0.069
6 months before	1.1	-6.0 to 8.1	0.769	-3.0	-10.4 to 4.4	0.425
9 months before	0.0	-5.9 to 5.9	0.997	-0.7	-8.8 to 7.4	0.865
1 month after	**-12.3**	**-2.0 to -22.6**	**0.019**	-5.3	-72.7 to 62.1	0.877
2 months after	-5.1	-12.8 to 2.7	0.198	-5.1	-48.6 to 38.5	0.819
3 months after	-4.8	-11.9 to 2.4	0.193	-4.5	-33.0 to 23.9	0.754
6 months after	-4.4	-10.7 to 1.8	0.165	-1.5	-20.3 to 17.2	0.873
9 months after	-2.4	-7.4 to 2.7	0.358	-1.8	-13.7 to 10.2	0.769
Step change	-1.5	-4.2 to 1.2	0.280	-1.5	-6.8 to 3.9	0.586

The results shown in Table 5.1 suggest there was no significant change in the rate of recording of smoking status in any country of the UK in the first quarter of the year in which smokefree legislation was introduced, nor was there an abrupt post-legislation change in the rate sustained to July 2009, the end of the study period. All four countries do, however, show significant short-lived reductions in the rate of recording either before or after the introduction of smokefree legislation, with no significant changes being detected which lasted more than three months.

5.3.2. Recording of cessation advice

Figure 5.3 shows monthly rates of recording of cessation advice amongst current smokers in THIN in each of the four jurisdictions of the UK. The time series show a similar pattern to those depicting rates of recording of smoking status; rates of advice recording are initially low, followed by a period of relatively rapid increase in 2003 and a levelling off from the start of 2004.

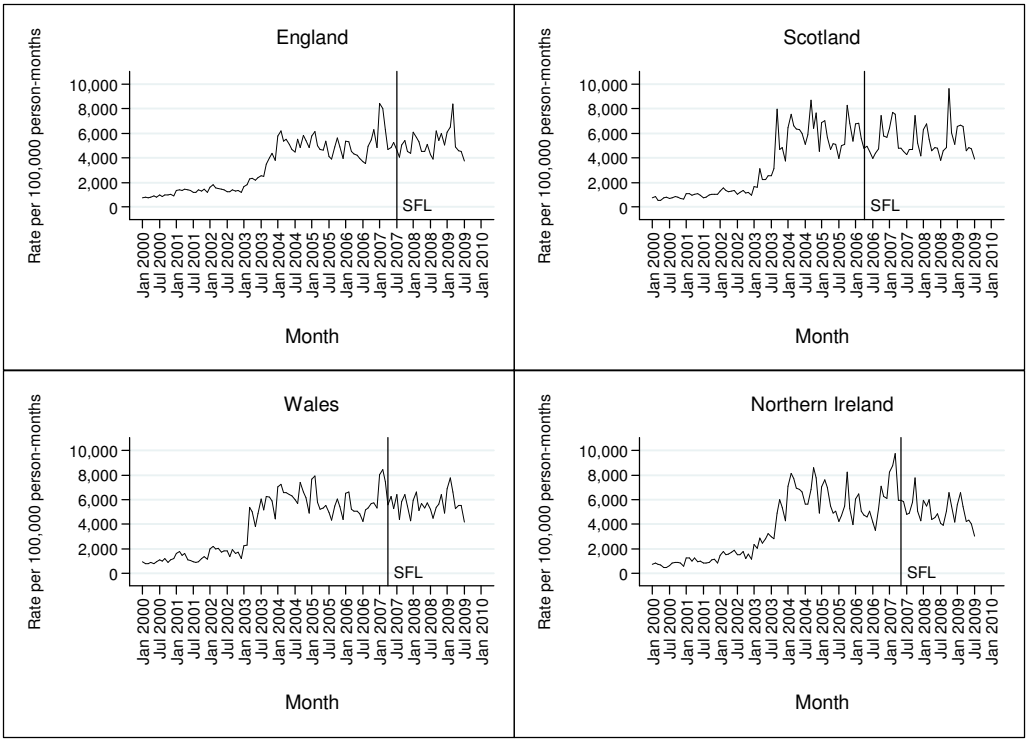


Figure 5.3 Rates of recording of cessation advice in current smokers in THIN

Again there is variation in the rate of recording from one month to the next in each country, with the largest magnitude of variation seen in Northern Ireland and the smallest in England. There appear to be peaks in the recording of advice in England, Wales and Northern Ireland at the start of 2007, a few months before the introduction of smokefree legislation, though again it is difficult to judge visually whether these peaks are outside of the normal behaviour of the series.

Table 5.2 shows the results of the ARIMA modelling assessing the impact of the introduction of smokefree legislation on monthly rates of recording of cessation advice amongst current smokers in THIN.

Table 5.2 Time series analysis of changes in recording of cessation advice delivered to smokers

	England			Scotland		
Intervention effect	Estimate (%)	95% CI (%)	P-value	Estimate (%)	95% CI (%)	P-value
Q1 of SFL year	0.2	-8.8 to 9.3	0.960	-5.2	-37.8 to 27.3	0.752
1 month before	6.6	-59.7 to 72.9	0.846	-9.0	-81.5 to 63.4	0.807
2 months before	4.8	-41.6 to 51.1	0.840	-7.3	-48.5 to 33.9	0.727
3 months before	-7.0	-17.3 to 3.4	0.188	-5.2	-37.8 to 27.3	0.752
6 months before	-3.1	-8.9 to 2.8	0.301	-0.1	-12.1 to 11.9	0.987
9 months before	-1.5	-8.1 to 5.1	0.660	-0.1	-7.9 to 7.6	0.979
1 month after	-6.9	-110.7 to 96.8	0.896	7.3	-28.1 to 42.6	0.687
2 months after	-8.7	-69.0 to 51.5	0.776	2.7	-27.3 to 32.7	0.862
3 months after	-1.8	-18.8 to 15.1	0.834	0.5	-25.9 to 26.9	0.970
6 months after	-2.5	-11.7 to 6.7	0.588	0.5	-21.4 to 22.5	0.963
9 months after	-0.7	-7.9 to 6.6	0.859	2.0	-10.7 to 14.6	0.763
Step change	-1.4	-4.4 to 1.5	0.338	0.4	-8.8 to 9.6	0.933

	Wales			Northern Ireland		
Intervention effect	Estimate (%)	95% CI (%)	P-value	Estimate (%)	95% CI (%)	P-value
Q1 of SFL year	3.4	-47.1 to 54.0	0.895	-2.0	-16.6 to 12.5	0.785
1 month before	9.7	-79.5 to 98.9	0.831	-23	-66.1 to 20.1	0.296
2 months before	7.0	-58.7 to 72.7	0.835	-6.1	-18.9 to 6.7	0.350
3 months before	3.4	-47.1 to 54.0	0.895	-4.5	-15.3 to 6.3	0.414
6 months before	4.7	-31.0 to 40.3	0.797	-1.6	-9.7 to 6.6	0.704
9 months before	3.6	-11.4 to 18.6	0.641	-0.8	-7.8 to 6.2	0.828
1 month after	-8.2	-44.4 to 27.9	0.655	-2.7	-85.4 to 80.1	0.949
2 months after	-2.0	-28.2 to 24.3	0.884	-3.4	-58.0 to 51.3	0.904
3 months after	-3.4	-26.3 to 19.5	0.770	-3.4	-47.8 to 41.0	0.880
6 months after	-2.1	-13.8 to 9.7	0.730	-2.8	-27.7 to 22.1	0.826
9 months after	-2.9	-14.3 to 8.4	0.611	-4.3	-19.7 to 11.2	0.589
Step change	-1.4	-8.4 to 5.6	0.687	-1.7	-8.4 to 5.0	0.617

Table 5.2 shows no significant changes in the rate of recording of cessation advice in current smokers in any of the intervention periods in any jurisdiction of the UK.

5.3.3. Recording of referral to stop smoking services

Figure 5.4 shows monthly rates of recording of referral to stop smoking services amongst current smokers in THIN. Rates of recording of referrals are much lower than those of recording of cessation advice, though, as discussed in Chapter 3, it is impossible to be sure whether all referrals are recorded in patients' notes. In England the rate of recording of referral of smokers to stop smoking services shows a similar pattern to that of recording of smoking status and cessation advice. In Scotland and Wales, rates of recording of referral are higher at the start of the series than in England, but in Northern Ireland almost no smokers have a referral to a stop smoking service recorded before 2006.

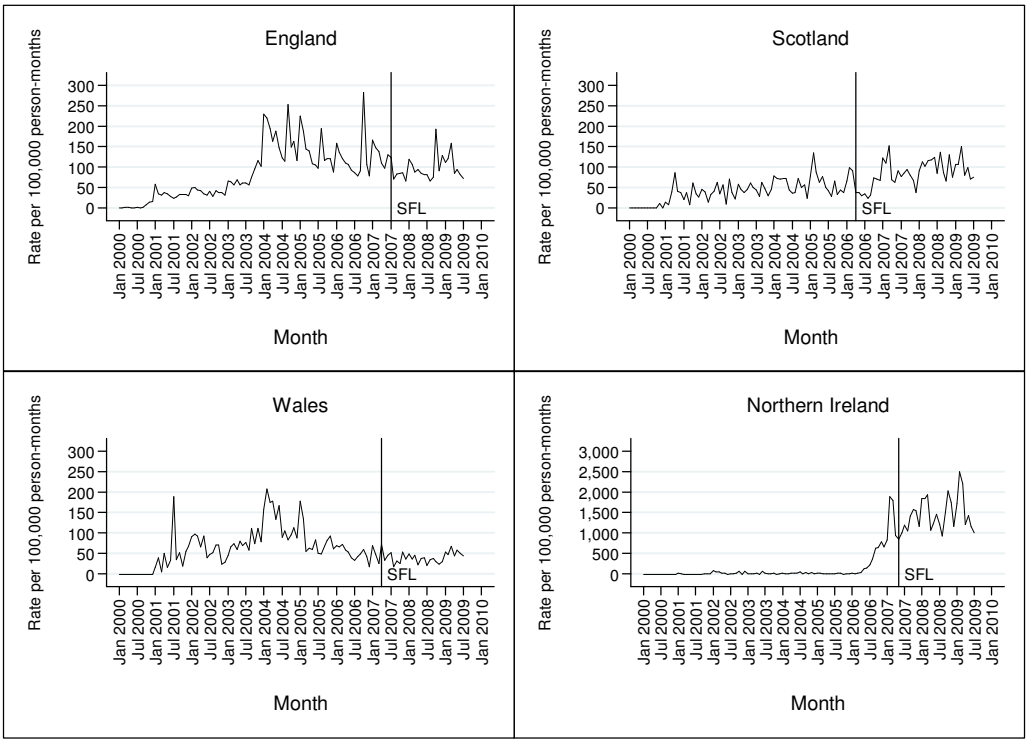


Figure 5.4 Rates of recording of referral to stop smoking services amongst current smokers in THIN

It should be noted that rates of recording of referral in Northern Ireland are approximately ten times higher than those in the other three countries and the series have been drawn on different scales so that the monthly variation in each

country can still be seen clearly. The absence of referrals in Northern Ireland in the period before the introduction of smokefree legislation means there are not enough monthly data points with which to fit an ARIMA model. Therefore, modelling the impact of smokefree legislation on this outcome variable will only be carried out for England, Scotland and Wales. Possible reasons for the pattern of recording of referral in Northern Ireland will be considered in the discussion.

In England, Scotland and Wales there is substantial monthly variation in the rate of recording of referral, with no clear seasonal patterns. There are no obvious changes in the series which may be attributable to the effect of smokefree legislation, though again it is difficult to tell given the high degree of variability in the data.

Table 5.3 shows the results of the ARIMA modelling assessing the impact of the introduction of smokefree legislation on monthly rates of referral to stop smoking services amongst current smokers in THIN.

As with the recording of cessation advice, Table 5.3 shows no significant changes in the rate of recording of referral to stop smoking services amongst current smokers in any of the intervention periods.

Table 5.3 Time series analysis of changes in recording of smokers referred to stop smoking services

	England			Scotland		
Intervention effect	Estimate (%)	95% CI (%)	P-value	Estimate (%)	95% CI (%)	P-value
Q1 of SFL year	1.4	-177.3 to 180.0	0.988	5.4	-89.1 to 100.0	0.910
1 month before	19.9	-215.5 to 255.4	0.868	-14.7	-127.2 to 97.9	0.798
2 months before	8.3	-105.2 to 121.7	0.887	3.2	-103.9 to 110.3	0.953
3 months before	2.5	-67.7 to 72.7	0.944	5.4	-89.1 to 100.0	0.910
6 months before	1.7	-55.4 to 58.8	0.954	-2.0	-46.7 to 42.7	0.930
9 months before	0.4	-24.8 to 25.5	0.978	-3.4	-32.9 to 26.1	0.822
1 month after	-7.9	-178.8 to 163.0	0.928	-55.6	-233.2 to 121.9	0.539
2 months after	-22.7	-107.7 to 62.4	0.602	-31.5	-126.9 to 63.9	0.517
3 months after	-17.4	-88.2 to 53.5	0.631	-21.6	-89.9 to 46.8	0.537
6 months after	-11.1	-55.8 to 33.6	0.626	-8.1	-53.8 to 37.5	0.728
9 months after	-6.9	-45.3 to 31.5	0.726	6.2	-18.1 to 30.5	0.617
Step change	-3.4	-22.4 to 15.6	0.729	0.6	-18.3 to 19.6	0.947

	Wales		
Intervention effect	Estimate (%)	95% CI (%)	P-value
Q1 of SFL year	0.5	-24.8 to 25.8	0.972
1 month before	-17.1	-81.2 to 47.1	0.602
2 months before	-7.6	-44.5 to 29.4	0.689
3 months before	0.5	-24.8 to 25.8	0.972
6 months before	-3.2	-16.2 to 9.9	0.633
9 months before	-2.8	-13.3 to 7.7	0.599
1 month after	19.4	-56.0 to 94.8	0.615
2 months after	-1.4	-46.2 to 43.4	0.951
3 months after	-2.4	-35.1 to 30.3	0.886
6 months after	-4.3	-20.5 to 12.0	0.606
9 months after	-1.1	-14.1 to 11.9	0.864
Step change	0.7	-7.7 to 9.0	0.876

5.3.4. Prescribing of smoking cessation medications

5.3.4.1. Nicotine replacement therapy

Figure 5.5 shows monthly rates of prescribing of NRT to current smokers in THIN. All four countries show a similar pattern of a slightly increasing trend in prescribing in the first half of the time period followed by a decreasing trend in the second half of the series. All series display a similar, regular seasonal pattern, with peaks in prescribing in the first three months of the year and troughs in the summer months. The lowest rates of prescribing are seen in England, though here the magnitude of variation in the series from one month to the next is smaller than in the other three countries. The rate of prescribing in Scotland and Wales, and the magnitude of the monthly variation, is slightly higher than in England.

Northern Ireland appears to have the highest rates of prescribing, but this series is also the most variable.

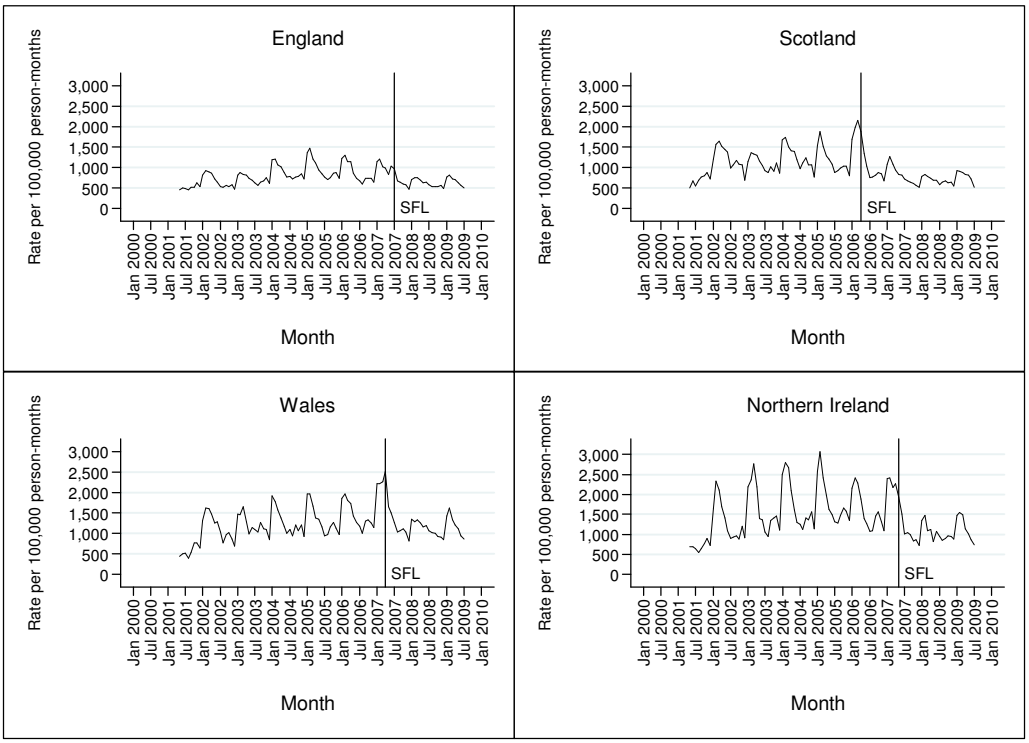


Figure 5.5 Rates of prescribing of NRT to current smokers in THIN

Table 5.4 shows the results of the ARIMA modelling assessing the impact of the introduction of smokefree legislation on monthly rates of prescribing of NRT to current smokers in THIN.

There was no significant change in the rate of prescribing of NRT in any country of the UK in the first quarter of the year in which smokefree legislation was introduced, nor was there an abrupt post-legislation change in the rate which was sustained to the end of the study period.

Table 5.4 Time series analysis of changes in prescribing of NRT

	England			Scotland		
Intervention effect	Estimate (%)	95% CI (%)	P-value	Estimate (%)	95% CI (%)	P-value
Q1 of SFL year	-2.7	-10.1 to 4.7	0.474	-1.8	-9.8 to 6.1	0.654
1 month before	**17.5**	**11.1 to 24.0**	**<0.001**	9.6	-5.6 to 24.8	0.215
2 months before	**13.6**	**8.1 to 19.1**	**<0.001**	10.8	-3.5 to 25.0	0.139
3 months before	**10.4**	**5.0 to 15.7**	**<0.001**	-1.8	-9.8 to 6.1	0.654
6 months before	**6.2**	**1.4 to 11.0**	**0.012**	6.3	-2.9 to 15.4	0.178
9 months before	4.0	-1.3 to 9.3	0.135	2.4	-5.6 to 10.4	0.558
1 month after	-1.1	-32.2 to 30.0	0.945	-1.3	-49.6 to 47.0	0.957
2 months after	**-6.9**	**-0.3 to -13.4**	**0.040**	-6.1	-16.9 to 4.6	0.265
3 months after	**-9.0**	**-3.9 to -14.2**	**0.001**	-5.5	-14.2 to 3.1	0.208
6 months after	**-6.7**	**-2.1 to -11.2**	**0.004**	-5.7	-12.3 to 0.9	0.091
9 months after	**-5.5**	**-2.3 to -8.7**	**0.001**	-3.0	-8.2 to 2.3	0.268
Step change	-1.7	-4.4 to 1.0	0.229	1.8	-1.7 to 5.3	0.313

	Wales			Northern Ireland		
Intervention effect	Estimate (%)	95% CI (%)	P-value	Estimate (%)	95% CI (%)	P-value
Q1 of SFL year	-4.2	-17.4 to 9.0	0.536	0.0	-14.1 to 14.0	0.996
1 month before	4.5	-25.3 to 34.4	0.767	21.4	-1.7 to 44.4	0.070
2 months before	1.7	-18.6 to 21.9	0.873	8.2	-3.2 to 19.6	0.161
3 months before	-4.2	-17.4 to 9.0	0.536	4.0	-7.1 to 15.2	0.478
6 months before	-1.3	-13.0 to 10.4	0.824	-2.9	-9.1 to 3.3	0.356
9 months before	-3.0	-12.1 to 6.1	0.521	-0.3	-6.3 to 5.6	0.912
1 month after	13.0	-9.9 to 35.9	0.267	21.3	-3.3 to 46.0	0.090
2 months after	3.1	-5.3 to 11.4	0.471	**14.9**	**6.1 to 23.7**	**0.001**
3 months after	1.9	-6.1 to 9.9	0.647	**8.1**	**1.6 to 14.6**	**0.015**
6 months after	-3.5	-10.3 to 3.2	0.307	**-6.1**	**-0.6 to -11.6**	**0.029**
9 months after	-2.8	-9.2 to 3.7	0.403	-3.7	-8.3 to 0.9	0.113
Step change	-1.1	-4.4 to 2.2	0.512	-0.5	-2.8 to 1.8	0.676

In England, statistically significant increases in the rate of prescribing of NRT are seen up to six months before the introduction of smokefree legislation. Whilst there was no significant change in prescribing in the first month after the smoking ban was enacted, significant declines in prescribing were estimated for the two month to nine month periods post-legislation. However, the reduced rate of prescribing was not sustained to the end of the study period.

In Northern Ireland a significant increase in the rate of NRT prescribing was seen in the two and three month periods post-legislation, converting to a decline in the six month post-ban period, though no significant changes in the rate of prescribing were detected in Scotland or Wales. However, in many of the intervention periods where non-significant changes in prescribing were detected, the direction of the point estimates support the apparent pattern of an increase in

prescribing followed by a decrease, with the turning point being at, or close to, the time when smokefree legislation was introduced.

5.3.4.2. Bupropion

Figure 5.6 shows monthly rates of prescribing of bupropion to current smokers in THIN. Bupropion was first made available on NHS prescription in June 2000 and the number of prescriptions issued to patients in THIN increased rapidly. However, on 18 February 2001 the Mail on Sunday reported the deaths of 18 smokers after they had taken the drug, as well as a number of potential side-effects, including chest pain, seizures and depression[164]. Almost immediately after this article was published rates of prescribing in THIN plummeted and have not recovered.

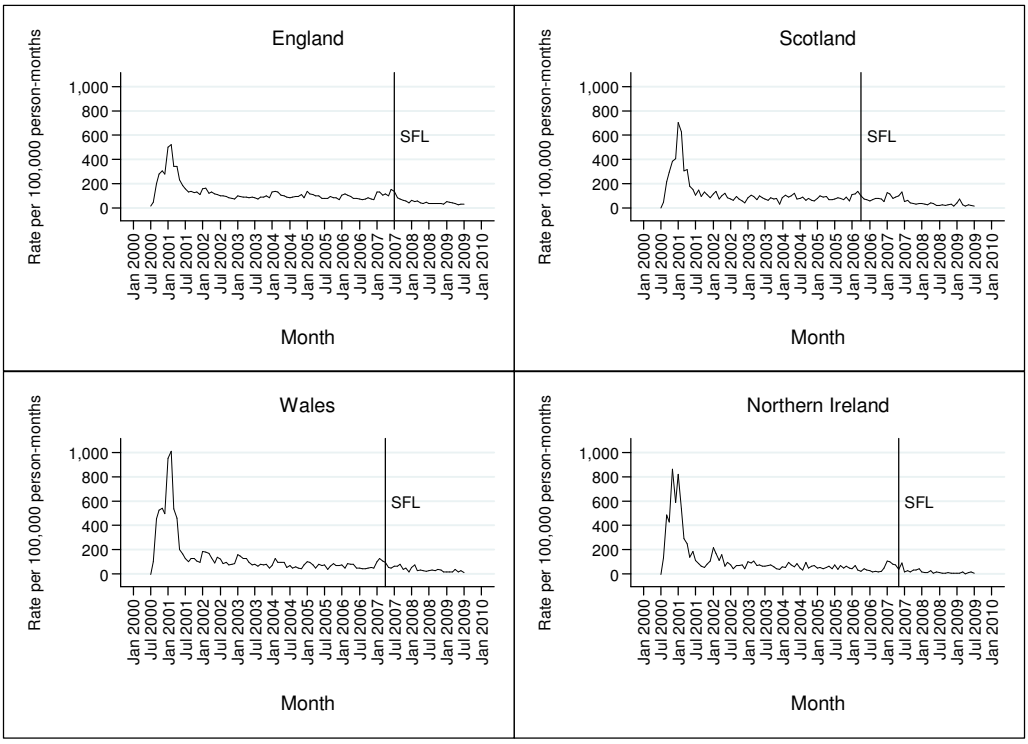


Figure 5.6 Rates of prescribing of bupropion to current smokers in THIN

The peak in bupropion prescribing in each country at the start of the time period is arguably an outlier when compared to prescribing rates in the remainder of the series, and as such the ARIMA modelling procedure must take account of this

anomaly. The outliers could be modelled by including a dummy variable in the ARIMA model, taking the value one for anomalous time points, and zero for all other months. However, it is not immediately clear how many months should be classed as anomalous time points. An alternative approach is to drop the first two years of data, modelling data from January 2002 onwards. This still leaves five years of observations (four in Scotland) with which to estimate the parameters of the ARIMA model which best represents the pre-intervention data, enough to take into account any underlying trend and seasonal pattern.

Figure 5.7 illustrates the bupropion prescribing series from January 2002 onwards, with an enlarged scale on the y-axis allowing the monthly variation in the data to be observed. In England there seems to be a regular seasonal pattern in rates of prescribing of bupropion, again with peaks at the start of each year and troughs in the summer months. The presence of any seasonal pattern in Scotland, Wales and Northern Ireland is less obvious. In all four countries there appear to be increased rates of prescribing of bupropion just before the introduction of smokefree legislation, though, given the variability in the data, it is hard to tell whether the apparent increased prescribing is outside of the normal behaviour of the series.

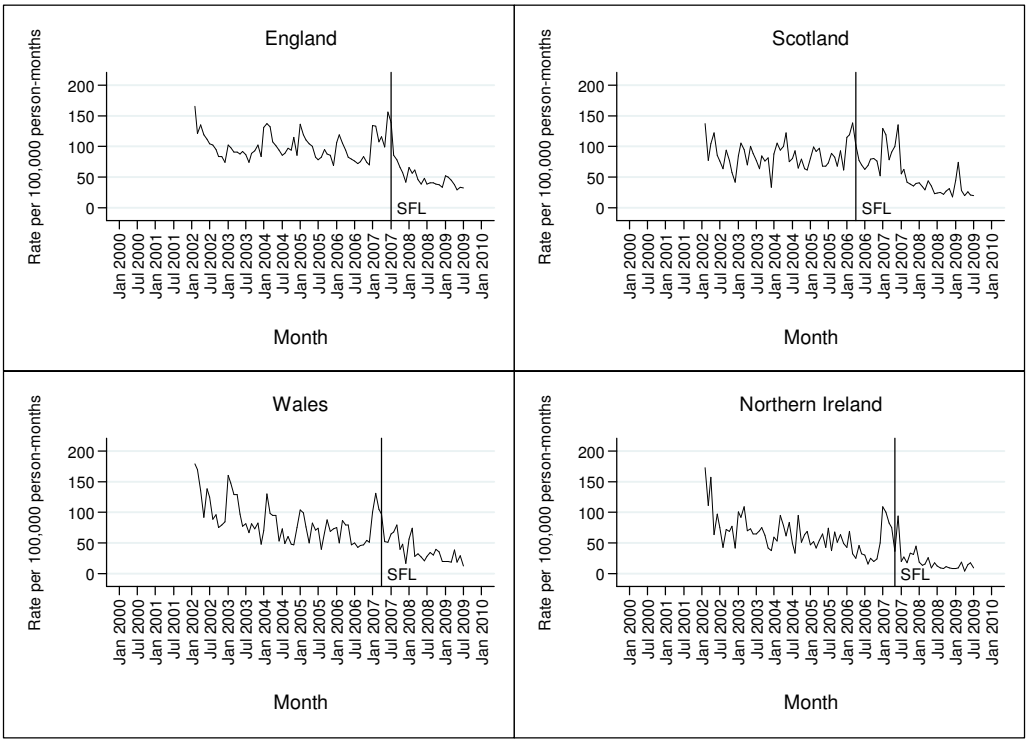


Figure 5.7 Rates of prescribing of bupropion to current smokers in THIN (from January 2002 onwards)

Table 5.5 shows the results of the ARIMA modelling assessing the impact of the introduction of smokefree legislation on monthly rates of prescribing of bupropion in current smokers in THIN, using data from January 2002 onwards.

The patterns in prescribing of bupropion are very similar to those seen in NRT prescribing. In all countries there was no significant change in the rate of prescribing of bupropion in the first quarter of the year in which smokefree legislation was introduced, nor was there an abrupt post-legislation change in the rate which was sustained to the end of the study period.

Table 5.5 Time series analysis of changes in prescribing of bupropion

	England			Scotland		
Intervention effect	Estimate (%)	95% CI (%)	P-value	Estimate (%)	95% CI (%)	P-value
Q1 of SFL year	1.7	-12.9 to 16.2	0.822	11.7	-17.4 to 40.9	0.431
1 month before	**44.7**	**20.4 to 69.0**	**<0.001**	16.5	-52.2 to 85.1	0.639
2 months before	**18.9**	**9.2 to 28.6**	**<0.001**	8.3	-32.9 to 49.6	0.693
3 months before	**13.2**	**4.3 to 22.2**	**0.004**	11.7	-17.4 to 40.9	0.431
6 months before	7.1	-0.4 to 14.5	0.062	5.0	-8.8 to 18.7	0.479
9 months before	5.2	-1.8 to 12.3	0.147	4.6	-8.1 to 17.3	0.474
1 month after	-6.8	-40.1 to 26.6	0.691	-34.0	-253.5 to 185.6	0.762
2 months after	**-25.3**	**-4.9 to -45.7**	**0.015**	-27.6	-186.6 to 131.4	0.734
3 months after	**-21.1**	**-2.1 to -40.1**	**0.029**	-22.2	-107.3 to 62.8	0.609
6 months after	**-19.7**	**-5.5 to -34.0**	**0.007**	-5.1	-38.8 to 28.5	0.765
9 months after	**-13.7**	**-4.6 to -22.8**	**0.003**	-4.7	-32.0 to 22.6	0.735
Step change	-3.5	-8.8 to 1.9	0.206	-4.5	-13.6 to 4.5	0.327

	Wales			Northern Ireland		
Intervention effect	Estimate (%)	95% CI (%)	P-value	Estimate (%)	95% CI (%)	P-value
Q1 of SFL year	**20.4**	**1.8 to 39.0**	**0.032**	**28.7**	**0.5 to 56.8**	**0.046**
1 month before	7.6	-59.4 to 74.6	0.825	-45.9	-142.1 to 50.3	0.350
2 months before	17.7	-12.2 to 47.7	0.246	-25.7	-109.7 to 58.4	0.550
3 months before	**20.4**	**1.8 to 39.0**	**0.032**	-2.8	-42.4 to 36.9	0.891
6 months before	**13.9**	**3.1 to 24.6**	**0.011**	**21.8**	**8.9 to 34.8**	**0.001**
9 months before	6.2	-0.8 to 13.1	0.083	10.9	-2.8 to 24.5	0.120
1 month after	-5.6	-61.7 to 50.5	0.845	-37.7	-107.1 to 31.7	0.287
2 months after	-10.5	-48.7 to 27.7	0.590	-12.2	-38.7 to 14.3	0.366
3 months after	-7.6	-34.2 to 19.0	0.575	**-29.8**	**-9.6 to -49.9**	**0.004**
6 months after	-6.7	-16.7 to 34	0.192	-14.9	-32.1 to 2.3	0.090
9 months after	**-8.0**	**-13.4 to -2.6**	**0.003**	-13.0	-27.7 to 1.6	0.082
Step change	-6.9	-14.7 to 0.8	0.078	-6.4	-15.8 to 3.0	0.181

In England, statistically significant increases in the rate of prescribing of bupropion are seen up to three months before the introduction of smokefree legislation. Again there was no significant change in prescribing of bupropion in the first month after the smoking ban was enacted, though significant declines in prescribing were estimated for the two month to nine month periods post-legislation.

Some significant changes in bupropion prescribing were detected in Wales and Northern Ireland, corresponding to the patterns seen in England of increased prescribing before the smoking ban was enacted and reduced prescribing afterwards. The direction of the non-significant point estimates in Scotland also supports this pattern.

5.3.4.3. Varenicline

Figure 5.8 shows monthly rates of prescribing of varenicline to current smokers in THIN. Varenicline was first made available on NHS prescription in December 2006, and in July 2007 the National Institute of Health and Clinical Excellence (NICE) issued guidelines recommending GPs prescribe the drug to smokers who wish to quit. As was seen when bupropion first became available, rates of prescribing of varenicline increased rapidly soon after its introduction, reaching a similar rate of prescribing as bupropion within just a few months. Prescribing of varenicline does not, however, show the slump seen in rates of prescribing of bupropion. Unfortunately, the timing of the introduction of varenicline means there are not enough data from the pre-smokefree period to model the impact of the introduction of smokefree legislation on rates of prescribing of this medication.

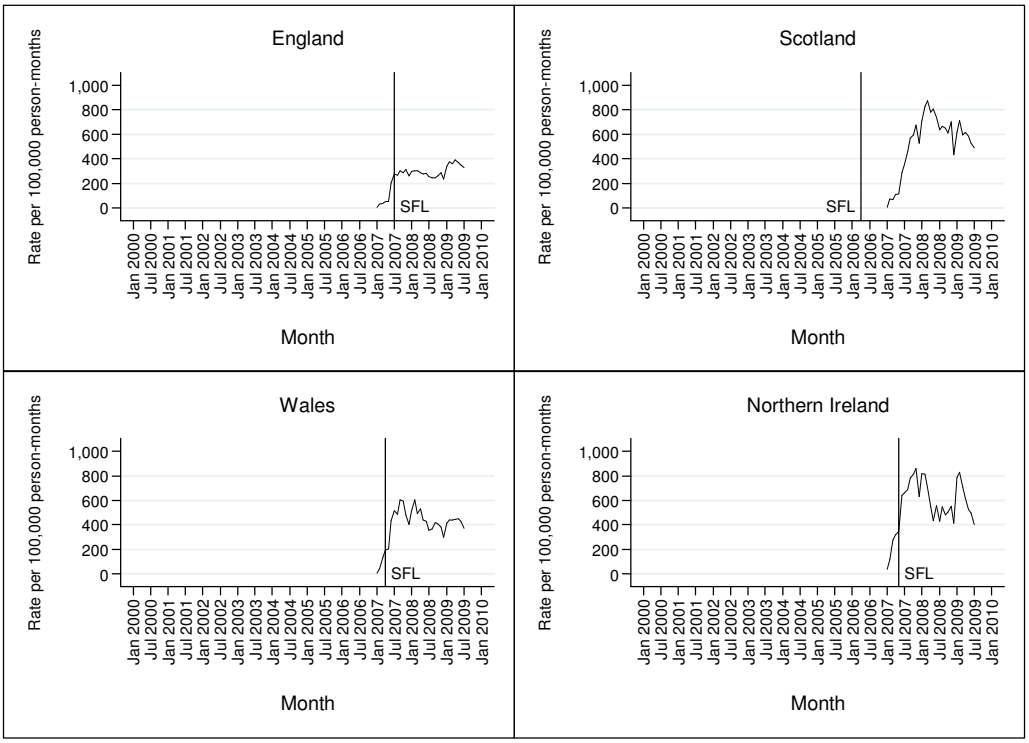


Figure 5.8 Rates of prescribing of varenicline to current smokers in THIN

5.3.4.4. All smoking cessation medications

Figure 5.9 shows monthly rates of prescribing of all smoking cessation medications (NRT, bupropion and varenicline) to current smokers in THIN in each of the four jurisdictions of the UK. The majority of this prescribing is NRT and therefore the patterns of prescribing of all medication are very similar to those of NRT discussed earlier.

All four countries show a similar pattern of a slightly increasing trend in prescribing in the first half of the time period followed by a decreasing trend in the second half of the series. All series display a similar, regular seasonal pattern, with peaks in prescribing in the first three months of the year and troughs in the summer months. The lowest rates of prescribing are seen in England, though here the magnitude of variation in the series from one month to the next is smaller than in the other three countries. The rate of prescribing in Scotland and Wales, and the magnitude of the monthly variation, is slightly higher than in England. Northern Ireland appears to have the highest rates of prescribing, but this series is also the most variable.

In England and perhaps Northern Ireland there appear to be increases in the rate of prescribing of all smoking cessation medications in the months immediately before the introduction of smokefree legislation which are not seen in other years. Again, however, it is difficult to judge whether these changes are outside of the normal behaviour of the series.

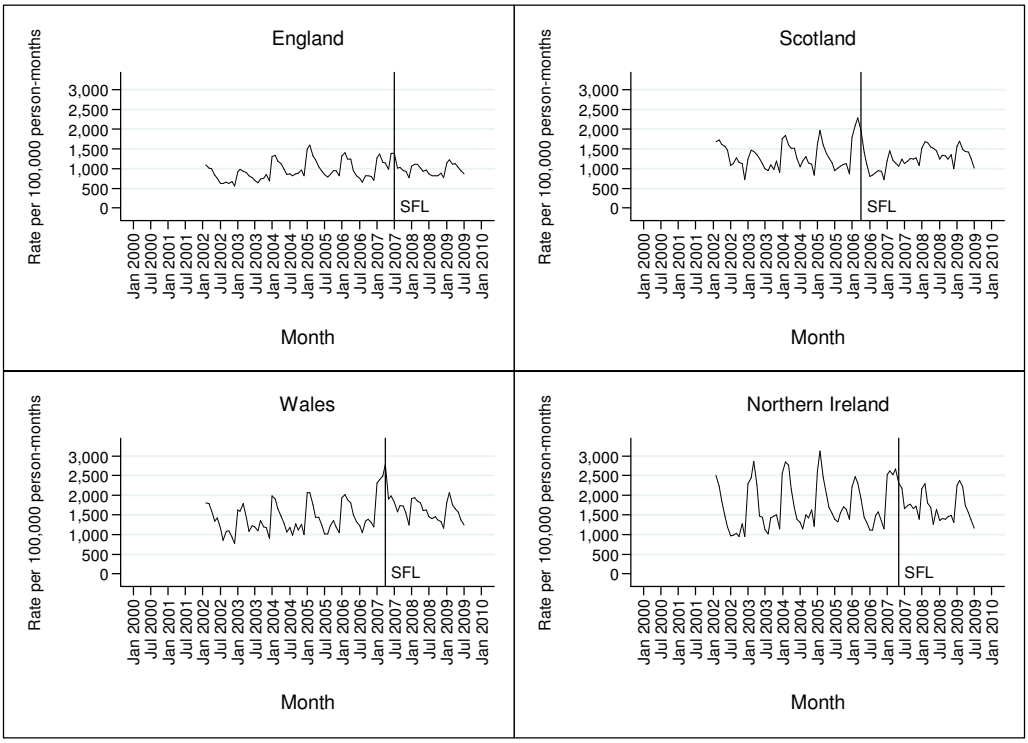


Figure 5.9 Rates of prescribing of all smoking cessation medications to current smokers in THIN

Table 5.6 shows the results of the ARIMA modelling assessing the impact of the introduction of smokefree legislation on monthly rates of prescribing of all smoking cessation medications to current smokers in THIN. The changes are estimated using data from January 2002 onwards to remove the peak in prescribing attributable to bupropion when this medication first became available on NHS prescription.

Table 5.6 Time series analysis of changes in prescribing of all smoking cessation medications

	England			Scotland		
Intervention effect	Estimate (%)	95% CI (%)	P-value	Estimate (%)	95% CI (%)	P-value
Q1 of SFL year	2.0	-18.6 to 22.7	0.847	6.0	-3.7 to 15.8	0.224
1 month before	**22.3**	**17.9 to 26.8**	**<0.001**	17.4	-0.4 to 35.2	0.055
2 months before	**14.7**	**10.4 to 19.1**	**<0.001**	10.0	-1.7 to 21.6	0.093
3 months before	**9.9**	**5.2 to 14.6**	**<0.001**	6.0	-3.7 to 15.8	0.224
6 months before	**11.1**	**5.5 to 16.7**	**<0.001**	5.6	-2.4 to 13.5	0.172
9 months before	**6.4**	**0.7 to 12.1**	**0.027**	2.2	-4.8 to 9.3	0.536
1 month after	7.7	-13.0 to 28.4	0.468	-0.3	-41.2 to 40.5	0.987
2 months after	-5.3	-17.2 to 6.7	0.387	-9.7	-20.2 to 0.7	0.068
3 months after	**-10.0**	**-0.2 to -19.9**	**0.046**	-5.3	-13.5 to 2.9	0.206
6 months after	-7.4	-16.3 to 1.5	0.101	-4.3	-11.7 to 3.0	0.251
9 months after	**-6.4**	**-1.1 to -11.7**	**0.019**	-1.7	-7.9 to 4.4	0.584
Step change	-2.2	-5.6 to 1.2	0.209	-0.5	-3.1 to 2.0	0.683

	Wales			Northern Ireland		
Intervention effect	Estimate (%)	95% CI (%)	P-value	Estimate (%)	95% CI (%)	P-value
Q1 of SFL year	-2.5	-10.2 to 5.2	0.521	11.3	-1.0 to 23.6	0.072
1 month before	8.2	-12.6 to 29.0	0.438	16.9	-2.2 to 36.1	0.083
2 months before	2.6	-11.1 to 16.2	0.714	6.8	-3.3 to 17.0	0.186
3 months before	-2.5	-10.2 to 5.2	0.521	1.8	-5.8 to 9.5	0.636
6 months before	3.8	-12.2 to 19.8	0.645	7.7	-0.6 to 16.1	0.068
9 months before	2.2	-7.7 to 12.1	0.660	5.9	-1.2 to 13.0	0.106
1 month after	15.4	-22.1 to 52.8	0.421	16.3	-5.5 to 38.2	0.143
2 months after	3.1	-7.3 to 13.5	0.554	**12.5**	**1.8 to 23.2**	**0.022**
3 months after	4.3	-5.4 to 14.0	0.381	7.0	-0.6 to 14.7	0.071
6 months after	0.1	-7.4 to 7.5	0.985	-0.1	-6.2 to 6.0	0.978
9 months after	-3.1	-9.0 to 2.7	0.294	-1.7	-6.6 to 3.1	0.490
Step change	-1.6	-4.7 to 1.6	0.336	-0.7	-3.4 to 2.0	0.603

The pattern of prescribing of all smoking cessation medications in England shown in Table 5.6 is very similar to those of prescribing of NRT and bupropion discussed previously. There is no evidence of a change in all prescribing in England in the first quarter of 2007, though significant increases in the monthly rate at which smokers were prescribed at least one of the three smoking cessation medications are observed up to nine months before the smoking ban was enacted. This period of increased prescribing is of a longer duration than the periods of increased prescribing estimated for NRT and bupropion. In England, a significant decrease in the rate of prescribing of all smoking cessation medications was estimated for the three and nine month periods after smokefree legislation was introduced, though not for the other intervention periods. As was seen in prescribing of NRT and bupropion, the decline in the rate of prescribing of all medication was not sustained to the end of the study period.

In all but one instance no significant changes in the rate of prescribing of all smoking cessation medications were detected in Scotland, Wales and Northern Ireland. Again, however, the direction of many of the point estimates support the apparent pattern of an increase in prescribing in the months leading up to the introduction of smokefree legislation followed by a decline in prescribing after the ban was enacted.

5.3.4.5. Sensitivity analyses

Appendix 8.13 shows the changes in the rates of recording of cessation advice, referral to cessation services and prescribing of cessation medications estimated to have occurred in all patients and not just those identified as smokers. The significance, magnitude and direction of the changes in all outcome variables are very similar when analysis is based upon intervention rates in all patients and not just those identified as smokers.

Appendix 8.14 shows the changes in the rates of recording of patients' smoking status, the delivery of cessation advice and referral of smokers to specialist cessation services estimated when analyses are based on data from April 2004 onwards. Using the shorter series significant increases in the rate of recording of smoking status are detected in some intervention periods, as well as significant declines in others; there is no consistent pattern to the results comparing one country to another. A small number of significant changes in the recording of advice and referral are detected, contrary to the results presented earlier in this chapter, though again these do not form a consistent pattern over time nor when comparing one country with another.

5.4. DISCUSSION

The results presented in this chapter highlight increases in the rate of prescribing of NRT and bupropion in England in the six and three months respectively leading up to the introduction of smokefree legislation, and decreases in prescribing up to nine months afterwards. Rates of prescribing of all medications were increased up to nine months before the smoking ban was enacted. Similar patterns were seen in Scotland, Wales and Northern Ireland, though generally were not statistically significant.

Some significant decreases in the rate of recording of patient smoking status were seen in all UK countries shortly before and/or after the introduction of smokefree legislation. No significant changes were observed in any country in either the rate of recording of cessation advice or referral of smokers to specialist cessation services.

5.4.1. Strengths of study

All of the time series analysed in this chapter show monthly variation in the data, sometimes forming a regular seasonal pattern repeated from one year to the next. Additionally, many of the series demonstrate a distinct upwards or downwards trend prior to the introduction of smokefree legislation. The ARIMA modelling method used here is able to filter out any trends and seasonal variation to assess whether there were any changes in the outcome variables above and beyond the normal behaviour of the series that may be associated with the introduction of smokefree legislation. The same algorithm was used to calculate the rate of recording of smoking status and delivery of interventions for each month of the study period in each country of the UK. In addition, the same analytical method was applied to all time series, and the use of the automated

ARIMA model identification procedure described earlier in this thesis has removed the potential for subjectivity from the data analysis process.

The results of the sensitivity analysis investigating changes in the rate of intervention recording in all patients, and not just those identified as current smokers, are encouraging. The similar changes in cessation advice, referral to cessation services and prescribing of cessation medications estimated to have occurred in all patients and current smokers suggest that improved recording of current smokers does not confound assessment of the impact of smokefree legislation on the series. The results of the sensitivity analysis using a shorter time series to assess the impact of smokefree legislation on the recording of patients' smoking status and the delivery of advice and referral suggest that, on the whole, increased recording of these outcomes in the run-up to the introduction of the QOF does not confound assessment of the impact of smokefree legislation on these series. However, examination of the output of the automated ARIMA model fitting procedure for these shorter time series does highlight some difficulties in fitting models using a smaller number of data points. Whilst an appropriate ARIMA model could be identified for each of the shorter time series, often the conclusions drawn about the direction and statistical significance of changes in the outcome variables during the intervention periods were less robust to the choice of model compared to analysis of a longer time series.

It should be remembered that one in twenty ARIMA models can be expected to produce a statistically significant estimate of a change in the outcome variable at the 5% significance level, and thus the results of multiple hypothesis testing should be interpreted with caution – some of the statistically significant results presented here may in fact be non-significant, and vice-versa. However, there is no recognised way to correct the p-values generated from interrupted time series analysis to account for such multiple hypothesis testing, and the need to do so

anyway has been vigorously debated in other types of study[165]. Instead, the strength of the ARIMA study design and plausibility of the results can be taken to support the significance of the findings reported here, as recommended when no correction for multiple significance testing is made[165].

5.4.2. Limitations of study

As discussed in Chapter 1, there are slight variations in the demographic and socio-economic structure of the THIN dataset compared to national population estimates, and so the results presented here may not be truly representative of all patients throughout the UK. Similarly, it was impossible to identify individual practices with poor smoking data recording, and so the monthly rates analysed in this chapter may be skewed by the inclusion of these practices in the analyses undertaken. Questions regarding the external validity of the results presented here can be addressed in part by analysing the impact of smokefree legislation on the management of smoking in individual subgroups of the population defined by demographic and socio-economic characteristics, analyses which will be undertaken in the next chapter.

5.4.2.1. The difficulty in attributing changes in a time series to an intervention

A major limitation of interrupted time series analysis is the inability to draw causal links between any statistically significant changes in a series and the introduction of an intervention such as smokefree legislation. Any changes in a series may be the result of other known or unknown events which occurred at the same time. The significant reductions in the rate of recording of patient smoking status observed shortly before and/or after the introduction of smokefree legislation in all four UK countries may not be an effect of smokefree legislation; there is no plausible mechanism to suggest why the introduction of legislation would lead to

decreased recording, particularly as prior to smokefree legislation being introduced increased prescribing of smoking cessation medications was observed, suggesting greater rather than less smoking-related clinical activity in primary care at this time. Perhaps reductions in the rate of recording of patient smoking status at certain times are related to the annual QOF cycle, where practices must prove their compliance with QOF targets once a year, though further work is needed to confirm or refute this hypothesis.

The increases in NRT and bupropion prescribing estimated to have occurred in England in the run up to the introduction of smokefree legislation do not appear to have been sustained post-legislation. This may be evidence that legislation brought forward to the start of the year quit attempts that would have been made in the second half of 2007, as has been suggested elsewhere[46]. However, the picture is complicated by the introduction of varenicline in December 2006. As seen in Figure 5.8, rates of prescribing of varenicline increased rapidly, and it is possible that prescribing of this new medication may have replaced some of the prescribing of NRT and bupropion, rather than increasing the overall level of prescribing, perhaps explaining some of the decline in NRT and bupropion prescribing observed post-legislation. Indeed, comparison of the magnitudes of declines in prescribing estimated by the ARIMA modelling show that the decline in all prescribing was generally less in all time periods than the declines seen in NRT and bupropion prescribing, suggesting that the declines in NRT and bupropion prescribing were partly, but not totally, offset by an increase in the prescribing of varenicline. Bupropion prescribing suffered the largest decrease, suggesting that GPs were more likely to prescribe varenicline as an alternative to bupropion, rather than instead of NRT. Interestingly, declines in prescribing of NRT, bupropion and all medications were not sustained to the end of the study period – inspection of the time plots suggests that rates of prescribing seem to increase again the first few months of 2009. It is not clear what may be responsible for

these apparent increases, though it may be that the introduction of smokefree legislation shifted quit attempts forward, resulting in reduced prescribing from July 2007 to December 2008, which then picked up again in 2009. More data are needed to assess whether this apparent increase in prescribing at the start of 2009 is sustained.

In most countries, smokefree legislation has been introduced as just one of a raft of tobacco control measures, and thus it is always likely to be difficult to assess the true impact of legislation alone. In the UK, tax on over-the-counter NRT was reduced to 5% in July 2007, and it may be that smokers who previously would have gone to their GP to get NRT instead bought it over the counter, contributing to the decline in prescribing detected in THIN data. However, the post-legislation decline seen in the rates of prescribing of bupropion cannot be attributed to this tax change, and so perhaps other factors also explain the decline in NRT prescribing.

5.4.2.2. Do changes in data recorded in primary care indicate actual behavioural change?

Prescribing of any medication does not necessarily mean patients will redeem their prescription and use the medication as directed, though the good agreement between THIN prescribing rates and rates of dispensed prescriptions suggests this first concern is not a major problem[162]. NRT is also available from sources other than a primary health care professional, such as through NHS Stop Smoking Services, and these prescriptions will not appear in THIN. In addition, some smokers may use NRT to support temporary abstinence from smoking[166]. Therefore, the changes in NRT prescribing reported here may not entirely reflect the impact of smokefree legislation on the total use of NRT or actual quitting activity. In Scotland, significant increases in over-the-counter sales of NRT were seen between January and June 2006, the six month period spanning the

introduction of smokefree legislation[43]. Any increased quitting activity which may have resulted from these purchases may have, at least in part, offset any reduction in the number of smokers attempting to quit attributable to the decline in prescribing in primary care.

5.4.2.3. Statistical power

In general, this study found few statistically significant changes in smoking-related clinical activity in Scotland, Wales or Northern Ireland, though the direction of the point estimates of changes in prescribing are in line with the patterns seen in England. A power analysis suggests the failure to detect significant changes in Scotland, Wales and Northern Ireland may not be because the response to smokefree legislation was different in these jurisdictions to that England, but because the ARIMA models are not adequately powered to detect changes in prescribing of a similar magnitude to those significant changes detected in England. Table 5.7 shows the minimum effect size which the ARIMA models are powered to detect in each country for a change in each outcome variable six months before the introduction of smokefree legislation. In addition, the effect sizes estimated to have occurred in each series are shown.

Table 5.7 The estimated power of ARIMA models to detect changes in smoking status and intervention recording

	England		**Scotland**	
Outcome variable	Estimate (95% CI)	Minimum effect detectable with 80% power	Estimate (95% CI)	Minimum effect detectable with 80% power
Smoking status	-2.5 (-7.4 to 2.3)	7.0	1.9 (-6.9 to 10.6)	12.6
Advice	-3.1 (-8.9 to 2.8)	8.4	-0.1 (-12.1 to 11.9)	17.0
Referral	1.7 (-55.4 to 58.8)	81.2	-2.0 (-46.7 to 42.7)	63.6
NRT	**6.2 (1.4 to 11.0)**	**7.0**	6.3 (-2.9 to 15.4)	13.1
Bupropion	7.1 (-0.4 to 14.5)	10.6	5.0 (-8.8 to 18.7)	19.5
All prescribing	**11.1 (5.5 to 16.7)**	**7.8**	5.6 (-2.4 to 13.5)	11.4

	Wales		**Northern Ireland**	
Outcome variable	Estimate (95% CI)	Minimum effect detectable with 80% power	Estimate (95% CI)	Minimum effect detectable with 80% power
Smoking status	1.1 (-6.0 to 8.1)	10.0	-3.0 (-10.4 to 4.4)	10.6
Advice	4.7 (-31.0 to 40.3)	50.8	-1.6 (-9.7 to 6.6)	11.4
Referral	-3.2 (-16.2 to 9.9)	18.7		
NRT	-1.3 (-13.0 to 10.4)	16.7	-2.9 (-9.1 to 3.3)	8.9
Bupropion	**13.9 (3.1 to 24.6)**	**15.3**	**21.8 (8.9 to 34.8)**	**18.4**
All prescribing	3.8 (-12.2 to 19.8)	22.9	7.7 (-0.6 to 16.1)	11.7

As Table 5.7 shows, the ARIMA models for the prescribing series in Scotland, Wales and Northern Ireland are, on the whole, only powered to detect statistically significant changes of a magnitude much larger than the point estimates of change in these locations, and effects larger than the significant changes detected in England. Prescribing data in Scotland, Wales and Northern Ireland ought to be complete, given that prescriptions are issued electronically and a record automatically appears in THIN, and the regular seasonal pattern seen in these time series, similar to that seen in England, suggests recording is indeed complete. However, there are considerably fewer THIN practices in Scotland (43 practices), Wales (30) and Northern Ireland (23) compared to England (350). The greater magnitude of monthly variation seen in the time series for Scotland, Wales and Northern Ireland, and hence the lower power to detect small changes in the series, may reflect the smaller number of practices in these locations.

Figure 5.10 shows the 95% confidence intervals around the rates of prescribing of all smoking cessation medications in each country. As can be seen, the 95% confidence intervals are much wider around the time series from Scotland, Wales and Northern Ireland compared to England, and similar patterns are also seen in the prescribing of NRT and bupropion. The greater monthly variation in prescribing in Scotland, Wales and Northern Ireland, which increases the magnitude of effect size which can be detected as outside of the normal behaviour of the series, might not be a true reflection of prescribing in the country as a whole, but simply a reflection of the smaller number of practices in these countries. It has not been possible in this work to account for the wide variations between practices demonstrated previously in the apparent completeness of recording of smoking status and cessation interventions. Unfortunately, analysis of data from these countries with fewer practices contributing to THIN has greater potential to be skewed by aberrant data recording in one or two practices which may increase the

variability of the series and reduce the power to detect small changes in outcomes.

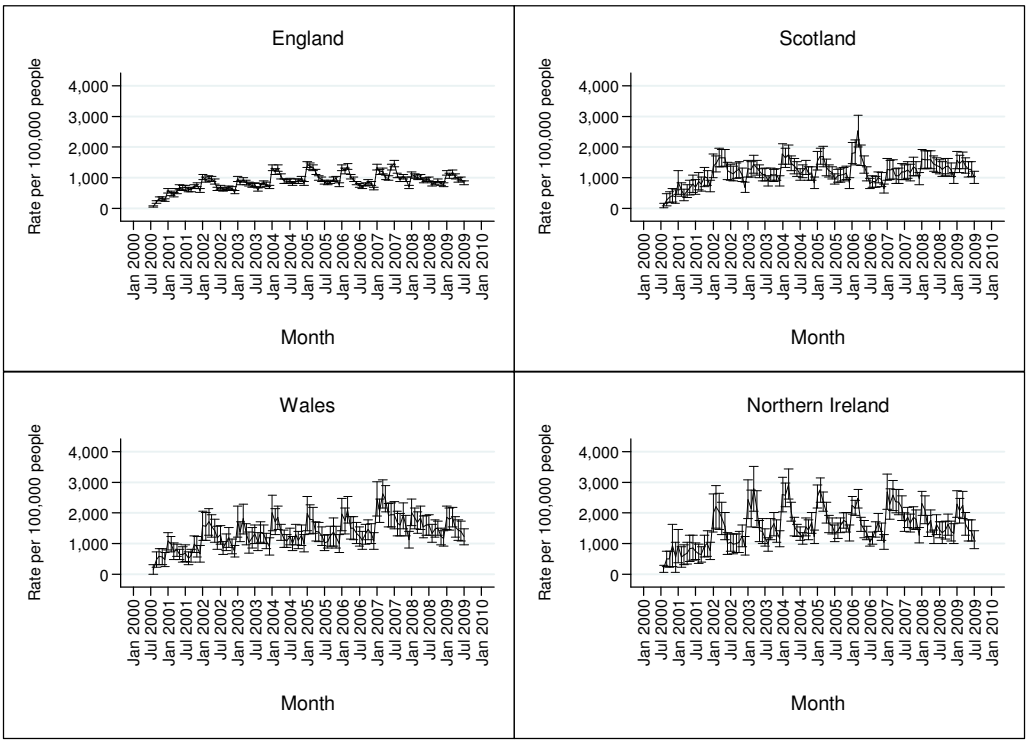


Figure 5.10 Rates of prescribing of all smoking cessation medications with 95% confidence intervals

Figure 5.4 showed that the rate of recording of referral of smokers to stop smoking services is approximately ten times higher in Northern Ireland than elsewhere in the UK. However, the 95% confidence intervals around these estimates suggest that this might just be a reflection of the smaller number of practices in Northern Ireland, and rates of referral may indeed be comparable to the rest of the UK. The differences between England, Wales, Scotland and Northern Ireland in the width of the 95% confidence intervals around rates of recording of smoking status and cessation advice are less marked, explaining the similar variation and power to detect changes in these series (figures not shown here).

5.5. CONCLUSIONS

The significant increases in the rate of prescribing of NRT and bupropion in the run-up to the introduction of smokefree legislation suggests that smokers looking to quit may indeed seek support to do so from primary care, or that GPs may see the introduction of legislation as a chance to pro-actively encourage smokers to quit. However, the decline in rates of all prescribing post-legislation suggests that this positive change may not be sustained. It could be argued that this highlights a missed opportunity to maximise the impact of smoking bans by ensuring that smokers are aware of, and indeed access, cessation support in primary care both before and after legislation is enacted, and should be noted by policy makers planning the introduction of smokefree legislation elsewhere.

The failure to detect significant changes in the recording of cessation advice and referral of smokers to stop smoking services again may reflect missed opportunities to maximise the impact of smokefree legislation, though incomplete recording of these interventions may also explain these results.

This chapter has assessed the impact of smokefree legislation on the management of smoking in primary care in all adults in each part of the UK. The size of the THIN dataset offers the opportunity to investigate the impact of legislation in subgroups of patients and the results of these subgroup analyses are presented in the following chapter.

6. DID THE INTRODUCTION OF SMOKEFREE LEGISLATION AFFECT POPULATION SUBGROUPS DIFFERENTLY?

6.1. INTRODUCTION

As outlined in the introduction to this thesis, variations in smoking prevalence by socioeconomic group are the major driver of health inequalities between rich and poor in the UK[10]. Reducing these inequalities is a priority for health policy and a specific target set by the Department of Health aims to halve the current prevalence of smoking in routine and manual groups by 2020[167].

To date little is known about which policies are most effective in reducing the inequalities in health caused by smoking, and it may be that policies which appear to improve the health of a population overall in fact widen inequalities in health if their benefits are concentrated in the most advantaged socio-economic groups[168]. The majority of studies which have attempted to evaluate the effects of population-level tobacco control policies on social inequalities in smoking have focused on the role of price, with the balance of evidence suggesting that increasing the cost of tobacco is most effective in reducing consumption and prevalence in adults with lower incomes and in manual occupations[169]. A systematic review of the effect of public and workplace tobacco control interventions on social inequalities in smoking found insufficient evidence of differential impacts of smokefree regulations by income, education level and ethnicity, inconsistent evidence of differential effects by age, and no evidence that restrictions have a differential impact in men and women[169].

Few studies which have evaluated national, comprehensive smokefree legislation have also set out to do so in population subgroups. The recent Cochrane review of the impact of legislative smoking bans describes just two studies where results are presented separately for men and women[36], and another study, published after the Cochrane review, reported that younger age groups were more likely to report having made a quit attempt in response to smokefree legislation, though there were no significant differences according to gender or social class[46]. In New Zealand, there were no changes in the proportion of smokers by sex or ethnic group registering with the national Quitline at the time smokefree legislation was introduced, though the proportion of registrations by smokers aged 35-44 did increase[47]. The large size of the THIN dataset potentially provides the statistical power to assess the impact of smokefree legislation on the management of smoking in primary care in different population subgroups.

This chapter uses THIN data to assess whether the changes in smoking-related clinical activity in primary care reported in all patients in the previous chapter differ by patient sex, age group, medical history and social class. As discussed previously, the small number of THIN practices in Scotland, Wales and Northern Ireland makes it difficult to detect small changes in clinical activity in these locations, and the power is likely to be compromised further by dividing the total population into smaller subgroups. In addition, changes in recording of smoking status seem unlikely to be related to the introduction of smokefree legislation, and the less robust quality of advice and referral data make it difficult to detect changes in these outcome variables. Therefore, this chapter will only assess the differential impact of smokefree legislation on prescribing of stop smoking medications in England.

6.2. METHODS

6.2.1. Extraction of time series from THIN

As in the analysis of data for England as a whole, for each month from January 2000 to July 2009 all patients were identified from the THIN dataset who were aged 16+ and registered with a practice for at least one day of the month. Current smokers were identified and, in addition, details of each patient's age, sex, medical history and social class (measured by quintile of the Townsend Index of Deprivation) were extracted from their medical records.

Monthly rates of prescribing of NRT, bupropion and all smoking cessation medications were calculated for each of the population subgroups shown in Table 6.1, expressed as the number of smokers with a record each month per 100,000 person-months of follow-up time.

Table 6.1 Population subgroups, showing the number of smokers in THIN in July 2007

Characteristic	Subgroup	Number of smokers
All patients	-	437,933
Gender	Men	232,413
	Women	205,520
Age group	16-19	20,101
	20-24	42,225
	25-34	90,805
	35-49	143,898
	50-59	68,595
	60+	72,309
Number of chronic conditions*	0	362,268
	1+	75,665
Townsend Index of Deprivation	Least deprived	77,307
	Quintile 2	77,345
	Quintile 3	91,989
	Quintile 4	96,884
	Most deprived	76,743
	Missing	17,665

*from asthma, chronic obstructive pulmonary disease, coronary heart disease, diabetes mellitus, hypertension and stroke or transient ischemic attack.

Preliminary analysis showed that analysing rates of prescribing in individual groups of patients with each of the six chronic conditions resulted in inadequate power to detect small changes in prescribing in any group. These variables will

not, therefore, be used in this subgroup analysis and instead the composite variable indicating patients with one or more of these conditions will be used.

Given the similarity demonstrated in the previous chapter between rates of prescribing in smokers and all in patients, this chapter only considers changes in rates of prescribing in smokers.

6.2.2. ARIMA modelling

ARIMA modelling was used to assess the impact of the introduction of smokefree legislation on prescribing in each subgroup, using the procedure outlined in Chapter 4 and applied in Chapter 5. The same intervention effects were modelled in each subgroup as in all patients in England, and again results are presented as percentage changes in the outcome variable in the intervention period.

There is no documented statistical method which can compare the results of several interrupted time series analyses to assess whether smokefree legislation had a differential effect in different population subgroups. Therefore, the magnitude of the effect sizes and 95% confidence intervals calculated in different subgroups will be compared visually and non-overlapping confidence intervals taken as evidence of a difference in effect between subgroups.

Changes in NRT prescribing were estimated using data from April 2001, the first month the medication became available on NHS prescription. Changes in prescribing of bupropion and all smoking cessation medications were estimated using data from January 2002, removing the outlying peak in bupropion prescribing when this medication first became available on NHS prescription.

As noted previously, a record of all issued prescriptions appears automatically in THIN, and so there is no potential confounding effect of increased computer use associated with the QOF when investigating the impact of smokefree legislation, and therefore no need to model a shorter data series.

6.3. RESULTS

6.3.1. Prescribing of NRT

The analysis of data from all patients in England, presented in Section 5.3.4.1, showed there was no change in NRT prescribing in the first quarter of 2007, though significant increases in the rate of NRT prescribing were observed up to six months before the introduction of smokefree legislation. Significant declines in prescribing were estimated two to nine months post-legislation, though this decline was not sustained to the end of the study period.

Figure 6.1 shows rates of prescribing of NRT by patient sex and whether they have a history of one or more chronic conditions.

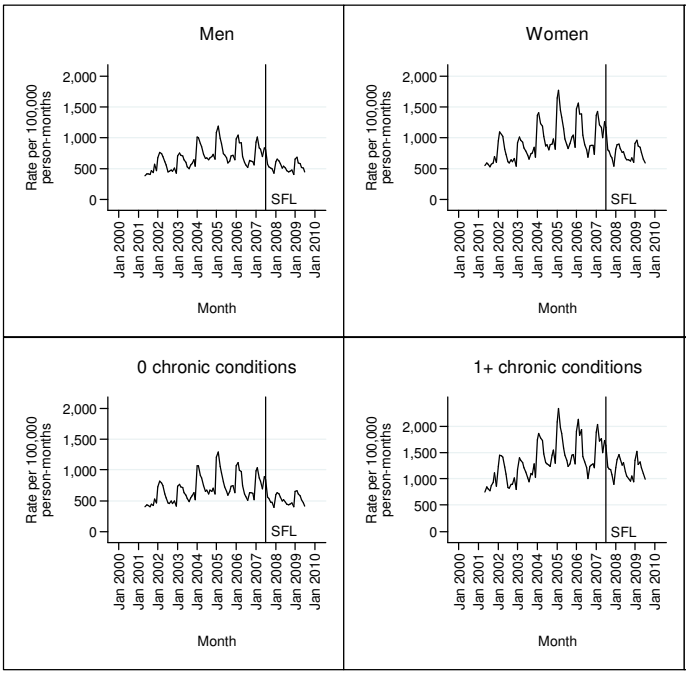


Figure 6.1 Rates of prescribing of NRT in England by sex and medical history

The rate of prescribing of NRT in women is higher, though more variable, than that in men, and is also higher but more variable in patients with a history of one or more chronic conditions compared to those without. In all subgroups there appears to be a decline in prescribing after the introduction of smokefree legislation, though, given the monthly variation in the series, it is hard to tell whether there are any significant increases in prescribing before the introduction of the smoking ban.

Figure 6.2 shows rates of prescribing of NRT by patient age group. The rate of NRT prescribing in all six age groups shows a regular seasonal pattern across the study period. The overall rate of prescribing is lowest in the two youngest age groups, though these groups also show the smallest variation in prescribing from one month to the next. In some age groups there appears to be an increase in prescribing immediately before the introduction of smokefree legislation, though it is hard to tell whether any increase is outside of the normal behaviour of the series. In all but the youngest and oldest age groups there appears to be a decline in NRT prescribing in the post-legislation period, though again the monthly

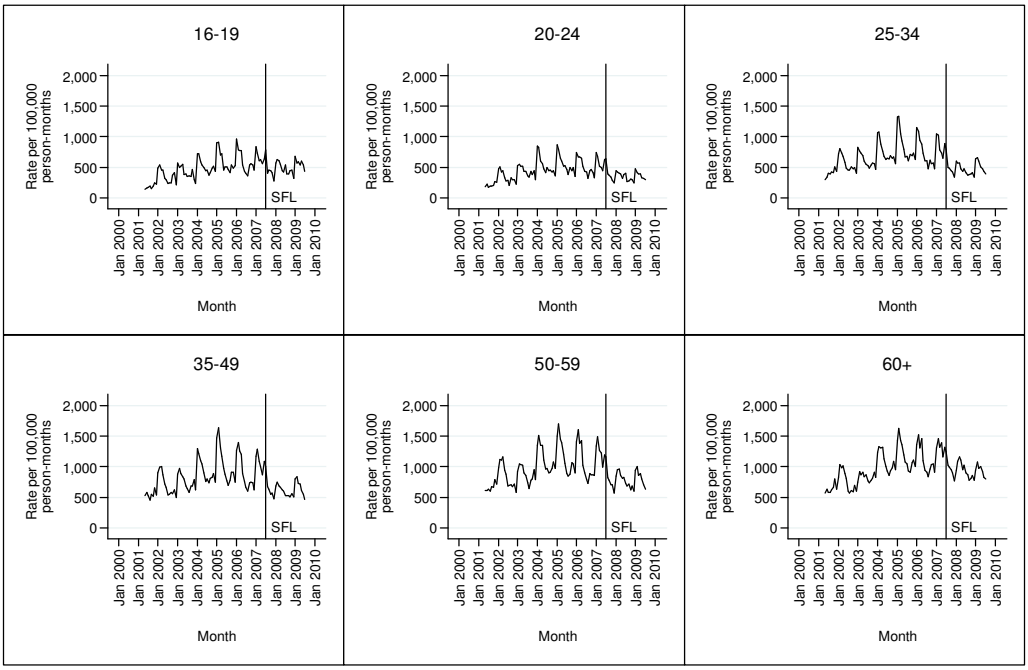


Figure 6.2 Rates of prescribing of NRT in England by age group

variation in the series makes it difficult to tell whether any decline would be judged statistically significant.

Figure 6.3 shows rates of prescribing of NRT by quintile of the Townsend Index of Deprivation. All series show seasonal variation in the rate of NRT prescribing, though this seasonal pattern is less regular in patients whose Townsend classification is missing in their THIN records. The rate of prescribing is very similar in all Townsend quintiles, and in all groups of patients except those with missing data there appears to be a decline in NRT prescribing after the introduction of smokefree legislation.

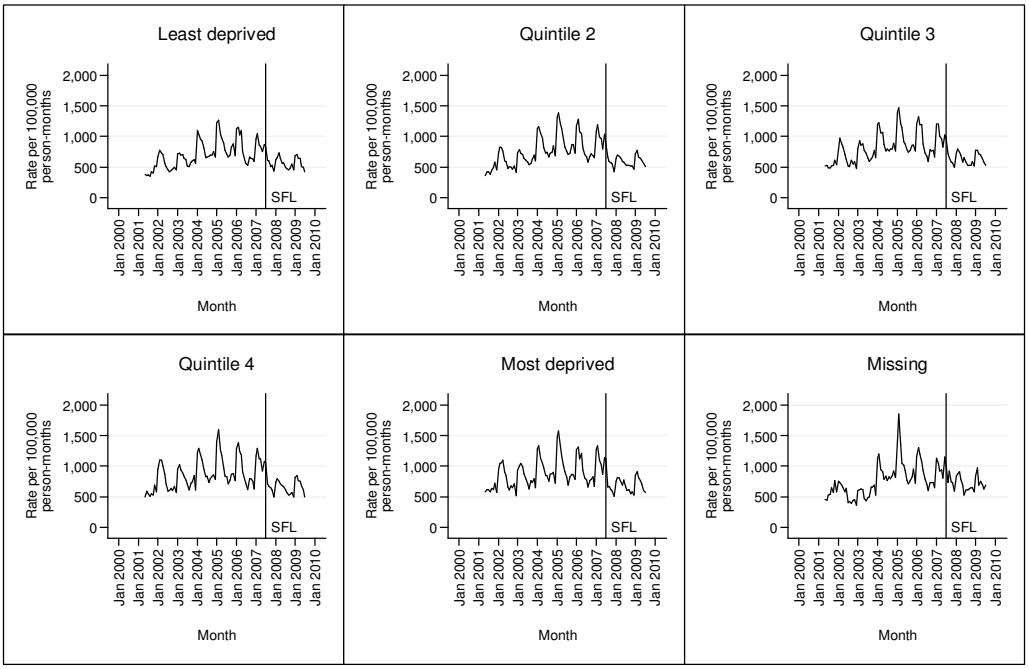


Figure 6.3 Rates of prescribing of NRT in England by quintile of the Townsend Index of Deprivation

Table 6.2 shows the estimates from interrupted time series analysis of changes in NRT prescribing before the introduction of smokefree legislation for each population subgroup, along with their 95% confidence intervals. Figures in bold print highlight statistically significant changes. Table 6.3 presents the estimates

for changes in NRT prescribing in the intervention periods after the introduction of smokefree legislation.

6.3.1.1. Changes in prescribing before the introduction of smokefree legislation

Increases in NRT prescribing were seen three months before the introduction of smokefree legislation in all population subgroups (except those with a missing Townsend score), and in most subgroups six months pre-ban. The point estimates presented in Table 6.2 suggest that the increase in prescribing may have been marginally greater in men compared to women, though the 95% confidence intervals around these estimates overlap, suggesting that the introduction of smokefree legislation did not have a differential effect according to patient sex. The magnitude of the increase in prescribing was similar in all age groups in the three month pre-legislation period and in those groups where significant changes were detected six months pre-ban, and again the confidence intervals overlap. Increases in NRT prescribing are seen both in patients with one or more chronic conditions and those who are otherwise healthy. The point estimates suggest that the increase in prescribing may have been marginally greater amongst those without a history of chronic disease than those with, though again the confidence intervals overlap. Finally, the overlapping confidence intervals for the estimates of the change in NRT prescribing according to Townsend score suggest that the introduction of smokefree legislation did not have a differential effect according to patient socio-economic status.

Table 6.2 Changes in NRT prescribing in England before the introduction of smokefree legislation

	Subgroup	2007 Q1	1 month before	2 months before	3 months before	6 months before	9 months before
All patients	**England**	-2.7 (-10.1 to 4.7)	**17.5 (11.1 to 24.0)**	**13.6 (8.1 to 19.1)**	**10.4 (5.0 to 15.7)**	**6.2 (1.4 to 11.0)**	4.0 (-1.3 to 9.3)
Gender	**Men**	1.9 (-15.9 to 19.7)	**19.8 (9.5 to 30.2)**	**15.0 (8.0 to 22.1)**	**10.8 (4.5 to 17.2)**	**7.0 (1.5 to 12.6)**	3.6 (-1.8 to 8.9)
	Women	-3.3 (-9.9 to 3.4)	**16.5 (10.4 to 22.6)**	**14.0 (8.6 to 19.5)**	**10.6 (5.2 to 15.9)**	**6.0 (1.1 to 10.9)**	4.0 (-1.1 to 9.2)
Age group	**16-19**	0.2 (-25.8 to 26.3)	7.4 (-37.9 to 52.7)	16.2 (-17.6 to 50.0)	**16.5 (0.3 to 32.8)**	5.9 (-5.0 to 16.9)	0.7 (-8.4 to 9.8)
	20-24	-3.6 (-27.3 to 20.2)	51.4 (-62.7 to 165.6)	**27.5 (10.0 to 45.0)**	**15.7 (5.4 to 25.9)**	4.1 (-2.9 to 11.1)	1.6 (-4.8 to 7.9)
	25-34	-1.0 (-11.1 to 9.1)	**27.2 (18.5 to 36.0)**	**19.0 (12.1 to 26.0)**	**13.3 (6.3 to 20.3)**	**9.6 (3.2 to 16.1)**	**8.5 (1.8 to 15.2)**
	35-49	-4.4 (-12.5 to 3.6)	**16.9 (8.4 to 25.4)**	**14.1 (7.3 to 20.9)**	**11.9 (5.8 to 18.0)**	**6.0 (0.9 to 11.1)**	4.5 (-0.7 to 9.6)
	50-59	-1.7 (-13.5 to 10.1)	**15.1 (7.0 to 23.3)**	**13.6 (7.0 to 20.1)**	**8.8 (3.1 to 14.6)**	**5.9 (0.4 to 11.4)**	-0.7 (-4.7 to 3.2)
	60+	2.7 (-12.4 to 17.7)	24.5 (-27.2 to 76.1)	**15.2 (6.4 to 23.9)**	**8.9 (2.0 to 15.8)**	5.8 (-0.3 to 11.9)	1.5 (-4.0 to 7.1)
Number of chronic conditions	**0**	-2.6 (-10.4 to 5.3)	**18.8 (12.6 to 25.0)**	**14.8 (9.1 to 20.5)**	**10.7 (5.0 to 16.3)**	**6.6 (1.4 to 11.8)**	4.5 (-0.8 to 9.7)
	1+	-2.1 (-9.4 to 5.1)	**16.3 (3.9 to 28.8)**	**12.9 (4.9 to 20.9)**	**10.2 (4.0 to 16.5)**	**6.1 (1.5 to 10.8)**	3.5 (-3.3 to 10.3)
Townsend Index of Deprivation	**Least deprived**	0.8 (-14.0 to 15.5)	27.5 (-6.6 to 61.6)	**21.9 (4.8 to 39.0)**	**14.0 (5.6 to 22.3)**	**8.1 (2.1 to 14.2)**	4.3 (-0.8 to 9.4)
	Quintile 2	-3.8 (-13.3 to 5.8)	**19.9 (11.6 to 28.1)**	**14.6 (8.9 to 20.3)**	**12.2 (7.2 to 17.2)**	**6.9 (1.8 to 12.0)**	4.4 (-0.7 to 9.4)
	Quintile 3	-3.6 (-10.8 to 3.7)	30.7 (-45.9 to 107.3)	**15.7 (9.8 to 21.6)**	**10.8 (5.4 to 16.2)**	**5.7 (0.1 to 11.4)**	0.0 (-3.8 to 3.8)
	Quintile 4	-2.2 (-13.1 to 8.8)	**16.6 (5.8 to 27.4)**	**13.5 (6.4 to 20.6)**	**11.9 (5.9 to 17.9)**	**7.3 (2.3 to 12.4)**	4.8 (-0.5 to 10.0)
	Most deprived	-2.3 (-11.9 to 7.2)	**20.6 (11.5 to 29.7)**	**16.0 (9.0 to 23.0)**	**6.7 (1.1 to 12.3)**	2.5 (-2.4 to 7.4)	4.7 (-1.4 to 10.8)
	Missing	-4.4 (-18.5 to 9.7)	**20.3 (5.6 to 35.0)**	7.5 (-4.2 to 19.1)	9.6 (-1.4 to 20.5)	1.4 (-8.2 to 11.1)	-1.6 (-7.9 to 4.6)

Table 6.3 Changes in NRT prescribing in England after the introduction of smokefree legislation

	Subgroup	1 month after	2 months after	3 months after	6 months after	9 months after	Step change
All patients	**England**	-1.1 (-32.2 to 30.0)	**-6.9 (-0.3 to -13.4)**	**-9.0 (-3.9 to -14.2)**	**-6.7 (-2.1 to -11.2)**	**-5.5 (-2.3 to -8.7)**	-1.7 (-4.4 to 1.0)
Gender	**Men**	0.5 (-28.6 to 29.6)	**-7.6 (-1.6 to -13.6)**	**-10.1 (-5.2 to -15.1)**	**-7.1 (-2.0 to -12.1)**	**-5.2 (-0.7 to -9.7)**	-1.5 (-4.8 to 1.9)
	Women	0.3 (-60.9 to 61.5)	-9.1 (-22.3 to 4.1)	**-15.1 (-5.7 to -24.4)**	**-11.0 (-2.9 to -19.1)**	**-7.3 (-2.1 to -12.4)**	-1.9 (-5.2 to 1.3)
Age group	**16-19**	11.1 (-4.3 to 26.5)	2.7 (-6.7 to 12.0)	1.5 (-4.9 to 7.8)	0.6 (-2.5 to 3.6)	0.8 (-1.3 to 3.0)	0.7 (-0.2 to 1.6)
	20-24	12.6 (-20.9 to 46.1)	-3.9 (-18.0 to 10.2)	**-10.4 (-0.3 to -20.5)**	**-6.8 (-0.1 to -13.5)**	-4.6 (-10.4 to 1.3)	-1.7 (-5.4 to 2.0)
	25-34	-12.9 (-78.1 to 52.2)	**-17.0 (-10.2 to -23.8)**	**-15.4 (-5.0 to -25.8)**	**-9.2 (-1.7 to -16.7)**	**-6.4 (-0.5 to -12.2)**	-1.9 (-5.4 to 1.6)
	35-49	4.3 (-93.3 to 101.8)	-5.3 (-13.3 to 2.7)	**-11.1 (-4.0 to -18.3)**	**-6.6 (-0.9 to -12.3)**	**-6.4 (-1.5 to -11.3)**	-1.8 (-5.1 to 1.5)
	50-59	1.8 (-17.6 to 21.2)	-5.0 (-10.7 to 0.7)	**-6.4 (-0.9 to -12.0)**	**-7.1 (-2.3 to -11.9)**	**-5.0 (-1.1 to -8.9)**	-1.5 (-4.1 to 1.1)
	60+	-5.0 (-51.4 to 41.3)	-5.0 (-23.8 to 13.8)	-7.9 (-22.9 to 7.1)	-6.7 (-16.6 to 3.2)	-4.3 (-9.3 to 0.7)	-1.6 (-4.0 to 0.9)
Number of chronic conditions	**0**	2.4 (-100.6 to 105.3)	**-7.8 (-0.8 to -14.7)**	**-12.1 (-5.8 to -18.4)**	**-7.6 (-2.3 to -12.9)**	**-5.8 (-1.3 to -10.3)**	-1.8 (-5.0 to 1.5)
	1+	-0.4 (-20.4 to 19.6)	-5.0 (-12.7 to 2.7)	**-7.8 (-1.5 to -14.0)**	**-6.8 (-2.5 to -11.0)**	**-4.9 (-1.5 to -8.3)**	-1.4 (-3.7 to 0.9)
Townsend Index of Deprivation	**Least deprived**	5.7 (-23.1 to 34.5)	-5.3 (-14.6 to 4.1)	**-9.4 (-0.5 to -18.3)**	**-7.0 (-1.3 to -12.8)**	-4.1 (-8.3 to 0.0)	-1.6 (-4.5 to 1.4)
	Quintile 2	-5.0 (-35.0 to 25.1)	-6.3 (-15.2 to 2.6)	**-8.6 (-1.7 to -15.6)**	**-7.6 (-2.1 to -13.1)**	**-6.3 (-1.9 to -10.6)**	-1.6 (-4.2 to 1.0)
	Quintile 3	1.9 (-40.7 to 44.6)	-5.8 (-14.6 to 3.0)	**-11.9 (-4.9 to -18.9)**	**-6.9 (-1.2 to -12.6)**	**-5.2 (-0.5 to -9.9)**	-1.5 (-4.4 to 1.3)
	Quintile 4	-2.8 (-18.2 to 12.7)	**-7.5 (-0.7 to -14.4)**	**-10.5 (-4.7 to -16.4)**	**-7.4 (-3.3 to -11.6)**	**-6.1 (-2.6 to -9.7)**	-2.0 (-4.7 to 0.7)
	Most deprived	0.3 (-21.4 to 22.0)	**-8.8 (-2.2 to -15.4)**	**-9.8 (-3.7 to -15.9)**	**-6.5 (-1.3 to -11.8)**	**-5.1 (-0.5 to -9.6)**	-1.6 (-4.4 to 1.1)
	Missing	14.4 (-18.8 to 47.6)	4.5 (-12.8 to 21.8)	2.9 (-13.3 to 19.1)	-2.1 (-15.0 to 10.8)	-2.3 (-13.0 to 8.3)	-0.4 (-5.4 to 4.5)

6.3.1.2. Changes in prescribing after the introduction of smokefree legislation

A decline in NRT prescribing was observed for both men and women for the nine month period after smokefree legislation was introduced. The decrease in prescribing may have been greater in women than men, though the 95% confidence intervals around these estimates overlap. No significant change in the rate of NRT prescribing was seen at any point after the introduction of smokefree legislation in patients aged 16-19 and 60 and above, though the estimates of change in the other age groups are of a similar magnitude. A decline in prescribing was seen both in patients with one or more chronic conditions and those who are otherwise healthy. The decrease may have been greater in patients without chronic conditions, though the overlapping confidence intervals again suggest that the introduction of smokefree legislation did not have a differential effect according to patient medical history. A similar magnitude of decline in NRT prescribing was observed in all quintiles of the Townsend Index in the six month post-legislation period, and in all but the least deprived quintile up to nine months post-ban.

6.3.2. Prescribing of bupropion

The analysis of bupropion prescribing data from all patients in England, presented in Section 5.3.4.2, showed a similar pattern of changes to those seen in NRT prescribing. Significant increases in the rate of prescribing were observed up to three months before the introduction of smokefree legislation, and declines in the prescribing of bupropion were estimated for the two to nine month periods post-legislation, though were not sustained to the end of the study period. The magnitude of the decline in bupropion prescribing in all patients was much larger than that seen in NRT prescribing, though the confidence intervals around the estimates of change in bupropion prescribing were wider.

Figure 6.4 shows rates of prescribing of bupropion by patient sex and whether they have a history of one or more chronic conditions.

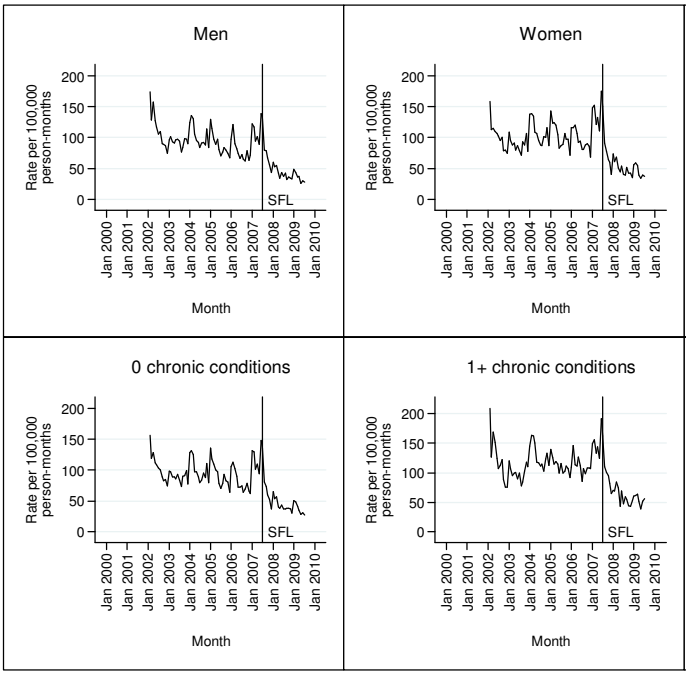


Figure 6.4 Rates of prescribing of bupropion in England by sex and medical history

There is monthly variation in the rate of bupropion prescribing in each subgroup, though there is a less obvious seasonal pattern than was seen in the prescribing of NRT. The rate of prescribing of bupropion is similar in men and women, with both series showing an apparent increase in prescribing immediately before the introduction of smokefree legislation and a decline in the post-legislation period. However, it is difficult to judge visually whether this decline is simply a continuation of a longer-term decline in the rate of prescribing of bupropion. The rate of prescribing of bupropion is higher in patients with a history of one or more chronic conditions compared to those who are otherwise healthy, though both groups again appear to show an increase in prescribing immediately before the introduction of smokefree legislation and a decline in the post-legislation period.

Figure 6.5 shows rates of prescribing of bupropion by patient age group.

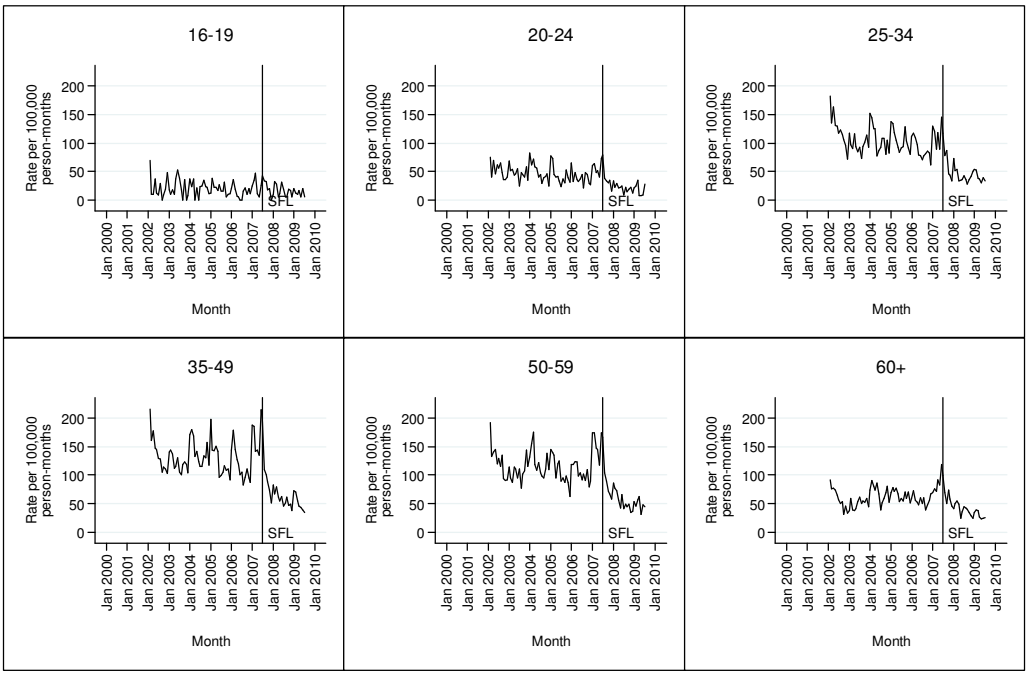


Figure 6.5 Rates of prescribing of bupropion in England by age group

The rate of bupropion prescribing is highly variable from month to month in each age group. The overall rate of prescribing is very low in patients aged 16-19, 20-24 and 60+ compared to the other age groups, making it difficult to see whether there were any changes in the rate of prescribing at the time smokefree legislation was introduced. In patients aged between 25 and 59 there appears to be an increase in prescribing just before smokefree legislation was introduced, and a decline in the post-legislation period, though again this decline may simply be a continuation of a longer-term trend.

Figure 6.6 shows rates of prescribing of bupropion by quintile of the Townsend Index of Deprivation.

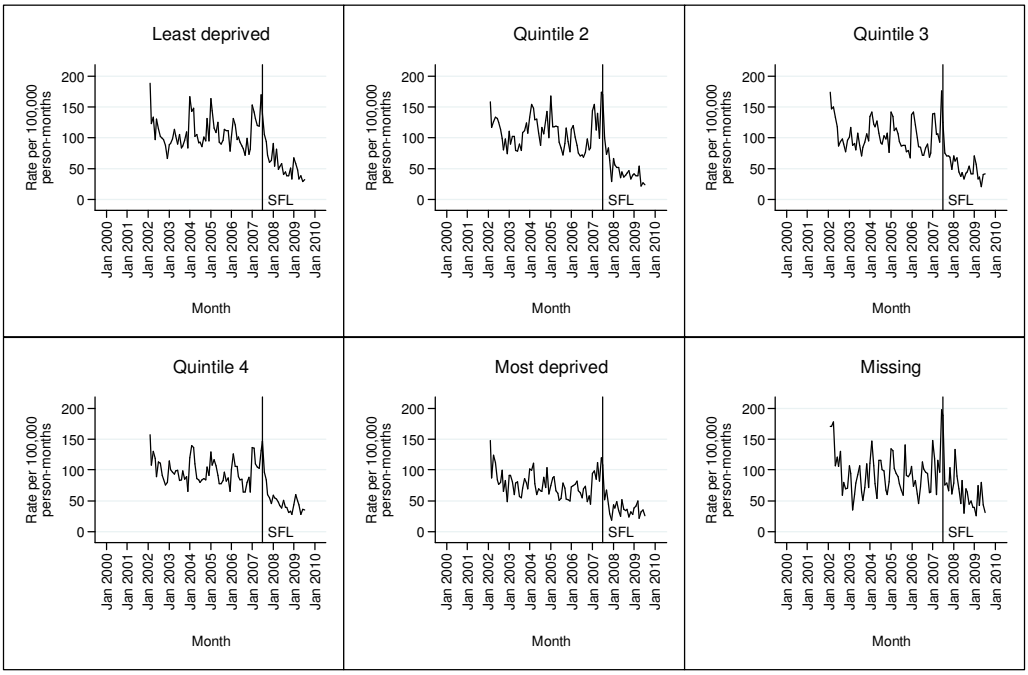


Figure 6.6 Rates of prescribing of bupropion in England by quintile of the Townsend Index of Deprivation

The rate of bupropion prescribing is very similar for each quintile of the Townsend Index of Deprivation, showing a large amount of monthly variation but no obvious seasonal pattern, and an apparent long-term decline in prescribing making it difficult to distinguish any additional decline after the introduction of smokefree legislation.

Table 6.4 shows the estimates of changes in bupropion prescribing before the introduction of smokefree legislation for each population subgroup, and Table 6.5 presents the estimates for changes in prescribing in the intervention periods after the introduction of smokefree legislation.

Table 6.4 Changes in bupropion prescribing in England before the introduction of smokefree legislation

	Subgroup	2007 Q1	1 month before	2 months before	3 months before	6 months before	9 months before
All patients	**England**	1.7 (-12.9 to 16.2)	**44.7 (20.4 to 69.0)**	**18.9 (9.2 to 28.6)**	**13.2 (4.3 to 22.2)**	7.1 (-0.4 to 14.5)	5.2 (-1.8 to 12.3)
Gender	**Men**	6.5 (-6.4 to 19.3)	37.1 (-1.5 to 75.8)	**19.7 (6.6 to 32.7)**	**16.8 (6.2 to 27.5)**	**10.0 (2.9 to 17.1)**	**10.8 (5.5 to 16.2)**
	Women	4.3 (-6.0 to 14.6)	**29.9 (15.0 to 44.8)**	**12.8 (2.9 to 22.6)**	5.6 (-2.1 to 13.4)	4.6 (-1.3 to 10.5)	1.4 (-4.3 to 7.1)
Age group	**16-19**	12.0 (-12.4 to 36.3)	39.2 (-201.9 to 280.2)	16.0 (-33.2 to 65.3)	5.9 (-21.6 to 33.4)	5.2 (-8.3 to 18.6)	1.9 (-48.8 to 52.6)
	20-24	15.9 (-16.6 to 48.3)	11.0 (-40.5 to 62.4)	3.9 (-23.8 to 31.6)	3.8 (-17.4 to 25.0)	6.1 (-7.9 to 20.1)	7.1 (-9.6 to 23.9)
	25-34	1.3 (-16.9 to 19.6)	**30.7 (1.3 to 60.1)**	16.6 (-1.2 to 34.4)	11.7 (-1.1 to 24.4)	5.8 (-3.3 to 14.8)	3.4 (-6.7 to 13.5)
	35-49	7.2 (-5.1 to 19.6)	47.0 (-14.3 to 108.3)	**24.2 (7.8 to 40.6)**	**18.6 (5.2 to 31.9)**	**11.1 (3.2 to 19.0)**	**10.6 (4.5 to 16.7)**
	50-59	11.5 (-2.7 to 25.7)	20.7 (-28.2 to 69.5)	9.6 (-9.6 to 28.8)	5.5 (-10.0 to 20.9)	6.8 (-2.6 to 16.1)	**7.3 (0.4 to 14.2)**
	60+	9.1 (-27.3 to 45.5)	22.6 (-47.4 to 92.6)	10.7 (-20.7 to 42.2)	11.2 (-13.9 to 36.3)	8.2 (-10.3 to 26.6)	8.8 (-7.9 to 25.4)
Number of chronic conditions	**0**	1.4 (-18.5 to 21.3)	**26.8 (14.2 to 39.5)**	**10.6 (1.2 to 19.9)**	5.4 (-2.0 to 12.9)	**11.8 (0.9 to 22.6)**	5.4 (-1.3 to 12.2)
	1+	7.9 (-7.8 to 23.7)	29.8 (-31.0 to 90.6)	9.5 (-6.6 to 25.6)	6.1 (-6.8 to 19.0)	5.9 (-3.5 to 15.4)	5.3 (-3.2 to 13.8)
Townsend Index of Deprivation	**Least deprived**	10.9 (-2.5 to 24.4)	27.3 (-42.2 to 96.8)	13.2 (-14.4 to 40.8)	10.5 (-9.1 to 30.0)	10.3 (-0.3 to 20.9)	**9.7 (2.8 to 16.6)**
	Quintile 2	9.7 (-6.8 to 26.3)	40.2 (-43.9 to 124.2)	15.8 (-3.2 to 34.7)	13.2 (-1.3 to 27.8)	9.1 (-0.8 to 19.0)	**10.7 (2.8 to 18.6)**
	Quintile 3	-5.2 (-25.2 to 14.7)	**51.1 (31.9 to 70.4)**	**14.3 (2.6 to 26.1)**	6.7 (-2.9 to 16.3)	1.4 (-7.0 to 9.8)	-1.0 (-7.0 to 5.0)
	Quintile 4	-0.9 (-16.0 to 14.3)	21.4 (-4.8 to 47.6)	15.4 (-4.8 to 35.7)	7.1 (-7.4 to 21.6)	4.0 (-6.6 to 14.6)	0.2 (-7.3 to 7.7)
	Most deprived	11.4 (-8.8 to 31.6)	-1.1 (-31.7 to 29.5)	0.5 (-19.6 to 20.7)	2.6 (-16.1 to 21.2)	6.0 (-6.1 to 18.2)	6.5 (-2.1 to 15.1)
	Missing	5.8 (-9.1 to 20.7)	23.4 (-15.3 to 62.1)	13.4 (-8.9 to 35.8)	9.3 (-6.9 to 25.5)	4.7 (-4.2 to 13.7)	2.8 (-3.7 to 9.3)

Table 6.5 Changes in bupropion prescribing in England after the introduction of smokefree legislation

	Subgroup	1 month after	2 months after	3 months after	6 months after	9 months after	Step change
All patients	**England**	-6.8 (-40.1 to 26.6)	**-25.3 (-4.9 to -45.7)**	**-21.1 (-2.1 to -40.1)**	**-19.7 (-5.5 to -34.0)**	**-13.7 (-4.6 to -22.8)**	-3.5 (-8.8 to 1.9)
Gender	**Men**	-6.7 (-48.4 to 35.1)	**-22.0 (-4.4 to -39.6)**	**-15.8 (-3.0 to -28.7)**	**-16.2 (-5.9 to -26.6)**	**-11.6 (-5.5 to -17.8)**	**-8.1 (-2.4 to -13.7)**
	Women	-7.8 (-37.8 to 22.2)	**-14.7 (-4.8 to -24.5)**	**-13.5 (-6.4 to -20.6)**	**-10.7 (-4.7 to -16.6)**	**-7.3 (-2.4 to -12.1)**	-2.3 (-5.9 to 1.3)
Age group	**16-19**	83.9 (-408.1 to 575.8)	21.2 (-60.9 to 103.3)	12.1 (-45.0 to 69.1)	5.8 (-36.6 to 48.1)	4.3 (-31.5 to 40.0)	-2.2 (-9.5 to 5.1)
	20-24	-22.6 (-63.6 to 18.4)	-24.6 (-55.9 to 6.6)	-20.9 (-46.2 to 4.4)	**-14.1 (-3.7 to -24.5)**	**-10.4 (-5.1 to -15.6)**	**-4.2 (-2.9 to -5.5)**
	25-34	-6.2 (-45.4 to 33.1)	-18.3 (-38.3 to 1.6)	**-18.9 (-2.5 to -35.2)**	**-8.9 (-1.4 to -16.4)**	**-8.2 (-2.0 to -14.4)**	-2.6 (-6.2 to 1.0)
	35-49	-2.1 (-41.7 to 37.5)	**-22.9 (-2.4 to -43.5)**	**-22.5 (-3.5 to -41.5)**	**-17.8 (-5.6 to -29.9)**	**-12.6 (-6.8 to -18.5)**	**-9.1 (-2.6 to -15.6)**
	50-59	-3.6 (-36.2 to 29.0)	**-21.4 (-2.0 to -40.7)**	**-20.1 (-2.8 to -37.4)**	**-14.5 (-3.7 to -25.3)**	**-11.4 (-5.1 to -17.7)**	**-5.7 (-0.8 to -10.7)**
	60+	-21.2 (-66.5 to 24.1)	-23.8 (-57.1 to 9.5)	-21.0 (-46.4 to 4.4)	**-13.0 (-2.2 to -23.8)**	**-8.6 (-0.7 to -16.6)**	**-5.5 (-1.0 to -10.0)**
Number of chronic conditions	**0**	-11.9 (-11.9 to -11.9)	-25.1 (-57.8 to 7.7)	-22.3 (-52.8 to 8.2)	**-20.5 (-3.8 to -37.1)**	**-14.5 (-3.8 to -25.1)**	-4.1 (-9.9 to 1.6)
	1+	-18.8 (-52.2 to 14.5)	-23.0 (-49.8 to 3.7)	-19.2 (-43.3 to 4.8)	-14.6 (-31.4 to 2.2)	**-9.4 (-2.3 to -16.4)**	**-4.5 (-0.8 to -8.2)**
Townsend Index of Deprivation	**Least deprived**	-7.5 (-62.3 to 47.4)	-14.9 (-54.2 to 24.3)	-14.6 (-39.5 to 10.3)	**-13.1 (-1.1 to -25.0)**	**-10.3 (-4.4 to -16.1)**	**-7.1 (-2.0 to -12.1)**
	Quintile 2	-5.8 (-43.9 to 32.4)	**-24.2 (-3.0 to -45.4)**	**-25.6 (-6.2 to -44.9)**	**-22.3 (-15.3 to -29.3)**	**-14.4 (-9.0 to -19.7)**	**-8.3 (-3.4 to -13.3)**
	Quintile 3	6.2 (-22.6 to 35.1)	-3.8 (-15.1 to 7.5)	-5.7 (-15.8 to 4.4)	-5.4 (-13.7 to 3.0)	**-7.0 (-1.2 to -12.8)**	-1.2 (-3.9 to 1.4)
	Quintile 4	13.2 (-57.4 to 83.7)	-5.3 (-24.1 to 13.5)	-8.8 (-23.8 to 6.2)	**-10.3 (-2.7 to -17.9)**	**-8.2 (-3.2 to -13.1)**	**-2.9 (-0.0 to -5.9)**
	Most deprived	**-30.6 (-6.4 to -54.8)**	**-33.3 (-14.9 to -51.8)**	**-26.0 (-15.1 to -36.9)**	**-19.0 (-12.9 to -25.0)**	**-12.3 (-9.0 to -15.7)**	**-6.2 (-1.7 to -10.7)**
	Missing	-16.3 (-58.3 to 25.6)	-19.9 (-52.6 to 12.8)	-14.5 (-39.1 to 10.1)	-8.1 (-18.8 to 2.7)	**-6.1 (-2.6 to -9.5)**	**-3.4 (-2.3 to -4.6)**

6.3.2.1. Changes in prescribing before the introduction of smokefree legislation

A significant increase in the rate of prescribing of bupropion was seen up to nine months before the introduction of smokefree legislation in men, but only two months before in women. Increases in prescribing before the introduction of legislation were detected only in patients between the ages of 25 and 59. An increased rate of prescribing was seen up to six months pre-legislation in patients with no history of chronic disease, though no significant changes were estimated in any pre-ban intervention period for patients with one or more chronic conditions. A significant increase in the rate of bupropion prescribing was detected in the third Townsend quintile up to two months before the introduction of smokefree legislation, and in the two least deprived quintiles in the nine month pre-legislation intervention period, though no change was seen in the population as a whole in this time period.

6.3.2.2. Changes in prescribing after the introduction of smokefree legislation

A decline in bupropion prescribing after the introduction of smokefree legislation occurred in both men and women. Contrary to the pattern seen in analysis of rates of NRT prescribing, the decrease in bupropion prescribing may have been greater in men than women, though the confidence intervals around these estimates again overlap. Between two and three months post-legislation declines in bupropion prescribing were detected only in patients aged 35 to 59. However, the decline extended to patients aged 20-24 and 60+ six to nine months post-ban, and were also sustained to the end of the study period in these groups. A decline in prescribing was seen in patients with no history of chronic disease between six and nine months after the introduction of smokefree legislation, and in patients with one or more chronic conditions from nine months post-ban to the end of the study period. The magnitude of decline may have been smaller in patients with a history of chronic disease, though the confidence intervals do

overlap. A decline in the rate of bupropion prescribing was seen in the most deprived Townsend quintile immediately after the introduction of legislation, though declines of a similar magnitude were also seen across all Townsend quintiles in the nine month period post-ban. Permanent declines in bupropion prescribing, sustained to the end of the study period, are seen in all but the third quintile.

6.3.3. Prescribing of all smoking cessation medications

In all patients in England, increases in the rate of prescribing of all smoking cessation medications were seen extending up to nine months before the introduction of smokefree legislation, compared to the six and three month pre-legislation increases seen in NRT and bupropion prescribing respectively. Significant declines in the rate of prescribing of all smoking-cessation medications were seen for the three and nine month periods after the introduction of smokefree legislation, though this decline was not sustained to the end of the study period.

Figure 6.7 shows rates of prescribing of all smoking cessation medications by patient sex and whether they have a history of one or more chronic conditions. The patterns seen in the prescribing of all smoking cessation medications are similar to those observed in rates of NRT prescribing. The rate of prescribing of all smoking cessation medications in women is higher, though more variable, than that in men, and is also higher but more variable in patients with a history of one or more chronic conditions compared to those without. In all subgroups there is no obvious decline in prescribing after the introduction of smokefree legislation, though the monthly variation in the series does seem to reduce.

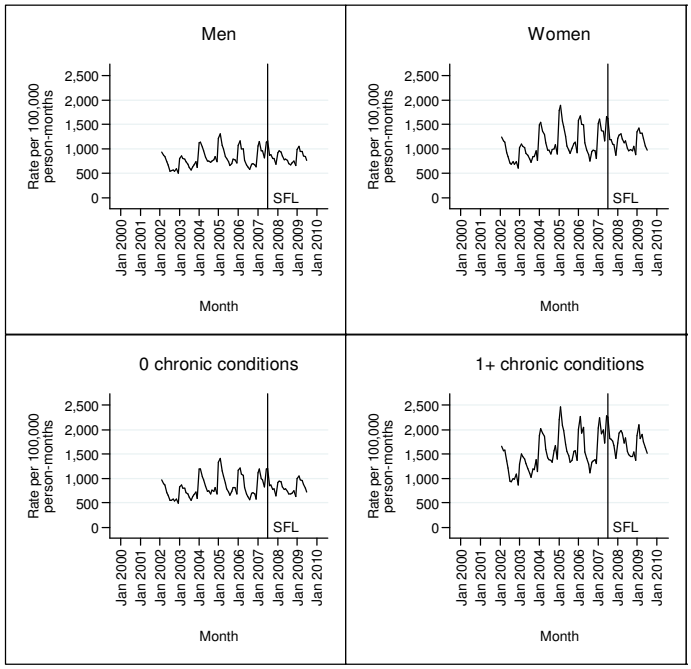


Figure 6.7 Rates of prescribing of all smoking cessation medications in England by sex and medical history

Figure 6.8 shows rates of prescribing of all smoking cessation medications by patient age group.

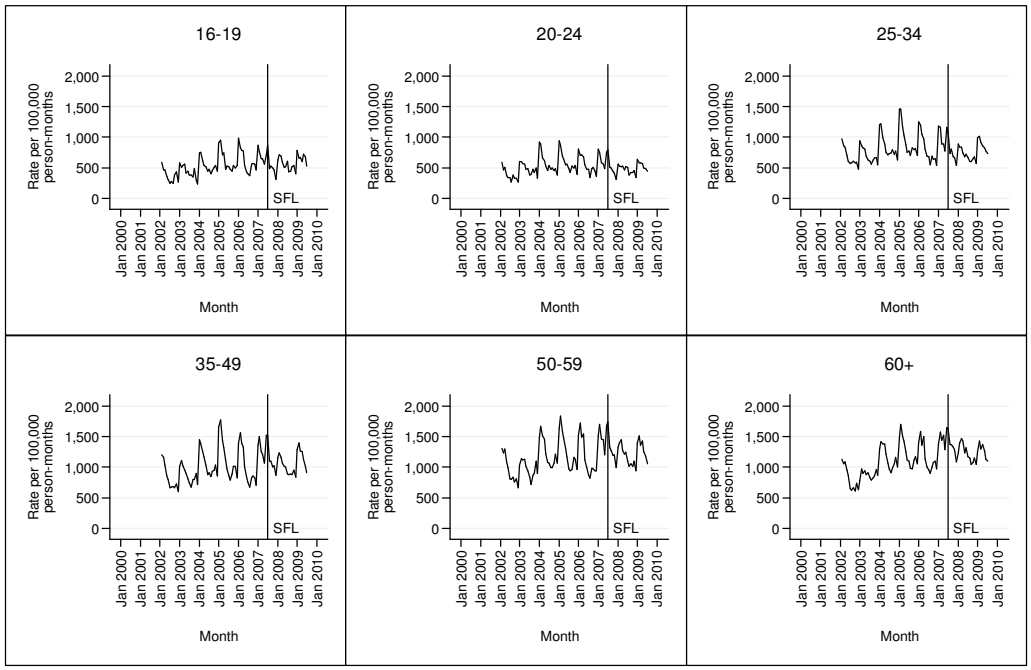


Figure 6.8 Rates of prescribing of all smoking cessation medications in England by age group

The rate of prescribing of all smoking cessation medications in all six age groups shows a regular seasonal pattern across the study period. The overall rate of prescribing is lowest in the two youngest age groups, though these groups also show the smallest variation in prescribing from one month to the next. In all age groups there appears to be an increase in prescribing in the month immediately before the introduction of smokefree legislation, though it is hard to tell whether any increase is outside of the normal behaviour of the series. The rate of prescribing does not appear to change substantially in any age group after the introduction of smokefree legislation.

Figure 6.9 shows rates of prescribing of all smoking cessation medications by quintile of the Townsend Index of Deprivation.

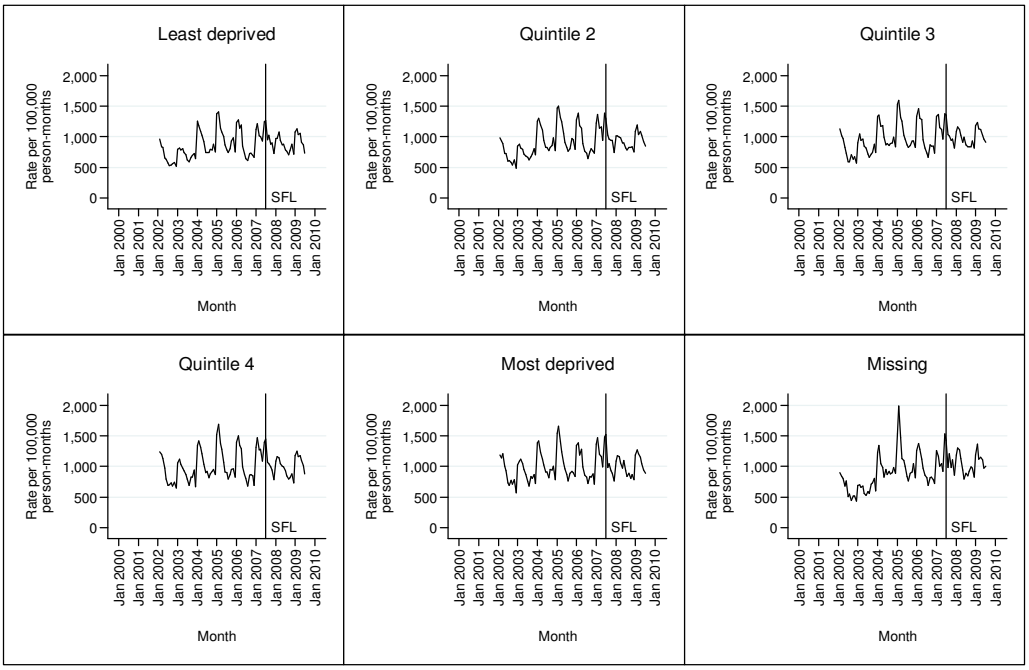


Figure 6.9 Rates of prescribing of all smoking cessation medications in England by quintile of the Townsend Index of Deprivation

All series show monthly variation in the rate of prescribing of all smoking cessation medications, though, as was seen in NRT prescribing, this seasonal pattern is less regular in patients whose Townsend classification is missing in their THIN records. The rate of prescribing is very similar in all Townsend quintiles, and

in all groups of patients there are no immediately obvious declines in prescribing after the introduction of smokefree legislation.

Table 6.6 shows the estimates of changes in all prescribing before the introduction of smokefree legislation for each population subgroup, and Table 6.7 presents the estimates for changes in all prescribing in the intervention periods after the introduction of smokefree legislation.

Table 6.6 Changes in all prescribing in England before the introduction of smokefree legislation

	Subgroup	2007 Q1	1 month before	2 months before	3 months before	6 months before	9 months before
All patients	**England**	2.0 (-18.6 to 22.7)	**22.3 (17.9 to 26.8)**	**14.7 (10.4 to 19.1)**	**9.9 (5.2 to 14.6)**	**11.1 (5.5 to 16.7)**	**6.4 (0.7 to 12.1)**
Gender	**Men**	2.5 (-17.7 to 22.8)	**22.1 (17.3 to 26.9)**	**20.9 (15.8 to 26.1)**	**13.8 (8.5 to 19.2)**	**11.0 (5.3 to 16.8)**	**6.3 (0.5 to 12.0)**
	Women	-3.6 (-9.7 to 2.4)	**22.1 (17.5 to 26.7)**	**14.1 (9.8 to 18.3)**	**9.7 (5.1 to 14.3)**	3.6 (-0.1 to 7.2)	**6.6 (0.5 to 12.7)**
Age group	**16-19**	1.5 (-23.1 to 26.1)	34.1 (-8.1 to 76.3)	23.4 (-5.1 to 51.9)	14.7 (-0.9 to 30.2)	7.0 (-2.8 to 16.8)	1.5 (-6.9 to 9.9)
	20-24	-2.7 (-22.7 to 17.4)	**41.2 (19.4 to 63.0)**	**22.7 (13.1 to 32.3)**	**15.4 (7.3 to 23.5)**	6.2 (-1.1 to 13.4)	2.9 (-3.7 to 9.6)
	25-34	-2.0 (-10.3 to 6.4)	**27.5 (21.8 to 33.3)**	**20.4 (14.2 to 26.6)**	**12.2 (6.3 to 18.1)**	**5.6 (0.6 to 10.6)**	3.0 (-2.3 to 8.2)
	35-49	-3.8 (-10.6 to 3.0)	**21.7 (16.4 to 27.0)**	**14.8 (9.8 to 19.8)**	**10.5 (5.2 to 15.7)**	3.8 (-0.1 to 7.8)	1.8 (-2.0 to 5.6)
	50-59	-2.7 (-11.6 to 6.2)	**21.5 (16.1 to 26.8)**	**13.0 (7.8 to 18.3)**	**7.9 (3.0 to 12.8)**	2.7 (-2.0 to 7.4)	3.0 (-3.0 to 9.0)
	60+	4.6 (-37.1 to 46.4)	**31.6 (13.7 to 49.5)**	**19.5 (12.9 to 26.0)**	**11.9 (6.0 to 17.8)**	**9.6 (3.5 to 15.7)**	5.2 (-0.9 to 11.3)
Number of chronic conditions	**0**	-2.8 (-9.3 to 3.8)	**21.0 (16.7 to 25.4)**	**13.9 (9.4 to 18.3)**	**9.3 (4.3 to 14.3)**	3.6 (-0.5 to 7.6)	**6.8 (0.6 to 13.0)**
	1+	1.5 (-29.0 to 32.0)	**22.9 (16.1 to 29.7)**	**25.4 (15.8 to 35.0)**	**16.2 (10.3 to 22.2)**	**8.7 (3.0 to 14.3)**	**5.7 (0.1 to 11.3)**
Townsend Index of Deprivation	**Least deprived**	0.5 (-41.6 to 42.7)	**37.8 (20.8 to 54.8)**	**24.9 (16.0 to 33.9)**	**15.4 (9.0 to 21.8)**	**11.3 (4.2 to 18.4)**	**7.2 (0.6 to 13.8)**
	Quintile 2	1.9 (-53.5 to 57.3)	**31.4 (23.8 to 38.9)**	**29.2 (22.7 to 35.7)**	**20.7 (14.5 to 26.9)**	**11.2 (4.8 to 17.5)**	**7.4 (1.5 to 13.3)**
	Quintile 3	-0.4 (-18.3 to 17.6)	**38.1 (24.2 to 52.0)**	**15.9 (10.9 to 20.9)**	**10.2 (5.0 to 15.4)**	**10.7 (4.7 to 16.7)**	5.7 (-0.7 to 12.0)
	Quintile 4	-1.5 (-8.8 to 5.8)	**19.7 (13.7 to 25.7)**	**17.0 (11.7 to 22.2)**	**14.0 (9.1 to 18.8)**	**4.6 (0.9 to 8.4)**	1.8 (-1.9 to 5.5)
	Most deprived	-1.9 (-11.4 to 7.5)	**30.7 (23.3 to 38.2)**	**19.7 (14.1 to 25.3)**	**10.4 (5.6 to 15.1)**	**4.5 (0.0 to 9.1)**	**6.1 (0.8 to 11.4)**
	Missing	-3.8 (-22.6 to 14.9)	**34.0 (20.7 to 47.4)**	**13.9 (4.3 to 23.6)**	**14.8 (5.7 to 23.9)**	5.4 (-2.4 to 13.3)	1.6 (-6.2 to 9.4)

Table 6.7 Changes in all prescribing in England after the introduction of smokefree legislation

	Subgroup	1 month after	2 months after	3 months after	6 months after	9 months after	Step change
All patients	**England**	7.7 (-13.0 to 28.4)	-5.3 (-17.2 to 6.7)	**-10.0 (-0.2 to -19.9)**	-7.4 (-16.3 to 1.5)	**-6.4 (-1.1 to -11.7)**	-2.2 (-5.6 to 1.2)
Gender	**Men**	5.9 (-32.3 to 44.1)	-3.1 (-10.5 to 4.3)	-6.6 (-13.6 to 0.5)	-5.0 (-11.0 to 1.0)	-4.1 (-8.5 to 0.3)	-1.7 (-4.6 to 1.1)
	Women	3.6 (-9.7 to 2.4)	-3.9 (-18.5 to 10.8)	-10.1 (-20.5 to 0.4)	-7.5 (-17.0 to 2.1)	**-6.5 (-1.0 to -12.0)**	-2.2 (-5.8 to 1.3)
Age group	**16-19**	18.7 (-18.5 to 55.9)	-8.2 (-21.3 to 5.0)	-5.9 (-13.8 to 2.1)	-3.2 (-6.6 to 0.3)	-1.7 (-4.5 to 1.2)	-1.4 (-5.4 to 2.7)
	20-24	13.0 (-4.4 to 30.4)	6.1 (-3.1 to 15.3)	2.7 (-5.7 to 11.2)	1.3 (-3.5 to 6.1)	1.0 (-2.4 to 4.3)	0.6 (-1.1 to 2.2)
	25-34	7.2 (-39.2 to 53.6)	-10.9 (-51.0 to 29.2)	-12.4 (-48.1 to 23.3)	-8.6 (-31.1 to 14.0)	-6.4 (-13.8 to 1.0)	-1.7 (-6.0 to 2.5)
	35-49	10.2 (-72.8 to 93.0)	-4.9 (-18.7 to 8.8)	-10.5 (-21.9 to 1.0)	-6.3 (-16.1 to 3.5)	**-7.4 (-1.3 to -13.6)**	-2.3 (-6.3 to 1.8)
	50-59	5.9 (-7.3 to 19.0)	-1.4 (-7.8 to 4.9)	-3.5 (-9.4 to 2.5)	-4.2 (-9.8 to 1.4)	-3.9 (-8.3 to 0.6)	-1.0 (-4.3 to 2.4)
	60+	10.3 (-8.0 to 28.6)	-3.7 (-21.2 to 13.9)	-6.1 (-21.3 to 9.1)	-6.4 (-20.2 to 7.4)	-5.2 (-11.4 to 0.9)	-2.2 (-5.7 to 1.3)
Number of chronic conditions	**0**	17.5 (-13.5 to 48.4)	-7.7 (-19.7 to 4.3)	**-11.8 (-1.2 to -22.4)**	-7.7 (-16.6 to 1.2)	**-7.0 (-1.1 to -12.8)**	-2.3 (-6.0 to 1.5)
	1+	8.1 (-8.8 to 25.0)	0.5 (-18.2 to 19.3)	-5.7 (-16.2 to 4.7)	-6.6 (-16.6 to 3.3)	-5.0 (-10.2 to 0.3)	-2.0 (-5.3 to 1.3)
Townsend Index of Deprivation	**Least deprived**	8.7 (-32.1 to 49.6)	-2.5 (-12.4 to 7.5)	-5.9 (-15.3 to 3.6)	-5.2 (-12.8 to 2.4)	-3.8 (-9.4 to 1.8)	-2.1 (-5.7 to 1.5)
	Quintile 2	-1.8 (-82.5 to 89.0)	-6.0 (-69.2 to 57.1)	-11.9 (-29.0 to 5.2)	-9.7 (-20.4 to 0.9)	**-8.2 (-1.3 to -15.1)**	-2.2 (-6.1 to 1.7)
	Quintile 3	8.2 (-8.4 to 24.9)	-3.7 (-19.1 to 11.8)	**-12.5 (-3.2 to -21.8)**	-7.0 (-15.4 to 1.4)	**-6.1 (-0.4 to -11.8)**	-1.9 (-6.0 to 2.2)
	Quintile 4	6.1 (-41.4 to 53.5)	-1.0 (-11.6 to 9.6)	-7.7 (-16.1 to 0.6)	-4.9 (-12.4 to 2.5)	-5.0 (-10.1 to 0.1)	-2.0 (-4.9 to 1.0)
	Most deprived	21.3 (-42.3 to 85.0)	-11.5 (-23.1 to 0.1)	-10.6 (-22.1 to 0.9)	-7.9 (-17.8 to 2.1)	-6.4 (-12.9 to 0.1)	-2.3 (-6.4 to 1.8)
	Missing	11.7 (-51.7 to 75.1)	0.5 (-16.4 to 17.5)	0.1 (-16.5 to 16.7)	-2.1 (-15.1 to 10.9)	-1.7 (-12.9 to 9.5)	-1.2 (-6.5 to 4.1)

6.3.3.1. Changes in prescribing before the introduction of smokefree legislation

The majority of all smoking-cessation medication prescribing is for NRT, and so the patterns of change in all prescribing before the introduction of smokefree legislation presented in Table 6.7 are very similar to those seen in NRT prescribing. Increases in all prescribing are seen in all subgroups up to three months before legislation was enacted, with the exception of the youngest age group, and in many subgroups for the six and nine month pre-ban periods. Overlapping confidence intervals suggest the magnitude of the increase in prescribing was similar in men and women and across age groups. Increases in all prescribing were also seen in both patients with and without a history of chronic disease. The increase in prescribing may have been larger in patients with one or more chronic conditions; again, however, the confidence intervals around these point estimates overlap. Increases in prescribing were seen in all quintiles of the Townsend Index of Deprivation. The overlapping confidence intervals suggest that smokefree legislation had no differential impact on prescribing according to patient socio-economic group.

6.3.3.2. Changes in prescribing after the introduction of smokefree legislation

Significant declines in all prescribing are detected in very few population subgroups after the introduction of smokefree legislation. In the three month period post-legislation a decline in all prescribing was estimated to have occurred in the population as a whole, though the estimates of decline just fail to reach statistical significance when men and women are analysed separately. A significant decline in all prescribing is seen in women for the nine month period after the introduction of smokefree legislation, though the estimate of decline in men is only marginally non-significant. A decline in all prescribing is seen in patients aged 35-49 in the nine month post-legislation period, but not in the other age groups. A significant decline in all prescribing is seen only in patients without

a history of chronic disease. Reductions in the rate of all prescribing are detected only in Townsend quintiles two and three, though in many other groups the estimates of change only marginally fail to reach statistical significance.

6.4. DISCUSSION

The results presented in this chapter suggest that there were similar changes in the prescribing of smoking cessation medications in different subgroups of the population before and after the introduction of smokefree legislation in England, and that the introduction of legislation did not have a differential effect on prescribing to patients with different characteristics.

Increases in the prescribing of NRT and all smoking cessation medications before the smoking ban was enacted were seen in both men and women, in all age groups (except 16-19 year olds in the case of all prescribing), in patients both with and without a history of chronic disease, and in all quintiles of the Townsend Index of Deprivation. Increases in the rate of prescribing of bupropion were also seen in both sexes, though significant changes were not detected in patients with a history of chronic disease, nor in the youngest and oldest age groups or most deprived Townsend quintiles.

After the introduction of smokefree legislation declines in the rate of prescribing of NRT and bupropion were seen in both men and women. A decline in NRT prescribing was detected in all but the youngest and oldest age groups, and declines in bupropion prescribing were seen in patients over the age of 20, though there was no significant change amongst those aged 16-19. Declines in the rate of prescribing of NRT and bupropion appear first in patients with no history of chronic disease and in patients in the most deprived Townsend quintiles, before extending to include those with one or more chronic conditions and less deprived groups.

6.4.1. Strengths of study

To my knowledge, this study is the first to use data from primary care to assess the impact of smokefree legislation on the management of smoking in different population subgroups. The large size of the THIN dataset allows the population to be broken down into smaller groups whilst, on the whole, preserving statistical power to detect small changes in prescribing.

As in the previous analysis of data from all patients in each of the four jurisdictions of the UK, the results of these subgroup analyses are strengthened by the use of ARIMA modelling which is able to filter out any secular trends and seasonal variation in prescribing to assess whether there were any changes in the outcome variables above and beyond the normal behaviour of the series that may be associated with the introduction of smokefree legislation.

6.4.2. Limitations of study

The current study is, however, hampered by the two same problems identified in the previous chapter, namely the difficulty in attributing any changes in prescribing to smokefree legislation and a lack of power to detect small changes in the outcome variables in some subgroups. It is likely that these issues explain many of the patterns observed in the results, as will now be discussed.

Declines in bupropion prescribing in many subgroups were sustained to the end of the study period. However, there were no permanent changes in the prescribing of NRT or all smoking cessation medications despite having adequate power to detect relatively small changes in these series. As noted previously, a new aid to smoking cessation, varenicline, became available on NHS prescription in December 2006 and in July 2007 NICE issued guidelines recommending GPs

prescribe it to smokers who wish to quit. It is possible that prescribing of varenicline compensated for the permanent decline in bupropion prescribing in these subgroups, with the result that there was no overall permanent change in the rate of prescribing of all smoking cessation medications. Thus, it is difficult to attribute any changes detected in an outcome variable to an intervention such as the introduction of smokefree legislation when, at the same time, other changes are taking place which may have an impact on the series.

A lack of statistical power may explain the failure to detect an increase in all prescribing pre-legislation in smokers aged 16-19, as well as explain the no change observed in bupropion prescribing in teenagers either before or after the smoking ban was enacted. As Figure 6.8 illustrates, the rate of all prescribing was lower in the two youngest age groups than in other ages, which will reduce the power of an ARIMA model to detect small changes in prescribing in younger patients. There is a less obvious seasonal pattern in bupropion prescribing than is seen in NRT and all prescribing, and this, combined with the overall low prescribing of bupropion in patients aged 16-19, makes it difficult to detect small changes in bupropion prescribing in this subgroup.

Table 6.8 shows the minimum effect size which the ARIMA models were powered to detect in NRT, bupropion and all prescribing in each subgroup six months before the introduction of smokefree legislation. In addition, the effect sizes estimated to have occurred in each series are shown.

Table 6.8 The power to detect statistically significant changes in NRT, bupropion and all prescribing six months before the introduction of smokefree legislation, by subgroup

	NRT prescribing		Bupropion prescribing		All prescribing	
Series	Estimate observed in series (95% CI)	Minimum effect detectable with 80% power	Estimate observed in series (95% CI)	Minimum effect detectable with 80% power	Estimate observed in series (95% CI)	Minimum effect detectable with 80% power
All patients	**6.2 (1.4 to 11.0)**	**7.0**	7.1 (-0.4 to 14.5)	10.6	**11.1 (5.5 to 16.7)**	**7.8**
Men	**7.0 (1.5 to 12.6)**	**7.8**	**10.0 (2.9 to 17.1)**	**10.0**	**11.0 (5.3 to 16.8)**	**8.1**
Women	**6.0 (1.1 to 10.9)**	**7.0**	4.6 (-1.3 to 10.5)	8.4	3.6 (-0.1 to 7.2)	5.3
16-19	5.9 (-5.0 to 16.9)	15.6	5.2 (-8.3 to 18.6)	19.3	7.0 (-2.8 to 16.8)	14.0
20-24	4.1 (-2.9 to 11.1)	10.0	6.1 (-7.9 to 20.1)	20.1	6.2 (-1.1 to 13.4)	10.3
25-34	**9.6 (3.2 to 16.1)**	**9.2**	5.8 (-3.3 to 14.8)	12.8	**5.6 (0.6 to 10.6)**	**7.3**
35-49	**6.0 (0.9 to 11.1)**	**7.3**	**11.1 (3.2 to 19.0)**	**11.2**	3.8 (-0.1 to 7.8)	5.6
50-59	**5.9 (0.4 to 11.4)**	**7.8**	6.8 (-2.6 to 16.1)	13.4	2.7 (-2.0 to 7.4)	6.7
60+	5.8 (-0.3 to 11.9)	8.6	8.2 (-10.3 to 26.6)	26.2	**9.6 (3.5 to 15.7)**	**8.6**
0 chronic conditions	**6.6 (1.4 to 11.8)**	**7.5**	**11.8 (0.9 to 22.6)**	**15.3**	3.6 (-0.5 to 7.6)	5.9
1+ chronic conditions	**6.1 (1.5 to 10.8)**	**6.7**	5.9 (-3.5 to 15.4)	13.4	**8.7 (3.0 to 14.3)**	**8.1**
Least deprived	**8.1 (2.1 to 14.2)**	**8.6**	10.3 (-0.3 to 20.9)	15.1	**11.3 (4.2 to 18.4)**	**10.0**
Quintile 2	**6.9 (1.8 to 12.0)**	**7.3**	9.1 (-0.8 to 19.0)	14.2	**11.2 (4.8 to 17.5)**	**8.9**
Quintile 3	**5.7 (0.1 to 11.4)**	**8.1**	1.4 (-7.0 to 9.8)	12.0	**10.7 (4.7 to 16.7)**	**8.6**
Quintile 4	**7.3 (2.3 to 12.4)**	**7.3**	4.0 (-6.6 to 14.6)	15.1	**4.6 (0.9 to 8.4)**	**5.3**
Most deprived	2.5 (-2.4 to 7.4)	7.0	6.0 (-6.1 to 18.2)	17.3	**4.5 (0.0 to 9.1)**	**6.4**
Missing	1.4 (-8.2 to 11.1)	7.0	4.7 (-4.2 to 13.7)	12.8	5.4 (-2.4 to 13.3)	11.2

Figures highlighted in bold are statistically significant at the 5% significance level

As Table 6.8 shows, ARIMA modelling was only powered to detect a 15.6% change in NRT prescribing in smokers aged 16-19 six months before smokefree legislation was introduced, a larger minimum detectable effect than was seen in any other subgroup for NRT prescribing. In every subgroup ARIMA modelling had less power to detect changes in bupropion prescribing compared to NRT, a reflection of the less obvious seasonal pattern and lower overall rate of prescribing of bupropion. Modelling was particularly underpowered to detect small changes in bupropion prescribing in the oldest and two youngest age groups.

A similar lack of power may explain the failure to detect significant changes in prescribing in patients with a history of one or more chronic conditions when a

significant change has been detected in healthy patients. As Figure 2.3 showed, smoking prevalence is lower in patients in THIN with chronic conditions than in otherwise healthy patients, resulting in a smaller denominator of smokers with chronic conditions in whom to assess prescribing. This is likely to result in more variable monthly rates of prescribing and hence lower power to detect small changes that may be associated with the introduction of smokefree legislation. Similarly, smoking prevalence in THIN is lower in patients in the least deprived Townsend quintile, resulting in fewer smokers and less power to detect changes in prescribing in this group.

Using primary care data to investigate differential impacts of smokefree legislation is complicated by the knowledge that underlying rates of smoking-related clinical activity vary according to patient characteristics, as outlined in Section 1.1.1, and patients with different characteristics also visit their GPs with different frequencies[13]. For each group of patients there is likely to be a 'natural' maximum rate of prescribing each month, driven by the frequency with which patients visit their GP and the likelihood of GPs intervening to offer smoking cessation support. In some cases, no increase in cessation activity before or after the introduction of smokefree legislation may be seen because GPs are already intervening at this maximum rate. For example, the introduction of smokefree legislation may be expected to have a different effect on patients according to their medical history. Underlying prescribing rates are higher in those with chronic conditions[85], many of which are smoking-related, and therefore a smaller or no increase in prescribing when smokefree legislation is introduced might be expected in this subgroup. Assessing changes in prescribing in all smokers registered in THIN each month, regardless of whether they have actually visited their GP surgery, allows changes in the number of patients who visit their GP, perhaps prompted by smokefree legislation to seek cessation support, to be captured, as well as changes in the rate at which GPs offer interventions to smokers. Modelling monthly rates of

prescribing in patients who have visited their GP in the month in question would allow assessment of the potential impact of smokefree legislation purely on GPs clinical practice. However, it is very difficult to identify individual patient visits to a practice in THIN (though steps have been taken in the most recent update of the database to address this), and this would further reduce the number of smokers included in the denominator each month and hence further compromise the power to detect small changes in the outcome variables.

This study has only assessed changes in prescribing in population subgroups defined by a single characteristic, though it is arguably important to assess whether there are any interactions between different patient characteristics to assess whether there was a differential impact of smokefree legislation in more-specific groups of patients. For example, the underlying rate at which GPs intervene with smokers may be lower in young men, who visit a GP less frequently, compared to young women, and thus the impact of smokefree legislation may differ between these groups. Unfortunately, however, the lack of power demonstrated in the youngest age group and patients with one or more chronic conditions is likely to be compounded by further subdividing these patients according to other characteristics. In addition, as discussed in the previous chapter, one in twenty ARIMA models can be expected to produce a statistically significant estimate of a change in the outcome variable at the 5% significance level, and thus the results of multiple hypothesis testing should be interpreted with caution. However, as noted previously, the strength of the ARIMA study design and plausibility of the results can be taken to support the significance of the findings reported here[165].

6.5. CONCLUSIONS

This study suggests that the changes in prescribing of smoking cessation medications in primary care reported in all patients in the previous chapter do not differ by patient sex, age group, medical history and social class, though a lack of power to detect small changes in prescribing hampers analysis in some subgroups. Reassuringly, these results do not imply that smokefree policies will widen inequalities in health as the benefit of increased prescribing before the introduction of smokefree legislation does not appear to be concentrated in the most advantaged socioeconomic groups. However, as smokefree legislation appears to have had a similar effect across all subgroups investigated this suggests that it may not be effective in reducing the inequalities in health caused by smoking.

7. SUMMARY CONCLUSIONS AND DIRECTIONS FOR FUTURE RESEARCH

7.1. SUMMARY OF FINDINGS

Smokefree policies have been introduced in many locations worldwide and have been successful in reducing non-smokers' exposure to environmental tobacco smoke. In addition, the limited body of existing research reviewed systematically in Chapter 1 suggests that in populations where well-enforced, comprehensive smokefree policies have been implemented, quitting activity in smokers increased in the run up to, and/or following, the introduction of the legislation, suggesting that smoking bans may also have a positive effect on smokers.

The Health Improvement Network (THIN) database was introduced as a source of data which could potentially be used to monitor the impact of smokefree legislation on the management of smoking in primary care to assess whether this was a pathway through which legislation helped smokers to make positive changes in their smoking behaviour. Overall, the work presented in this thesis suggests that THIN is a valid tool to evaluate the effectiveness of tobacco control policies, such as smokefree legislation, providing data that cannot easily be collected from such a large number of patients using survey methods.

Historically, many patients did not have their smoking status recorded in their primary care medical records, and the ability to identify current smokers from their notes was poor. Chapter 2 showed improvements in recent years in these measures; the proportion of patients whose smoking status is recorded in their medical records has increased to almost 90% in 2009, and the prevalence of current smoking amongst THIN patients has converged towards the prevalence

estimated from the General Lifestyle Survey, the current 'gold standard' source of smoking prevalence statistics. There does, however, remain some variation in the quality of smoking status recording in THIN between some population subgroups and individual practices.

THIN data are also useful to investigate changes in the prescribing of smoking cessation medications as a record of all issued prescriptions appears automatically in the dataset. However, the dataset may be less useful to investigate changes in the recording of advice and referral as recorded rates may not be a true reflection of the number of smokers offered these cessation interventions. The findings presented in Section 3.4 suggest that the introduction of the QOF in 2004 may have prompted increased recording of cessation advice though perhaps not an increase in the amount of advice actually offered to smokers. There are no incentives for GPs to record having referred smokers to specialist cessation services, and the low rates of referral recording seen in primary care records may not be a true reflection of the actual number of smokers referred to specialist services for help to quit. With the proviso that recorded cessation advice and referral may not indicate the actual delivery of a cessation intervention, and that a prescription for a smoking cessation medication does necessarily mean the medication was used for quitting, the THIN dataset offers the chance to quantify long-term trends in the management of smoking in primary care and assess whether there were any changes in clinical activity above and beyond these trends at the time smokefree legislation was introduced.

Chapter 4 outlined the use of ARIMA modelling to assess the impact of smokefree legislation on monthly recorded rates of smoking-related clinical activity in the THIN dataset, and the results of a number of novel sensitivity analyses were presented discussing the implications of decisions made during the data analysis process. An automated procedure was developed for the Stata data management

and statistical analysis package which allows several ARIMA models to be estimated and their adequacy to be assessed. In addition, the command allows the analyst to judge whether the selection of different ARIMA models to describe a time series ultimately leads to different conclusions regarding the impact of an intervention on the outcome under investigation. This procedure was then applied to investigate changes in the rates of recording of patients' smoking status and the delivery of cessation interventions in the months leading up to, and after, the introduction of smokefree legislation in the UK.

Increases in NRT prescribing occurred in the six months before smokefree legislation was introduced in England, and increases in bupropion prescribing three months pre-ban, followed by declines in the rate of prescribing of both medications up to nine months after the legislation was enacted. These declines were offset to an extent, but not completely, by prescribing of varenicline which was first available on prescription in December 2006. Similar, though non-statistically significant, patterns were seen in Scotland, Wales and Northern Ireland, where the smaller number of practices in THIN in these countries reduced the power to detect small changes in prescribing. In England, the patterns of change in prescribing do not differ by patient sex, age group, medical history or social class.

Some decreases in the rate of recording of patients' smoking status were seen in all UK countries shortly before and/or after the introduction of smokefree legislation, though these may not be related to the introduction of smokefree legislation. No statistically significant changes were observed in any part of the UK in either the rate of recording of cessation advice or referral of smokers to stop smoking services.

7.2. IMPLICATIONS OF FINDINGS AND AVENUES FOR FURTHER RESEARCH

The implications of the findings presented in this thesis, and the avenues for further research which arise from this work, can be broadly divided into three areas – those relating to the use of THIN, and primary care data more generally, for epidemiological and public health research, those concerning the methods that can be used to evaluate public health policies and those pertaining to the impacts of smokefree legislation. These will now be discussed in turn.

7.2.1. The use of THIN data for epidemiological and public health research

The demonstrated improvements in the quality of the smoking status data recorded in THIN, and comparability between the national smoking prevalence estimates from this dataset and those from the current 'gold standard', the General Lifestyle Survey, suggest that THIN could potentially be used to monitor national smoking trends. Further research demonstrating the continued concordance of THIN-recorded, GLF-predicted and actual GLF smoking prevalence estimates in future years would confirm the utility of THIN as a potential complement to national surveys. As THIN is so large, is released three or four times annually and has a lag of only three to eight months between clinical data becoming available, it has advantages over national survey data for monitoring national smoking prevalence. The standard error of the national smoking prevalence estimate derived from THIN is considerably smaller than that derived from the GLF and thus THIN can potentially provide more precise smoking prevalence estimates both nationally and at the level of Government Office Regions.

A major government-commissioned report in England, the Wanless report, has called for the organisations responsible for delivering community health services to make better use of data from primary care to help understand the prevalence of disease risk factors within their local populations[54]. Though THIN data are not identifiable at a geographical level finer than that of Government Office Regions, if the inter-practice variation in the quality of smoking data recording in THIN is representative of all UK practices, primary care data may not be suitable for local-level smoking prevalence estimation. Some practices may need support to optimise their recording of patients' smoking status before medical records data could be used for local estimates of smoking prevalence. However, once the quality of smoking status recording is deemed acceptable, primary care data may offer a less-costly means of monitoring smoking prevalence, both nationally and locally, than commissioned surveys.

A recurring issue in the studies undertaken to assess the quality of the smoking status and intervention recording in THIN is the variation in data quality between practices contributing to the dataset, despite a certain amount of auditing being undertaken before a practice joins the dataset to assess the quality of their data recording[170]. In THIN it is impossible to know whether extremely low or high estimates of smoking prevalence and recorded cessation interventions in some practices are simply a reflection of the characteristics of the patients they serve. A practice serving a very affluent area may be expected, for example, to have fewer smokers in their care and therefore to deliver fewer cessation interventions. Further work in THIN is recommended to explore the variations in smoking information recording by practice. One approach that could be used to assess whether an apparently low smoking prevalence is in fact correct may be to undertake a case-control study using THIN data to investigate whether the strength of association reported in other studies between smoking behaviour and an outcome such as lung cancer is replicated using the data recorded in that

practice. Alternatively, if the resources are available, a survey could be attempted to compare patients' self-reported smoking behaviour and recall of cessation interventions with those recorded in their medical records, though such methods are subject to the limitations outlined in Section 1.9.1.

The large size of the THIN dataset may provide an opportunity to quantify accurately smoking behaviour in particular groups of patients for whom data are currently lacking. The prevalence of smoking by women during pregnancy is currently measured only every five years using a national survey of approximately 20,000 mothers[171]. In 2005, 33% of mothers reported smoking at some point before or during their pregnancy, and 17% reported smoking throughout pregnancy. Given the highly detrimental effects of smoking during pregnancy[172], a more accurate, up-to-date knowledge of the extent of this behaviour is surely an important first step in planning and delivering heath services and health promotion interventions to reduce the number of women who smoke whilst pregnant. Further work to assess whether the quality of smoking status information recorded during pregnancy has improved in line with the improvements demonstrated in the population as a whole would be useful to assess whether THIN could be used for this purpose.

This study assessed the impact of smokefree legislation in a limited number of population subgroups, though, given the number of patients in the THIN dataset and the amount of information potentially recorded about each person, THIN offers the opportunity to investigate the effect of a range of health promotion policies in a variety of different types of patient. Smoking prevalence is known to vary by ethnic group, and proportionally fewer smokers from minority groups attempt to quit smoking than smokers in the general population[173]. At present, few patients have their ethnicity recorded in THIN, though this may improve in the future as it is now a QOF requirement for practices to record the ethnic

background of all new patients registering with the practice. It is conceivable that practices may also record the ethnicity of their existing patients, and, as this is not a characteristic which changes over time, records can be back-dated to allow the classification of patients by ethnic group at the time smokefree legislation was introduced. It would be worthwhile monitoring the completeness of ethnicity recording in future updates of the THIN dataset to assess whether the completeness of recording improves to an extent that will allow exploration of the impact of smokefree legislation by ethnic group.

As mentioned previously, other datasets of primary care records are available in the UK, such as the General Practice Research Database[104] (GPRD) and QRESEARCH[105]. These datasets are similar to THIN (indeed, some practices historically contributed data to both the GPRD and THIN) and so it could be expected that the improvements in data quality presented in this thesis are also seen in the other datasets. The methods used here to investigate the quality of THIN data could equally be applied to GPRD and QRESEARCH data to enable researchers to understand and account for changes in smoking status and intervention data quality when undertaking studies investigating the impact of policies on these measures, or when using smoking information as an explanatory variable in other studies. Datasets of primary care records from other countries are also available to researchers[106], and similar methods to those employed here could be used to assess the completeness of smoking status recording and the utility of the data for monitoring national smoking prevalence in these countries and investigating the impact of health policies on the management of smoking in primary care.

7.2.2. Methods to evaluate public health policies

The recording of patients' smoking status and smoking cessation interventions in THIN show long-term trends and seasonal variation which must be taken into account when assessing whether there were any changes in recording at the time smokefree legislation was introduced. The majority of the studies reviewed in Section 1.6 simply compared data from one or two surveys carried out before and after smokefree legislation was enacted, thus failing to capture and remove the confounding effects of underlying patterns of behaviour when investigating the impact of the smoking ban. The technique of interrupted time series analysis used in this thesis has proved a useful method to assess changes in measures of smoking-related clinical activity in primary care at the time smokefree legislation was introduced, taking into account long term trends and seasonal variation in the outcome variables and thus strengthening the conclusions drawn about the impact of legislation. ARIMA modelling could potentially be employed in evaluations of other health promotion policies using THIN data, or indeed using longitudinal data from other sources.

The automated method developed in this thesis to aid ARIMA model selection removes the degree of judgement involved in selecting a model to represent a time series; its use is recommended for other studies undertaking interrupted time series analysis, particularly where multiple data series are being examined. This thesis presented a number of sensitivity analyses assessing the impacts of decisions which must be made during the process of using ARIMA modelling to carry out interrupted time series analysis. It is recommended that all analysts undertaking interrupted time series analysis carry out a range of sensitivity analyses to improve the confidence they hold in their results and conclusions, and report the findings of these analyses when writing up results for publication.

The longitudinal nature of the THIN dataset means this study benefited from up to 115 monthly data points for each time series examined. However, data from other sources which could potentially be used to carry out interrupted time series analysis may not have the luxury of such a large number of data points. Further work is warranted to investigate how many data points are needed to successfully fit an ARIMA model to a time series and to assess the impact of an intervention on the outcome variable, and whether the length of the series which is analysed ultimately influences a study's results and conclusions.

A lack of power to detect small changes in a time series was encountered in the analyses presented in this thesis, particularly in assessing the impact of smokefree legislation in Scotland, Wales and Northern Ireland, and in subgroups of the population in England. Section 5.4 illustrated the wider confidence intervals around monthly measures of smoking-related clinical activity in Scotland, Wales and Northern Ireland, where there are relatively few THIN practices. However, despite the small number of practices, the number of smokers registered in THIN for whom data are available would be the envy of many experimental studies – in Scotland 48,880 smokers are registered in THIN on 1st July 2007, with 37,998 smokers in Wales and 23,917 in Northern Ireland (compared to 440,802 in England). This raises the question as to whether these patients' data could be used in alternative ways to assess the impacts of smokefree legislation on the management of smoking in primary care.

Interrupted time series analysis may not be the best way to study the impact of smokefree legislation in smaller groups of patients, in whom monthly rates of clinical activity will be more variable over time resulting in lower power to detect small changes in an outcome variable. Further research would be valuable to assess whether a group of individuals in THIN can be followed over time in a quasi-experimental design. For example, trajectories of smoking behaviour before

and after the introduction of smokefree legislation could be tracked to assess whether smokers who attempt to quit are offered an intervention to help them do so, and whether those who do succeed in quitting remain abstinent. However, the ability to undertake such an analysis requires patients to have their smoking status recorded frequently in their medical records, which in turn is dependent upon how frequently patients visit their GP or practice nurse. In patients with a history of chronic disease, their smoking status should be recorded every 15 months, potentially providing enough data to assess their smoking behaviour regularly and more power to investigate the impact of smokefree legislation on smoking behaviour than an interrupted time series analysis of aggregated rates of measures of clinical activity. A first stage in further work would be to assess just how frequently records of smoking status are updated and whether this varies by patient characteristic or practice.

7.2.3. Maximising the positive impacts of smokefree legislation

The findings presented in Chapters 5 and 6 allow conclusions to be drawn about the impact of smokefree legislation on smokers' behaviour, and recommendations to be made suggesting how any positive benefits of a new smoking ban might be maximised.

The significant increases in the rate of prescribing of NRT and bupropion seen in all population subgroups in England in the run-up to the introduction of smokefree legislation suggests that smokers looking to quit may indeed seek support to do so from primary care. This new finding suggests that further qualitative research may be of value to explore smokers' and health care professionals' behaviours and attitudes related to smokefree legislation, investigating whether smokers actively sought cessation support from their general practice or whether GPs saw the

introduction of the smoking ban as an opportunity to encourage smokers pro-actively to quit.

The declines in NRT and bupropion prescribing seen after the introduction of smokefree legislation, which were not totally offset by prescribing of varenicline, suggest that the positive changes in prescribing seen pre-legislation were not sustained. Interestingly, similar patterns are seen in throughput figures from the NHS smoking cessation services in England[174], Scotland[175] and Wales[176], where more smokers set quit dates or were treated in the months immediately before the introduction of smokefree legislation compared to other years, but there was no increase in the months after the smoking bans were enacted. Additionally, over-the-counter sales of NRT were increased in the six month period spanning the introduction of smokefree legislation in Scotland, but not in the longer term[43], and self-reported NRT use was higher in Scotland than in the rest of the UK six months before the introduction of the Scottish legislation, and declined more post-ban[44].

In England, the Department of Health gave local councils £29.5 million to help raise awareness about the impending smokefree legislation, and in some areas, such as the London Borough of Greenwich, campaigns were launched to encourage people to quit before the legislation was enacted[177]. However, it is known that many quit attempts do not succeed, and many long-term smokers have tried to quit several times[178-180]. As quitting is difficult and smokers may benefit from sustained cessation support over a long period of time, an opportunity may have been missed to maximise the impact of smokefree legislation. If campaigns such as that in place in Greenwich had been extended after smokefree legislation was introduced this may have ensured that smokers were reminded of the support available through primary care to help them quit at this time and measures of quitting activity might not have declined.

Reassuringly, the results presented in this thesis show that the benefits of increased prescribing of smoking cessation medications in the run-up to the introduction of smokefree legislation are not concentrated in particular population subgroups and are therefore not likely to widen inequalities in health. However, the similar change in prescribing observed across subgroups suggests that smokefree legislation may not be effective in reducing such inequalities either. Further work would be of benefit to understand whether any other public health interventions, such as media campaigns promoting the cessation support available in primary care or novel ways of making cessation support available in disadvantaged communities, have the potential when delivered alongside the introduction of smokefree legislation to increase quitting activity and reduce the devastating effects of tobacco use in the least advantaged sections of society.

8. APPENDICES

8.1. SEARCH STRATEGY FOR SYSTEMATIC REVIEW OF THE EFFECT OF SMOKEFREE LEGISLATION ON SMOKING BEHAVIOUR

Pubmed

(smok* OR tobacco) AND ((ban OR bans OR banned) OR (prohibit*) OR (restrict*) OR (policy OR policies) OR (legislat*) OR (regulat*) OR (law OR laws)) AND (Humans[Mesh]) Limits: Humans, Publication Date from 2002/01/01 to 2009/11/30

CINAHL

((smok* OR tobacco)) and (((ban OR bans OR banned) OR (prohibit*) OR (restrict*) OR (policy OR policies) OR (legislat*) OR (regulat*) OR (law OR laws))) Limiters - ; Published Date from: 20020101-20091131

PsycINFO

((smok* OR tobacco) AND (ban OR bans OR banned) OR (prohibit*) OR (restrict*) OR (policy OR policies) OR (legislat*) OR (regulat*) OR (law OR laws)):Any Field and [2002 TO 2009]:PublicationYear

Conference Proceedings Citation Index - Science

Topic=((smok* OR tobacco) AND ((ban OR bans OR banned) OR (prohibit*) OR (restrict*) OR (policy OR policies) OR (legislat*) OR (regulat*) OR (law OR laws))) Timespan=2002-2009. Databases=CPCI-S.

8.2. HOW IS SMOKING INFORMATION RECORDED IN THIN?

THIN data are provided to researchers in six files, linked by a unique patient identifier. The contents of these six files are outlined in Table 8.1.

Table 8.1 Structure of the THIN dataset

Data file name	Contents
Patient	Patient demographic and registration details
Medical	Records of symptoms, diagnoses and interventions
Therapy	Formulation, strength, dose and quantity of prescribed medications
Dosage	Prescription dosage instructions recorded as free text
Additional Health Data (AHD)	Multiple types of data, including lifestyle indicators, test results and physical measurements
Postcode Variable Indicators (PVI)	Postcode-linked area based socioeconomic, ethnicity and environmental indices

During clinical practice, primary health care professionals document smoking-related information using Read Codes, and this information appears in the THIN dataset in either the Medical file or AHD file. Of 17,949,672 individual uses of a smoking-relevant Read Codes in the THIN dataset to the end of July 2009, 15.4% were recorded in the Medical file where researchers using THIN are able to view the specific Read Code entered and the date on which it was recorded. The majority of smoking-related Read Codes appear in the AHD file. Researchers can view the date each Read Code is recorded and, in addition, further information about the patient's smoking behaviour which may have been documented by the health care professional, such as whether the patient is a current, ex or never smoker, and, where relevant, the number of cigarettes smoked per day.

Previous studies using primary care medical records typically define a patient's smoking status at any given point in time as the last recorded smoking status documented in their medical records. This is equally possible using THIN - a patient's medical history is searched for all occurrences of relevant Read Codes appearing in their electronic records prior to the reference date of interest, and the last recorded Read Code before the reference date is retained. There are 113 different Read Codes used in the THIN dataset to record smoking behaviour,

including codes which describe smoking status, quantify tobacco consumption and detail the delivery of cessation interventions. In order to make the use of these codes more manageable, and to allow classification of patient smoking status at a given point in time, the 113 Read Codes were grouped as shown in Table 8.2 to give a categorical indicator of smoking status. Some Read Codes, such as '137..00 Tobacco consumption', are ambiguous and in isolation cannot be used to classify a patient as, for example, a current rather than an ex-smoker. However, where such ambiguous Read Codes are recorded in the AHD file, the additional information which clinicians have the option to enter can be inspected for further information which can be used to more confidently assign a patient a known smoking status. Where no additional information is available to qualify an ambiguous Read Code, the Read Code is classified as indicating an unknown smoking status.

Table 8.2 Classification of smoking Read Codes into patient smoking status

Read Code		Categorised smoking status	Frequency (% of all codes)
137P.00	Cigarette smoker	Current	1,994,070 (13.86)
6791.00	Health ed. - smoking	Current	1,184,524 (8.23)
8CAL.00	Smoking cessation advice	Current	1,703,452 (11.84)
1374.00	Moderate smoker - 10-19 cigs/d	Current	144,897 (1.01)
137R.00	Current smoker	Current	215,581 (1.50)
1373.00	Light smoker - 1-9 cigs/day	Current	102,677 (0.71)
137P.11	Smoker	Current	35,200 (0.24)
1375.00	Heavy smoker - 20-39 cigs/day	Current	76,238 (0.53)
137G.00	Trying to give up smoking	Current	66,572 (0.46)
1372.11	Occasional smoker	Current	36,754 (0.26)
1372.00	Trivial smoker - < 1 cig/day	Current	19,167 (0.13)
137M.00	Rolls own cigarettes	Current	22,087 (0.15)
137J.00	Cigar smoker	Current	11,779 (0.08)
137H.00	Pipe smoker	Current	12,794 (0.09)
137..11	Smoker - amount smoked	Current	17,478 (0.12)
1376.00	Very heavy smoker - 40+cigs/d	Current	6,661 (0.05)
8H7i.00	Referral to smoking cessation advisor	Current	36,056 (0.25)
8HTK.00	Referral to stop smoking clinic	Current	27,862 (0.19)
8B2B.00	Nicotine replacement therapy	Current	26,161 (0.18)
13p0.00	Negotiated date for cessation of smoking	Current	19,737 (0.14)
137C.00	Keeps trying to stop smoking	Current	4,332 (0.03)
137Q.11	Smoking restarted	Current	2,613 (0.02)
137d.00	Not interested in stopping smoking	Current	116 (0.00)
ZG23300	Advice on smoking	Current	4,188 (0.03)
137Q.00	Smoking started	Current	1,839 (0.01)
137b.00	Ready to stop smoking	Current	10,867 (0.08)
13p5.00	Smoking cessation programme start date	Current	5,272 (0.04)
137V.00	Smoking reduced	Current	1,712 (0.01)
137c.00	Thinking about stopping smoking	Current	3,482 (0.02)
E251.00	Tobacco dependence	Current	2,362 (0.02)
67H1.00	Lifestyle advice regarding smoking	Current	1,972 (0.01)
8B3f.00	Nicotine replacement therapy provided free	Current	1,584 (0.01)
8CAg.00	Smoking cessation advice provided by community pharmacist	Current	102 (0.00)
8BP3.00	Nicotine replacement therapy provided by community pharmacist	Current	58 (0.00)
745H200	Nicotine replacement therapy using nicotine inhalator	Current	260 (0.00)
745H100	Nicotine replacement therapy using nicotine gum	Current	160 (0.00)
8I39.00	Nicotine replacement therapy refused	Current	45 (0.00)
745H300	Nicotine replacement therapy using nicotine lozenges	Current	63 (0.00)

745Hy00	Other specified smoking cessation therapy	Current	52 (0.00)
ZRBm200	Fagerstrom test for nicotine dependence	Current	1,125 (0.01)
137h.00	Minutes from waking to first tobacco consumption	Current	1,188 (0.01)
745H000	Nicotine replacement therapy using nicotine patches	Current	1,223 (0.01)
67A3.00	Pregnancy smoking advice	Current	479 (0.00)
9OO7.00	Stop smoking monitor verb.inv.	Current	298 (0.00)
137e.00	Smoking restarted	Current	1,993 (0.01)
8B3Y.00	Over the counter nicotine replacement therapy	Current	385 (0.00)
9OO8.00	Stop smoking monitor phone inv	Current	227 (0.00)
E251z00	Tobacco dependence NOS	Current	236 (0.00)
ZRBm211	FTND - Fagerstrom test for nicotine dependence	Current	16 (0.00)
ZV6D800	[V]Tobacco abuse counselling	Current	10 (0.00)
E251100	Tobacco dependence, continuous	Current	9 (0.00)
745H400	Smoking cessation drug therapy	Current	133 (0.00)
ZRh4.00	Reasons for smoking scale	Current	3 (0.00)
8I2I.00	Nicotine replacement therapy contraindicated	Current	2 (0.00)
ZRaM.11	MFS - Motives for smoking scale	Current	1 (0.00)
ZRaM.00	Motives for smoking scale	Current	1 (0.00)
)ZRao.00	Occasions for smoking scale	Current	1 (0.00)
137f.00	Reason for restarting smoking	Current	49,774 (0.35)
ZRh4.11	RFS - Reasons for smoking scale	Current	1 (0.00)
137S.00	Ex smoker	Ex	2,326,595 (16.17)
137F.00	Ex-smoker - amount unknown	Ex	3 (0.00)
137K.00	Stopped smoking	Ex	38,630 (0.27)
1379.00	Ex-moderate smoker (10-19/day)	Ex	73,832 (0.51)
1378.00	Ex-light smoker (1-9/day)	Ex	51,546 (0.36)
137A.00	Ex-heavy smoker (20-39/day)	Ex	46,451 (0.32)
1377.00	Ex-trivial smoker (<1/day)	Ex	12,418 (0.09)
137B.00	Ex-very heavy smoker (40+/day)	Ex	2,748 (0.02)
137T.00	Date ceased smoking	Ex	14,839 (0.10)
137N.00	Ex pipe smoker	Ex	3,322 (0.02)
137O.00	Ex cigar smoker	Ex	2,042 (0.01)
E251300	Tobacco dependence in remission	Ex	1 (0.00)
9hG1.00	Excepted from smoking quality indicators: Informed dissent	Exception	5,827 (0.04)
9hG0.00	Excepted from smoking quality indicators: Patient unsuitable	Exception	3,103 (0.02)
9hG..00	Exception reporting: smoking quality indicators	Exception	85 (0.00)
1371.00	Never smoked tobacco	Never	4,493,667 (31.23)
137L.00	Current non-smoker	Ambiguous[a]	131,442 (0.91)
1371.11	Non-smoker	Ambiguous[a]	241,538 (1.68)
9N2k.00	Seen by smoking cessation advisor	Unknown	66,850 (0.46)
13p..00	Smoking cessation milestones	Unknown	47,405 (0.33)
9OO..12	Stop smoking monitoring admin.	Unknown	22,078 (0.15)
137E.00	Tobacco consumption unknown	Unknown	287 (0.00)
9OO4.00	Stop smoking monitor 1st lettr	Unknown	10,931 (0.08)
13p1.00	Smoking status at 4 weeks	Unknown	11,097 (0.08)
9OOA.00	Stop smoking monitor.chck done	Unknown	9,507 (0.07)
9N4M.00	DNA - Did not attend smoking cessation clinic	Unknown	10,610 (0.07)
9OO..00	Anti-smoking monitoring admin.	Unknown	7,444 (0.05)
745H.00	Smoking cessation therapy	Unknown	10,765 (0.07)
9OOZ.00	Stop smoking monitor admin.NOS	Unknown	6,765 (0.05)
9OO2.00	Refuses stop smoking monitor	Unknown	3,136 (0.02)
4I90.00	Expired carbon monoxide concentration	Unknown	3,080 (0.02)
13p4.00	Smoking free weeks	Unknown	2,124 (0.01)
137g.00	Cigarette pack-years	Unknown	1,662 (0.01)
13p2.00	Smoking status between 4 and 52 weeks	Unknown	1,727 (0.01)
13p6.00	Carbon monoxide reading at 4 weeks	Unknown	1,683 (0.01)
E023.00	Nicotine withdrawal	Unknown	596 (0.00)
9OO..11	Stop smoking clinic admin.	Unknown	2,113 (0.01)
9OO3.00	Stop smoking monitor default	Unknown	698 (0.00)
137D.00	Admitted tobacco cons untrue ?	Unknown	4,655 (0.03)
13p3.00	Smoking status at 52 weeks	Unknown	362 (0.00)
9OO5.00	Stop smoking monitor 2nd lettr	Unknown	334 (0.00)
745Hz00	Smoking cessation therapy NOS	Unknown	232 (0.00)
9OO6.00	Stop smoking monitor 3rd lettr	Unknown	64 (0.00)
9OO9.00	Stop smoking monitoring delete	Unknown	3 (0.00)
ZV11600	[V]Personal history of tobacco abuse	Unknown	1 (0.00)
9OO1.00	Attends stop smoking monitor.	Unknown	25,156 (0.17)
137..00	Tobacco consumption	Ambiguous[b]	821,305 (5.71)
137Z.00	Tobacco consumption NOS	Ambiguous[b]	2,076 (0.01)
137a.00	Pipe tobacco consumption	Ambiguous[b]	3,416 (0.02)
137Y.00	Cigar consumption	Ambiguous[b]	2,620 (0.02)
137X.00	Cigarette consumption	Ambiguous[b]	2,119 (0.01)
6893.00	Tobacco usage screen	Ambiguous[b]	473 (0.00)
68T..00	Tobacco usage screen	Ambiguous[b]	403 (0.00)
ZV4K000	[V]Tobacco use	Ambiguous[b]	27 (0.00)

[a]Non-smoker unless further information available in AHD file to classify as ex or never smoker
[b]Unknown smoking status unless further information available in AHD file to classify as current, ex or never smoker

The categorised version of the last recorded Read Code in a patient's notes prior to a given index date is taken as the patient's smoking status at that date. If the patient has no smoking Read Codes recorded in their notes their smoking status is defined as unknown. If more than one Read Code is recorded on the same day, and these contradict each other (e.g. one code indicating a never smoker and one code indicating a current smoker), the patient's smoking status is defined as unknown at that point in time.

8.3. CALCULATION OF THE TOWNSEND INDEX OF DEPRIVATION

The Townsend Index produces an ecological-level measure of material deprivation based on the combination of four equally-weighted census variables[113]:

- The percentage of all economically active residents aged 16-64 (excluding students) who are unemployed.
- The percentage of all private households who do not possess a car or van.
- The percentage of all private households which are not owner-occupied.
- The percentage of all private households which are overcrowded (>1 person per room).

Variables 1 and 4 are transformed using a log transformation to normalise their skewed distributions, and then z-scores are calculated for each variable:

$$\mathrm{z-score} = \mathrm{variable} - \frac{\mathrm{mean(variable)}}{\mathrm{standard\ deviation(variable)}}$$

The final Townsend Index is the sum of the four z-scores which, in the case of THIN, are categorised into quintiles to preserve patient anonymity.

8.4. IS SMOKING STATUS ROUTINELY RECORDED WHEN PATIENTS REGISTER WITH A NEW GP?

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Is smoking status routinely recorded when patients register with a new GP?

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Background. The process of registering new patients in primary care provides an ideal opportunity to assess their smoking status systematically and record this in electronic medical records; this identification then allows smokers to be targeted with effective cessation interventions.

Objective. To use a dataset of electronic primary care medical records to assess the extent to which primary care patients' smoking status is recorded in their electronic records at the time of their registering with a new GP.

Methods. Patients who registered with a general practice contributing data to The Health Improvement Network (THIN) database each year between 1990 and 2006 were identified, and their electronic medical records examined to identify the date on which their smoking status was first recorded.

Results. In total, 74.2% of adults registering with a new GP in 1990 failed to have their smoking status recorded in their electronic medical records within 90 days of registration, improving to 26.7% of adults registering in 2006.

Conclusions. That over one-quarter of adults registering with a THIN practice in 2006 did not have their smoking status recorded at registration represents substantial missed opportunities for identifying smokers and also, potentially, for offering them support to quit.

Keywords. Computer systems, family practice, medical records, smoking.

Introduction

Quitting smoking is arguably the single most important lifestyle change a smoker can make to improve their health and GPs are well-placed to encourage and support smokers to make this change, having at their disposal a range of interventions proven to increase the likelihood of successful cessation.[1] On average, adults in Great Britain see a GP five times per year,[2] with each consultation representing an opportunity to assess a patient's smoking behaviour and, if appropriate, advise and support them to quit. The World Health Organization has called for smoking cessation to be integrated into primary health care worldwide, and although the UK has a particularly well-developed primary care network and tobacco control movement, such a strategy is appropriate in countries with any type of widely available health care services.[3]

GPs are more likely to deliver cessation interventions where a systematic approach is taken to identifying smokers and documenting this in their medical records.[4] Current UK guidelines recommend that general practices establish monitoring systems to ensure that all health care professionals have access to information on the current smoking status of their patients,[5] and a voluntary pay-for-performance scheme implemented in 2004, and taken up by almost all practices,[6] rewards GPs for regularly updating their records of patients' smoking status.[7] For example, in the 2006/07 financial year, practices were required to ensure that they had recorded the smoking status of patients aged ⩾15 years at least once in the previous 27 months, with the exception of never-smokers whose status had only to be recorded once since registration with the practice. The maximum payment was available to practices who met this requirement for at least 90% of eligible patients. In a 2002 survey of 336 GPs in England, 98% reported routinely recording patients' smoking status, either on the practice computer system or in the patient's paper notes,[8] when they first register. However, no studies have inspected medical records to validate this figure nor have assessed the impact of the Quality and Outcomes Framework (QOF) on data recording habits. Therefore, this study

uses a dataset of electronic primary care medical records [The Health Improvement Network (THIN)] to assess the extent to which primary care patients' smoking status is recorded in their electronic medical records at the time of their registering with a new GP.

Methods

THIN contains the electronic medical records of over 6 million patients from 415 practices throughout the UK and is broadly representative of the UK population in terms of patient demographic characteristics.[9] The dataset includes information on symptoms, diagnoses, treatments and lifestyle indicators, such as smoking status, recorded on practice computers using Read codes; previous studies have shown that consultation rates and levels of recording of clinical information are comparable to national data sources.[10] For each year between 1990 and 2006, we extracted demographic details of all adults (aged ≥16 years) who registered with a practice in that year and who remained registered with the practice 1 year later. The number of practices contributing data to THIN has increased over the time period studied, and some practices have also withdrawn from data collection so the number of practices included each year varies. For each new patient, we identified the date on which their smoking status was first recorded in their electronic medical record and calculated the difference, in days, between the date they registered and this first recorded smoking entry. We used the proportion of patients having their smoking status recorded within 90 days of registration as a proxy for smoking status being recorded at patient registration. We believed that this period allowed sufficient time for any smoking data written on paper during registration appointments to be entered onto practice computers. Also, the QOF only includes patients who have been registered with a practice for at least 90 days; consequently, it is likely that most practices will try hard to record all QOF relevant information, such as patients' smoking status, prior to this time period elapsing.[7] All analyses were carried out using Stata version 11.0 (Stata Corp., College Station, TX).

Results

The number of new patients registering with practices increased from 56 595 patients across 103 practices in 1990 to 155 359 patients across 399 practices in 2006. On average, 52.8% of new patients each year were female, with an average age of 39 years (interquartile range 26–48). Figure 1 shows that the proportion of new patients annually who have their smoking status recorded within 90 days of registration has steadily

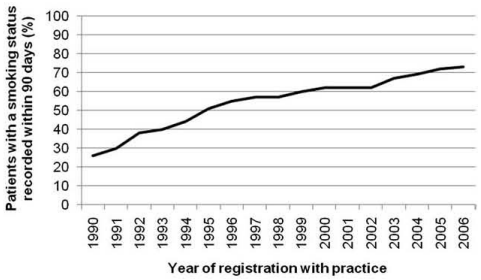

FIGURE 1 *Proportion of new patients aged ≥16 registering with a GP each year who have their smoking status recorded within 90 days of registration*

increased since 1990. In 2006, 73.3% of new patients (71.4% men and 75.0% women) had their smoking status recorded within 90 days of registering, with 44% of these entries being recorded on the day of registration. However, the notes of 16.6% patients (19.4% men and 14.1% women) still lacked a recording of smoking status by the first anniversary of their registration. As expected, these figures represent a considerable improvement since 1990, when just 25.8% of patients had their smoking status recorded in their electronic medical records at registration, and 63.1% of patients lacked a recording of smoking status 1 year after registration. In all years, there was considerable variation between practices in the recording of recently registered patients' smoking status; for example, in 2006, while one practice recorded the smoking status of all its new patients, the worst performer did so in just 7.8% of cases (interquartile range: 62.5%–88.2%).

Discussion

A new patient questionnaire or health check provides an ideal opportunity for general practices to assess and document a patient's smoking status, both to aid the clinical management of that patient and, since 2004, to meet the requirements of the QOF. However, this study suggests that many practices are failing to seize this opportunity and indeed are falling short of the 90% threshold for receiving the maximum available financial reward for recording patients' smoking status. In the early years of this analysis, it is, of course, possible that many practices used paper records alongside more recently introduced computerized clinical information systems, and patients' smoking status may not have been as comprehensively documented in electronic records as in later years. It is also possible that the recording habits of the general practices contributing data to THIN are not representative of all UK practices, and further work is warranted to investigate the reasons for the considerable variation in data

recording between the practices contributing to THIN. That one-quarter of new patients registering with a THIN practice in 2006 did not have their smoking status recorded when they registered with their practice must be seen as a missed opportunity; maximizing the use of such opportunities would increase identification of smokers in primary care consultations, which has been shown to increase the likelihood of smokers being targeted with support to help them to quit.[4]

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Declaration

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Conflict of interest: In the last 5 years, TC has been paid for consultancy work by Johnson and Johnson and Pierre Fabre Laboratories (manufacturers of nicotine replacement therapy). However, this manuscript has not been discussed with any third parties.

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8.5. ARE RECORDED READ CODES AN ACCURATE REFLECTION OF A PATIENT'S SMOKING STATUS AT THAT POINT IN TIME?

Without being able to directly question each individual patient in THIN about their smoking status at any given point in time it is difficult to assess whether each record of smoking status documented in THIN is correct. However, it is possible to gain an estimate of the proportion of patients with data entry errors in their electronic medical records.

Methods

Patients were identified from the THIN dataset who were over the age of 16 and registered with a practice on an index date of 1st July 2008. All records of smoking status, identified by relevant Read Codes, entered into a patient's notes on or after their registration date were extracted, and the last recorded Read Code prior to the index date were used to assign each patient a smoking status. To gain an appreciation of the correctness of smoking recording, the number of patients with two or more contradictory Read Codes documented as the last mention of smoking before the index date was calculated. In addition, the proportion of patients identified as never smokers on the basis of their last recorded Read Code, but who have a Read Code indicating current or ex smoking documented earlier in their medical histories, was also determined.

Results

Table 8.3 illustrates discrepancies observed in the recording of patients' smoking status, showing pairs of Read Codes recorded on the same day as the last record before the index date. The shaded cells highlight combinations of Read Codes which are contradictory; a patient cannot, for example, be both a current smoker and an ex-smoker at the same time.

Table 8.3 Discrepancies between smoking status Read Codes recorded in patients' notes on the same day

		Read Code 2			
		Non	Current	Ex	Total
Read Code 1	Never	503	57,182	3,535	61,220
	Non	0	4	69	73
	Current	0	0	45,311	45,311
	Ex	0	0	0	0
	Total	503	57,186	48,915	106,604

As can be seen, the recording of contradictory information is not an uncommon occurrence. In this case, of 2,511,909 patients registered in THIN on 1st July 2008, 106,032 (4.2%) had two contradictory smoking-status Read Codes in their notes as the last smoking-related entry before the index date. A small number of patients had more than two contradictory smoking status Read-codes recorded at the same time; in the worst case scenario one patient was recorded simultaneously as a never, non, current and ex-smoker.

The table below shows the proportion of patients identified as a never smoker on the basis of their last recorded Read Code who have a current or ex smoking Read Code recorded earlier in their medical history.

Table 8.4 Discrepancies in the recording of never smokers

	Number of never smokers	Number with a previous current or ex-smoker code	% illogical
Men	508,857	58,282	11.5
Women	689,578	86,200	12.5
Total	1,198,435	144,482	12.1

In 2008, 12.1% of never smokers have a Read Code recorded earlier in their medical records which contradicts this smoking status. Female never smokers are more likely than men to have evidence to the contrary recorded in their medical history, and there is also a gradient across age groups with older patients being more likely to have contradictory Read Codes (figures not shown). These figures indicate the persistence of the tendency noted in earlier studies for GPs to record patients as never smokers when they would perhaps better be described as ex-smokers[118].

Discussion and conclusions

It is difficult to know exactly how these apparent data entry errors have made it into patients' electronic notes and ultimately into the THIN dataset. It is possible that the simple passage of time and consequent increasing number of consultations with a GP provide more opportunities for data entry errors to creep into a patient's notes. In addition, the process of entering information on a patient's smoking status onto the practice computer during the course of a consultation may introduce errors into the medical record; if GPs have to use a mouse to manually select the Read Code they wish to use from a list it might be easy for them to accidentally select a different code without realising.

Patients with contradictory smoking status Read Codes in their medical notes must be coded as having an unknown smoking status at a particular point in time if these are the records closest to the index date. Such patients might not be current smokers and therefore may not be subject to increased delivery of smoking cessation interventions at the time smokefree legislation was introduced.

It may be that the use of a patient's last recorded Read Code is a relatively accurate way to identify current smokers, but perhaps cannot be relied upon to distinguish between ex and never smokers. In the context of the work presented in this thesis, investigating the management of smoking in primary care at the time smokefree legislation was introduced, the ability to identify current smokers is of primary importance as these are the patients who would be the subjects of increased delivery of smoking cessation interventions at the time smokefree legislation was introduced. The ability to identify ex and never smokers is of less importance, though this issue must be addressed by other researchers who need to be able to confidently identify these smoking behaviours.

8.6. HOW UP-TO-DATE ARE SMOKING STATUS RECORDS IN THIN?

Smoking is a behaviour which can change over time, and thus taking a patient's last recorded smoking status as indicative of their current smoking behaviour may not provide an accurate up-to-date indicator, particularly if the last recorded smoking status was documented long before the reference date of interest. This study investigates how long before a given index date THIN patients' last recorded smoking status was documented in their medical records, assessing whether there has been an improvement in the currency of smoking status records over time, and discusses the implications for identifying THIN patients who were current smokers at the time smokefree legislation was introduced.

Methods

For 2000, 2004 and 2008 all patients were identified from the THIN dataset who were over the age of 16 and registered with a practice on an index date of 1st July of that year. For all patients with a smoking Read Code in their medical history prior to each index date, the date of their last recorded smoking status was noted. Cumulative frequency graphs were drawn to show how long before each index date patients' last recorded smoking status was documented.

Results

Figure 8.1 illustrates, for those patients registered in THIN on 1st July 2000, 2004 and 2008, how long before these dates their last recorded smoking entry in their medical records was documented.

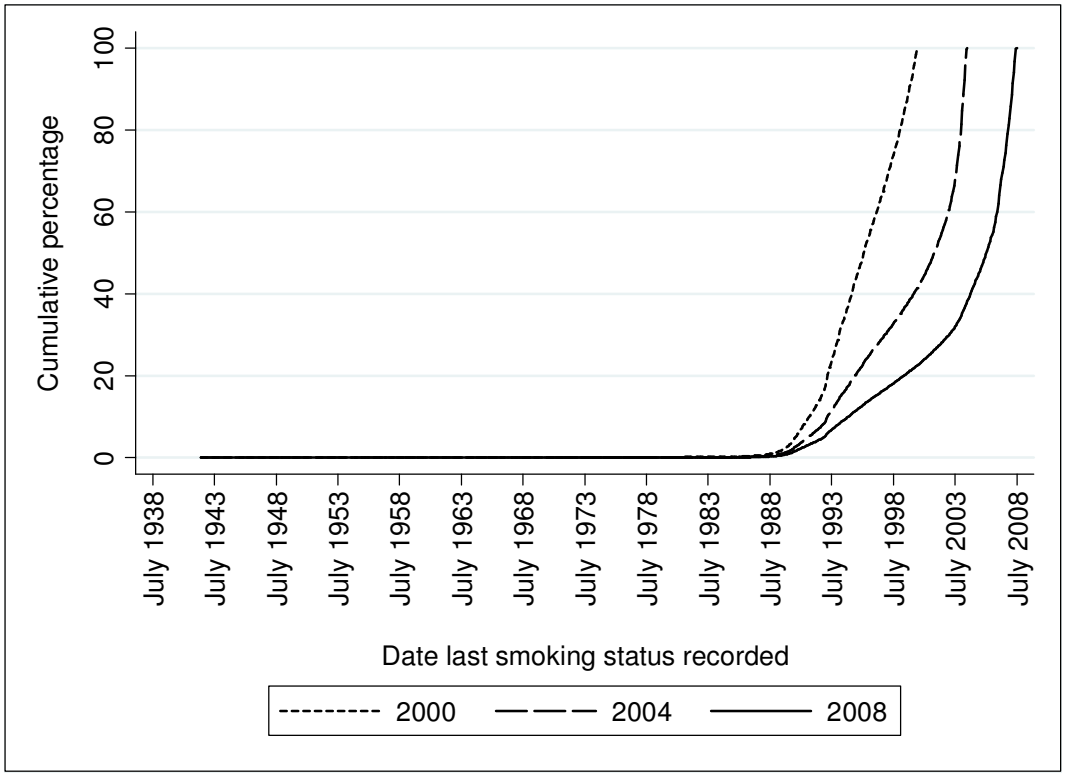

Figure 8.1 The proportion of THIN patients with a recent recording of smoking status

There has been an improvement over time in the proportion of patients registered in THIN at a particular point in time who have comparatively recent recordings of their smoking status. Of those patients in THIN on 1st July 2000, just 8.4% had a smoking status recorded in their medical records in the last six months, 15.1% within the last year, and 27.0% within the last two years. By 2008, 17.1% of patients registered on 1st July had their smoking status recorded within the previous six months, 28.9% within the last year and 46.3% within the last two years. In all years, however, a sizeable minority of patients had their smoking status recorded many years before the index date of interest, with, at worst, smoking status being last recorded as early as 1942.

Discussion and conclusions

Although there have been improvements over time in the currency of smoking status records in THIN there remains a substantial minority of patients whose

smoking status has not been updated in the recent past. Very few people begin smoking after the age of 25[126], and so it may not be a problem if the last recorded smoking status in people over this age indicates they were a never smoker at that point in time, regardless of how long ago this status was documented. However, some patients recorded many years ago as current smokers may since have quit, though with no further information available it is impossible to identify these patients. There is perhaps an argument for re-classifying patients last recorded as a current smoker many years ago as having an unknown smoking status. However, it is not obvious how long a current smoking code should be considered valid, and therefore this thesis takes the approach of leaving these patients classified as current smokers. Further work is warranted in this area, perhaps employing a modelling approach to predict smoking trajectories and allow more accurate estimation of population-level smoking prevalence at any point in time, if not allowing the identification of individual continuing smokers and quitters.

8.7. DIAGNOSTIC READ CODES USED TO IDENTIFY PATIENTS WITH CHRONIC CONDITIONS IN THIN

Asthma

H33..00	Asthma	H331100	Intrinsic asthma with status asthmaticus
H33..11	Bronchial asthma	H331111	Intrinsic asthma with asthma attack
H330.00	Extrinsic (atopic) asthma	H331z00	Intrinsic asthma NOS
H330.11	Allergic asthma	H332.00	Mixed asthma
H330.12	Childhood asthma	H334.00	Brittle asthma
H330.13	Hay fever with asthma	H33z.00	Asthma unspecified
H330.14	Pollen asthma	H33z.11	Hyperreactive airways disease
H330000	Extrinsic asthma without status asthmaticus	H33z000	Status asthmaticus NOS
H330011	Hay fever with asthma	H33z011	Severe asthma attack
H330100	Extrinsic asthma with status asthmaticus	H33z200	Late-onset asthma
H330111	Extrinsic asthma with asthma attack	H33zz00	Asthma NOS
H330z00	Extrinsic asthma NOS	H33zz11	Exercise induced asthma
H331.00	Intrinsic asthma	H33zz12	Allergic asthma NEC
H331.11	Late onset asthma	H33zz13	Allergic bronchitis NEC
H331000	Intrinsic asthma without status asthmaticus		

Chronic obstructive pulmonary disease (COPD)

H3...00	Chronic obstructive pulmonary disease	H320200	Giant bullous emphysema
H3...11	Chronic obstructive airways disease	H320300	Bullous emphysema with collapse
H31..00	Chronic bronchitis	H320311	Tension pneumatocoele
H310.00	Simple chronic bronchitis	H320z00	Chronic bullous emphysema NOS
H310000	Chronic catarrhal bronchitis	H321.00	Panlobular emphysema
H310z00	Simple chronic bronchitis NOS	H322.00	Centrilobular emphysema
H311.00	Mucopurulent chronic bronchitis	H32y.00	Other emphysema
H311000	Purulent chronic bronchitis	H32y000	Acute vesicular emphysema
H311100	Fetid chronic bronchitis	H32y100	Atrophic (senile) emphysema
H311z00	Mucopurulent chronic bronchitis NOS	H32y111	Acute interstitial emphysema
H312.00	Obstructive chronic bronchitis	H32y200	MacLeod's unilateral emphysema
H312000	Chronic asthmatic bronchitis	H32yz00	Other emphysema NOS
H312011	Chronic wheezy bronchitis	H32yz11	Sawyer - Jones syndrome
H312100	Emphysematous bronchitis	H32z.00	Emphysema NOS
H312300	Bronchiolitis obliterans	H36..00	Mild chronic obstructive pulmonary disease
H312z00	Obstructive chronic bronchitis NOS	H37..00	Moderate chronic obstructive pulmonary disease
H313.00	Mixed simple and mucopurulent chronic bronchitis	H38..00	Severe chronic obstructive pulmonary disease
H31y.00	Other chronic bronchitis	H39..00	Very severe chronic obstructive pulmonary disease
H31y100	Chronic tracheobronchitis	H3y..00	Other specified chronic obstructive airways disease
H31yz00	Other chronic bronchitis NOS	H3y..11	Other specified chronic obstructive pulmonary disease
H31z.00	Chronic bronchitis NOS	H3y0.00	Chronic obstruct pulmonary dis with acute lower resp infectn
H32..00	Emphysema	H3y1.00	Chron obstruct pulmonary dis wth acute exacerbation, unspec
H320.00	Chronic bullous emphysema	H3z..00	Chronic obstructive airways disease NOS
H320000	Segmental bullous emphysema	H3z..11	Chronic obstructive pulmonary disease NOS
H320100	Zonal bullous emphysema		

Coronary heart disease

G3...00	Ischaemic heart disease	G32..11	Healed myocardial infarction
G3...11	Arteriosclerotic heart disease	G32..12	Personal history of myocardial infarction
G3...12	Atherosclerotic heart disease	G33..00	Angina pectoris
G3...13	IHD - Ischaemic heart disease	G330.00	Angina decubitus
G30..00	Acute myocardial infarction	G330000	Nocturnal angina
G30..11	Attack - heart	G330z00	Angina decubitus NOS
G30..12	Coronary thrombosis	G33z.00	Angina pectoris NOS
G30..13	Cardiac rupture following myocardial infarction (MI)	G33z000	Status anginosus
G30..14	Heart attack	G33z100	Stenocardia
G30..15	MI - acute myocardial infarction	G33z200	Syncope anginosa
G30..16	Thrombosis - coronary	G33z300	Angina on effort
G30..17	Silent myocardial infarction	G33z400	Ischaemic chest pain
G300.00	Acute anterolateral infarction	G33z500	Post infarct angina
G301.00	Other specified anterior myocardial infarction	G33z600	New onset angina
G301000	Acute anteroapical infarction	G33z700	Stable angina
G301100	Acute anteroseptal infarction	G33zz00	Angina pectoris NOS
G301z00	Anterior myocardial infarction NOS	G34..00	Other chronic ischaemic heart disease
G302.00	Acute inferolateral infarction	G340.00	Coronary atherosclerosis
G303.00	Acute inferoposterior infarction	G340.11	Triple vessel disease of the heart
G304.00	Posterior myocardial infarction NOS	G340.12	Coronary artery disease
G305.00	Lateral myocardial infarction NOS	G340000	Single coronary vessel disease
G306.00	True posterior myocardial infarction	G340100	Double coronary vessel disease
G307.00	Acute subendocardial infarction	G342.00	Atherosclerotic cardiovascular disease
G307000	Acute non-Q wave infarction	G343.00	Ischaemic cardiomyopathy
G307100	Acute non-ST segment elevation myocardial infarction	G344.00	Silent myocardial ischaemia
G308.00	Inferior myocardial infarction NOS	G34y.00	Other specified chronic ischaemic heart disease
G309.00	Acute Q-wave infarct	G34y000	Chronic coronary insufficiency
G30A.00	Mural thrombosis	G34y100	Chronic myocardial ischaemia
G30B.00	Acute posterolateral myocardial infarction	G34yz00	Other specified chronic ischaemic heart disease NOS
G30X.00	Acute transmural myocardial infarction of unspecif site	G34z.00	Other chronic ischaemic heart disease NOS
G30X000	Acute ST segment elevation myocardial infarction	G34z000	Asymptomatic coronary heart disease
G30y.00	Other acute myocardial infarction	G35..00	Subsequent myocardial infarction
G30y000	Acute atrial infarction	G350.00	Subsequent myocardial infarction of anterior wall

G30y100	Acute papillary muscle infarction	G351.00	Subsequent myocardial infarction of inferior wall
G30y200	Acute septal infarction	G353.00	Subsequent myocardial infarction of other sites
G30yz00	Other acute myocardial infarction NOS	G35X.00	Subsequent myocardial infarction of unspecified site
G30z.00	Acute myocardial infarction NOS	G36..00	Certain current complication follow acute myocardial infarct
G31..00	Other acute and subacute ischaemic heart disease	G360.00	Haemopericardium/current comp folow acut myocard infarct
G310.00	Postmyocardial infarction syndrome	G361.00	Atrial septal defect/curr comp folow acut myocardal infarct
G310.11	Dressler's syndrome	G362.00	Ventric septal defect/curr comp fol acut myocardal infarctn
G311.00	Preinfarction syndrome	G363.00	Ruptur cardiac wall w'out haemopericard/cur comp fol ac MI
G311.11	Crescendo angina	G364.00	Ruptur chordae tendinae/curr comp fol acute myocard infarct
G311.12	Impending infarction	G365.00	Rupture papillary muscle/curr comp fol acute myocard infarct
G311.13	Unstable angina	G366.00	Thrombosis atrium,auric append&vent/curr comp foll acute MI
G311.14	Angina at rest	G38..00	Postoperative myocardial infarction
G311000	Myocardial infarction aborted	G380.00	Postoperative transmural myocardial infarction anterior wall
G311011	MI - myocardial infarction aborted	G381.00	Postoperative transmural myocardial infarction inferior wall
G311100	Unstable angina	G382.00	Postoperative transmural myocardial infarction other sites
G311200	Angina at rest	G383.00	Postoperative transmural myocardial infarction unspec site
G311300	Refractory angina	G384.00	Postoperative subendocardial myocardial infarction
G311400	Worsening angina	G38z.00	Postoperative myocardial infarction, unspecified
G311500	Acute coronary syndrome	G3y..00	Other specified ischaemic heart disease
G311z00	Preinfarction syndrome NOS	G3z..00	Ischaemic heart disease NOS
G312.00	Coronary thrombosis not resulting in myocardial infarction	Gyu3.00	[X]Ischaemic heart diseases
G31y.00	Other acute and subacute ischaemic heart disease	Gyu3000	[X]Other forms of angina pectoris
G31y000	Acute coronary insufficiency	Gyu3100	[X]Other current complicatns following acute myocard infarct
G31y100	Microinfarction of heart	Gyu3200	[X]Other forms of acute ischaemic heart disease
G31y200	Subendocardial ischaemia	Gyu3300	[X]Other forms of chronic ischaemic heart disease
G31y300	Transient myocardial ischaemia	Gyu3400	[X]Acute transmural myocardial infarction of unspecif site
G31yz00	Other acute and subacute ischaemic heart disease NOS	Gyu3500	[X]Subsequent myocardial infarction of other sites
G32..00	Old myocardial infarction	Gyu3600	[X]Subsequent myocardial infarction of unspecified site

Diabetes mellitus

C10E.00	Type 1 diabetes mellitus	C10EL00	Type 1 diabetes mellitus with persistent microalbuminuria
C10E.11	Type I diabetes mellitus	C10EL11	Type I diabetes mellitus with persistent microalbuminuria
C10E.12	Insulin dependent diabetes mellitus	C10EM00	Type 1 diabetes mellitus with ketoacidosis
C10E000	Type 1 diabetes mellitus with renal complications	C10EM11	Type I diabetes mellitus with ketoacidosis
C10E011	Type I diabetes mellitus with renal complications	C10EN00	Type 1 diabetes mellitus with ketoacidotic coma
C10E012	Insulin-dependent diabetes mellitus with renal complications	C10EN11	Type I diabetes mellitus with ketoacidotic coma
C10E100	Type 1 diabetes mellitus with ophthalmic complications	C10EP00	Type 1 diabetes mellitus with exudative maculopathy
C10E111	Type I diabetes mellitus with ophthalmic complications	C10EP11	Type I diabetes mellitus with exudative maculopathy
C10E112	Insulin-dependent diabetes mellitus with ophthalmic comps	C10EQ00	Type 1 diabetes mellitus with gastroparesis
C10E200	Type 1 diabetes mellitus with neurological complications	C10ER00	Latent autoimmune diabetes mellitus in adult
C10E211	Type I diabetes mellitus with neurological complications	C10F.00	Type 2 diabetes mellitus
C10E212	Insulin-dependent diabetes mellitus with neurological comps	C10F.11	Type II diabetes mellitus
C10E300	Type 1 diabetes mellitus with multiple complications	C10F000	Type 2 diabetes mellitus with renal complications
C10E311	Type I diabetes mellitus with multiple complications	C10F011	Type II diabetes mellitus with renal complications
C10E312	Insulin dependent diabetes mellitus with multiple complicat	C10F100	Type 2 diabetes mellitus with ophthalmic complications
C10E400	Unstable type 1 diabetes mellitus	C10F111	Type II diabetes mellitus with ophthalmic complications
C10E411	Unstable type I diabetes mellitus	C10F200	Type 2 diabetes mellitus with neurological complications
C10E412	Unstable insulin dependent diabetes mellitus	C10F211	Type II diabetes mellitus with neurological complications
C10E500	Type 1 diabetes mellitus with ulcer	C10F300	Type 2 diabetes mellitus with multiple complications
C10E511	Type I diabetes mellitus with ulcer	C10F311	Type II diabetes mellitus with multiple complications
C10E512	Insulin dependent diabetes mellitus with ulcer	C10F400	Type 2 diabetes mellitus with ulcer
C10E600	Type 1 diabetes mellitus with gangrene	C10F411	Type II diabetes mellitus with ulcer
C10E611	Type I diabetes mellitus with gangrene	C10F500	Type 2 diabetes mellitus with gangrene
C10E612	Insulin dependent diabetes mellitus with gangrene	C10F511	Type II diabetes mellitus with gangrene
C10E700	Type 1 diabetes mellitus with retinopathy	C10F600	Type 2 diabetes mellitus with retinopathy
C10E711	Type I diabetes mellitus with retinopathy	C10F611	Type II diabetes mellitus with retinopathy
C10E712	Insulin dependent diabetes mellitus with retinopathy	C10F700	Type 2 diabetes mellitus - poor control
C10E800	Type 1 diabetes mellitus - poor control	C10F711	Type II diabetes mellitus - poor control
C10E811	Type I diabetes mellitus - poor control	C10F900	Type 2 diabetes mellitus without complication
C10E812	Insulin dependent diabetes mellitus - poor control	C10F911	Type II diabetes mellitus without complication
C10E900	Type 1 diabetes mellitus maturity onset	C10FA00	Type 2 diabetes mellitus with mononeuropathy
C10E911	Type I diabetes mellitus maturity onset	C10FA11	Type II diabetes mellitus with mononeuropathy
C10E912	Insulin dependent diabetes maturity onset	C10FB00	Type 2 diabetes mellitus with polyneuropathy
C10EA00	Type 1 diabetes mellitus without complication	C10FB11	Type II diabetes mellitus with polyneuropathy
C10EA11	Type I diabetes mellitus without complication	C10FC00	Type 2 diabetes mellitus with nephropathy
C10EA12	Insulin-dependent diabetes without complication	C10FC11	Type II diabetes mellitus with nephropathy
C10EB00	Type 1 diabetes mellitus with mononeuropathy	C10FD00	Type 2 diabetes mellitus with hypoglycaemic coma
C10EB11	Type I diabetes mellitus with mononeuropathy	C10FD11	Type II diabetes mellitus with hypoglycaemic coma
C10EB12	Insulin dependent diabetes mellitus with mononeuropathy	C10FE00	Type 2 diabetes mellitus with diabetic cataract
C10EC00	Type 1 diabetes mellitus with polyneuropathy	C10FE11	Type II diabetes mellitus with diabetic cataract
C10EC11	Type I diabetes mellitus with polyneuropathy	C10FF00	Type 2 diabetes mellitus with peripheral angiopathy
C10EC12	Insulin dependent diabetes mellitus with polyneuropathy	C10FF11	Type II diabetes mellitus with peripheral angiopathy
C10ED00	Type 1 diabetes mellitus with nephropathy	C10FG00	Type 2 diabetes mellitus with arthropathy
C10ED11	Type I diabetes mellitus with nephropathy	C10FG11	Type II diabetes mellitus with arthropathy
C10ED12	Insulin dependent diabetes mellitus with nephropathy	C10FH00	Type 2 diabetes mellitus with neuropathic arthropathy
C10EE00	Type 1 diabetes mellitus with hypoglycaemic coma	C10FH11	Type II diabetes mellitus with neuropathic arthropathy
C10EE11	Type I diabetes mellitus with hypoglycaemic coma	C10FJ00	Insulin treated Type 2 diabetes mellitus
C10EE12	Insulin dependent diabetes mellitus with hypoglycaemic coma	C10FJ11	Insulin treated Type II diabetes mellitus
C10EF00	Type 1 diabetes mellitus with diabetic cataract	C10FK00	Hyperosmolar non-ketotic state in type 2 diabetes mellitus
C10EF11	Type I diabetes mellitus with diabetic cataract	C10FL00	Type 2 diabetes mellitus with persistent proteinuria
C10EF12	Insulin dependent diabetes mellitus with diabetic cataract	C10FL11	Type II diabetes mellitus with persistent proteinuria
C10EG00	Type 1 diabetes mellitus with peripheral angiopathy	C10FM00	Type 2 diabetes mellitus with persistent microalbuminuria
C10EG11	Type I diabetes mellitus with peripheral angiopathy	C10FM11	Type II diabetes mellitus with persistent microalbuminuria
C10EG12	Insulin dependent diab mell with peripheral angiopathy	C10FN00	Type 2 diabetes mellitus with ketoacidosis
C10EH00	Type 1 diabetes mellitus with arthropathy	C10FN11	Type II diabetes mellitus with ketoacidosis
C10EH11	Type I diabetes mellitus with arthropathy	C10FP00	Type 2 diabetes mellitus with ketoacidotic coma
C10EH12	Insulin dependent diabetes mellitus with arthropathy	C10FP11	Type II diabetes mellitus with ketoacidotic coma
C10EJ00	Type 1 diabetes mellitus with neuropathic arthropathy	C10FQ00	Type 2 diabetes mellitus with exudative maculopathy
C10EJ11	Type I diabetes mellitus with neuropathic arthropathy	C10FQ11	Type II diabetes mellitus with exudative maculopathy

C10EJ12	Insulin dependent diab mell with neuropathic arthropathy	C10FR00	Type 2 diabetes mellitus with gastroparesis
C10EK00	Type 1 diabetes mellitus with persistent proteinuria	C10FS00	Maternally inherited diabetes mellitus
C10EK11	Type I diabetes mellitus with persistent proteinuria		

Hypertension

G2...00	Hypertensive disease	G240000	Secondary malignant renovascular hypertension
G2...11	BP - hypertensive disease	G240z00	Secondary malignant hypertension NOS
G20..00	Essential hypertension	G241.00	Secondary benign hypertension
G20..11	High blood pressure	G241000	Secondary benign renovascular hypertension
G200.00	Malignant essential hypertension	G241z00	Secondary benign hypertension NOS
G201.00	Benign essential hypertension	G244.00	Hypertension secondary to endocrine disorders
G202.00	Systolic hypertension	G24z.00	Secondary hypertension NOS
G203.00	Diastolic hypertension	G24z000	Secondary renovascular hypertension NOS
G20z.00	Essential hypertension NOS	G24zz00	Secondary hypertension NOS
G20z.11	Hypertension NOS	G2y..00	Other specified hypertensive disease
G24..00	Secondary hypertension	G2z..00	Hypertensive disease NOS
G240.00	Secondary malignant hypertension		

Stroke and Transient Ischemic Attack (TIA)

G61..00	Intracerebral haemorrhage	G66..12	Stroke unspecified
G61..11	CVA - cerebrovascular accid due to intracerebral haemorrhage	G66..13	CVA - Cerebrovascular accident unspecified
G61..12	Stroke due to intracerebral haemorrhage	G660.00	Middle cerebral artery syndrome
G610.00	Cortical haemorrhage	G661.00	Anterior cerebral artery syndrome
G611.00	Internal capsule haemorrhage	G662.00	Posterior cerebral artery syndrome
G612.00	Basal nucleus haemorrhage	G663.00	Brain stem stroke syndrome
G613.00	Cerebellar haemorrhage	G664.00	Cerebellar stroke syndrome
G614.00	Pontine haemorrhage	G665.00	Pure motor lacunar syndrome
G615.00	Bulbar haemorrhage	G666.00	Pure sensory lacunar syndrome
G616.00	External capsule haemorrhage	G667.00	Left sided CVA
G618.00	Intracerebral haemorrhage, multiple localized	G668.00	Right sided CVA
G61X.00	Intracerebral haemorrhage in hemisphere, unspecified	G669.00	Cerebral palsy, not congenital or infantile, acute
G61X000	Left sided intracerebral haemorrhage, unspecified	G676000	Cereb infarct due cerebral venous thrombosis, nonpyogenic
G61X100	Right sided intracerebral haemorrhage, unspecified	G6W..00	Cereb infarct due unsp occlus/stenos precerebr arteries
G61z.00	Intracerebral haemorrhage NOS	G6X..00	Cerebrl infarctn due/unspcf occlusn or sten/cerebrl artrs
G63y000	Cerebral infarct due to thrombosis of precerebral arteries	Gyu6200	[X]Other intracerebral haemorrhage
G63y100	Cerebral infarction due to embolism of precerebral arteries	Gyu6300	[X]Cerebrl infarctn due/unspcf occlusn or sten/cerebrl artrs
G64..00	Cerebral arterial occlusion	Gyu6400	[X]Other cerebral infarction
G64..11	CVA - cerebral artery occlusion	Gyu6500	[X]Occlusion and stenosis of other precerebral arteries
G64..12	Infarction - cerebral	Gyu6600	[X]Occlusion and stenosis of other cerebral arteries
G64..13	Stroke due to cerebral arterial occlusion	Gyu6F00	[X]Intracerebral haemorrhage in hemisphere, unspecified
G64..00	Cerebral arterial occlusion	Gyu6G00	[X]Cereb infarct due unsp occlus/stenos precerebr arteries
G64..11	CVA - cerebral artery occlusion	G65..00	Transient cerebral ischaemia
G64..12	Infarction - cerebral	G65..11	Drop attack
G64..13	Stroke due to cerebral arterial occlusion	G65..12	Transient ischaemic attack
G640.00	Cerebral thrombosis	G65..13	Vertebro-basilar insufficiency
G640000	Cerebral infarction due to thrombosis of cerebral arteries	G650.00	Basilar artery syndrome
G641.00	Cerebral embolism	G650.11	Insufficiency - basilar artery
G641.11	Cerebral embolus	G651.00	Vertebral artery syndrome
G641000	Cerebral infarction due to embolism of cerebral arteries	G651000	Vertebro-basilar artery syndrome
G64z.00	Cerebral infarction NOS	G652.00	Subclavian steal syndrome
G64z.11	Brainstem infarction NOS	G653.00	Carotid artery syndrome hemispheric
G64z.12	Cerebellar infarction	G654.00	Multiple and bilateral precerebral artery syndromes
G64z000	Brainstem infarction	G656.00	Vertebrobasilar insufficiency
G64z100	Wallenberg syndrome	G65y.00	Other transient cerebral ischaemia
G64z111	Lateral medullary syndrome	G65z.00	Transient cerebral ischaemia NOS
G64z200	Left sided cerebral infarction	G65z000	Impending cerebral ischaemia
G64z300	Right sided cerebral infarction	G65z100	Intermittent cerebral ischaemia
G64z400	Infarction of basal ganglia	G65zz00	Transient cerebral ischaemia NOS
G66..00	Stroke and cerebrovascular accident unspecified	F423600	Amaurosis fugax
G66..11	CVA unspecified		

Asthma drug treatment codes

Read Drug and Appliance Directory code	BNF code	Drug type
c1...% Selective beta-adrenoceptor stimulants	3.1.1.1	Bambuterol hydrochloride
		Fenoterol hydrobromide
		Formoterol fumerate
		Salbutamol
		Salmeterol
		Terbutaline sulphate
c2...% Other beta-adrenoceptor stimulants	3.1.1.2	Ephedrine hydrochloride
		Orciprenaline sulphate
c3...% Anticholinergic bronchodilators	3.1.2.0	Ipratropium bromide
		Tiotropium
c4...% Xanthine bronchodilators	3.1.3.0	Aminophylline
		Theophylline
c5...% Compound bronchodilators	3.1.4.0	Combivent®
		Duovent®
c6...% Corticosteroids	3.2.0.0	Belcometasone bipropionate
		Budesonide
		Budesonide with formoterol fumerate
		Ciclesonide
		Fluticasone propionate
		Mometasone furoate
	6.3.2.0	Betamethasone
		Cortisone acetate
		Deflazacort
		Dexamethasone
		Hydrocortisone
		Methlyprednisolone
		Prednisolone
		Triamcinolone
c7...% Asthma prophylaxis	3.3.1.0	Nedocromil sodium
	3.4.2.0	Sodium cromoglicate
		Omalizumab
cA...% Leukotriene receptor antagonists	3.3.2.0	Montelukast
		Zafirlukast

8.8. READ CODES RECORDING THE DELIVERY OF CESSATION ADVICE IN THIN

6791.00	Health ed. - smoking
67A3.00	Pregnancy smoking advice
67H1.00	Lifestyle advice regarding smoking
8CAL.00	Smoking cessation advice
ZG23300	Advice on smoking

8.9. READ CODES RECORDING THE REFERRAL OF SMOKERS TO STOP SMOKING SERVICES IN THIN

8H7i.00	Referral to smoking cessation advisor
8HTK.00	Referral to stop smoking clinic

8.10. MULTILEX DRUG CODES FOR SMOKING CESSATION MEDICATIONS

Multilex drug code	Type	Formulation	Dose
89112998	NICOTINE	Chewing gum	2mg
91248998	NICOTINE	Chewing gum	2mg
92840998	NICOTINE	Chewing gum	2mg
92841998	NICOTINE	Chewing gum	2mg
95727998	NICOTINE	Chewing gum	2mg
98904998	NICOTINE	Chewing gum	2mg
89110998	NICOTINE	Chewing gum	4mg
91248997	NICOTINE	Chewing gum	4mg
95727996	NICOTINE	Chewing gum	4mg
95727997	NICOTINE	Chewing gum	4mg
98904996	NICOTINE	Chewing gum	4mg
98904997	NICOTINE	Chewing gum	4mg
88288998	NICOTINE	Inhalator	10mg
88291998	NICOTINE	Inhalator	10mg
89863998	NICOTINE	Lozenge	0.35mg
92840997	NICOTINE	Lozenge	0.35mg
84442998	NICOTINE	Lozenge	1.5mg
84443998	NICOTINE	Lozenge	1.5mg
91248996	NICOTINE	Lozenge	1mg
98430998	NICOTINE	Lozenge	1mg
87920998	NICOTINE	Lozenge	2mg
87922998	NICOTINE	Lozenge	2mg
91162998	NICOTINE	Lozenge	2mg
91384998	NICOTINE	Lozenge	2mg
92889990	NICOTINE	Lozenge	2mg
87919998	NICOTINE	Lozenge	4mg
91848998	NICOTINE	Lozenge	4mg
92888990	NICOTINE	Lozenge	4mg
98082998	NICOTINE	Lozenge	4mg
92840996	NICOTINE	Tabs	2mg
92841997	NICOTINE	Microtab	2mg
92657998	NICOTINE	Nasal spray	10mg/ml
92836998	NICOTINE	Nasal spray	10mg/ml
93447992	NICOTINE	Patch	0
96844992	NICOTINE	Patch	0
96845992	NICOTINE	Patch	0
97737998	NICOTINE	Patch	10 square cm
96869992	NICOTINE	Patch	10mg
97739997	NICOTINE	Patch	10mg
97763997	NICOTINE	Patch	10mg
92892997	NICOTINE	Patch	11mg/24 hr
98581997	NICOTINE	Patch	11mg/24 hr
88005997	NICOTINE	Patch	14mg
97673997	NICOTINE	Patch	14mg
97740997	NICOTINE	Patch	14mg
84468998	NICOTINE	Patch	14mg/24 hours
96930992	NICOTINE	Patch	15mg
97739996	NICOTINE	Patch	15mg
97763996	NICOTINE	Patch	15mg
97737997	NICOTINE	Patch	20 square cm
88005996	NICOTINE	Patch	21mg
97673996	NICOTINE	Patch	21mg
97740996	NICOTINE	Patch	21mg
84466998	NICOTINE	Patch	21mg/24 hours
92892998	NICOTINE	Patch	22mg/24 hr
98581998	NICOTINE	Patch	22mg/24 hr
97737996	NICOTINE	Patch	30 square cm
96924992	NICOTINE	Patch	30mg
96868992	NICOTINE	Patch	5mg
97739998	NICOTINE	Patch	5mg
97763998	NICOTINE	Patch	5mg
88005998	NICOTINE	Patch	7mg
97673998	NICOTINE	Patch	7mg
97740998	NICOTINE	Patch	7mg
84469998	NICOTINE	Patch	7mg/24 hours
92309998	BUPROPION	Modified release tablet	150mg
92311998	BUPROPION	Modified release tablet	150mg
85397998	VARENICLINE	Tabs	1mg
85398998	VARENICLINE	Tabs	500 micrograms
85399998	VARENICLINE	Tabs	500micrograms + 1mg
85400998	VARENICLINE	Tabs	1mg
85401998	VARENICLINE	Tabs	500 micrograms
85403998	VARENICLINE	Tabs	500micrograms + 1mg

8.11. STATA COMMANDS FOR TIME SERIES ANALYSIS

To declare data to be time series data:
tsset timevar

To draw a simple time plot of a series:
tsline series

To draw an autocorrelation function (ACF) up to lag 40:
ac series, lags(40) yscale(range(-1/1))

To draw a partial autocorrelation function (PACF) up to lag 40:
pac series, lags(40) yscale (range(-1/1))

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

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

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

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)

Having fitted an ARIMA model, assess whether the parameters are collinear:
estat vce, corr

To draw a histogram of the standardised residuals from an ARIMA model:
predict residuals, residuals
egen standres = std(residuals)
hist standres

To draw a scatter graph of the standardised residuals over time:
twoway (scatter standres timevar)

To compute the Ljung-Box Q statistic on ARIMA model residuals up to lag 20:
wntestq residuals, lags(20)
NB. The p-value given by Stata does not use the correct number of degrees of freedom and should not be used. An external χ^2 calculator should be used to test the Q statistic against a χ^2 distribution with the number of degrees of freedom equal to 20 minus the number of parameters in the ARIMA model.

To generate a dummy variable indicating the presence of an intervention in a given month e.g. July 2007:
gen intervention = 0
recode intervention 0=1 if month==tm(2007-7)

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

8.12. THE ARIMAINTERVENTION COMMAND

The 'arimaintervention' command, accessed via a Stata ado. file, fits several different ARIMA models to a pre-intervention time series, systematically working through combinations of non-seasonal and seasonal autoregressive and moving average parameters of order zero, one and two. For each model, the output of the command indicates whether it is an adequate representation of the data, combining assessment of the statistical significance of the parameter estimates, whether the parameters fall within the bounds of stationarity and invertibility, and whether the residuals are a white noise process. In addition, the procedure highlights the absolute magnitude of the largest standardised residual to allow detection of possible outliers and computes two estimates of model fit, R^2 and the AIC, which can be used to choose between several adequate models. The procedure also, for each model, estimates the magnitude of change in the outcome variable in the intervention period, along with 95% confidence intervals and a Wald p-value for the parameter. The results can then be scanned visually to assess whether the choice of model influences the magnitude and statistical significance of the change in the outcome variable estimated in the intervention period.

The command is specified as follows:

arimaintervention *series*, time(*timevar*) logged(1) dif(1) seasdif(1) intstart(tm(2007-6)) intperiod(*interventionvar*) using("*dataset1*") output("*dataset2*")

where:

series = the name of the time series variable to be modelled

timevar = the variable indicating the point in time each observation was measured

logged = a binary variable to indicate whether the series should (1) or should not (0) be logged prior to model estimation

dif = a binary variable to indicate whether the series should (1) or should not (0) be first differenced to induce stationarity prior to model estimation

dif = a binary variable to indicate whether the series should (1) or should not (0) be seasonally differenced to induce stationarity prior to model estimation

intstart = the first month of the intervention period

interventionvar = a dummy variable coded 1 for all time points in the intervention period and 0 for all other time points

dataset1 = the name of the dataset in which the time series data are stored

dataset2 = the name of the dataset which will be created to store the results of the procedure

8.13. TIME SERIES ANALYSIS OF DATA FROM ALL PATIENTS

Recording of cessation advice

	England			Scotland		
	Estimate (%)	95% CI (%)	P-value	Estimate (%)	95% CI (%)	P-value
Q1 of SFL year	3.1	-7.1 to 13.3	0.553	-4.6	-33.4 to 24.2	0.754
1 month before	6.0	-78.6 to 90.6	0.890	-10.5	-89.5 to 68.4	0.794
2 months before	4.7	-47.8 to 57.3	0.859	-7.4	-46.3 to 31.6	0.711
3 months before	-6.9	-16.6 to 2.9	0.169	-4.6	-33.4 to 24.2	0.754
6 months before	-1.8	-9.0 to 5.3	0.613	1.0	-11.3 to 13.3	0.873
9 months before	-1.4	-8.1 to 5.2	0.672	-2.5	-12.6 to 7.6	0.624
1 month after	-6.1	-88.5 to 76.3	0.885	9.0	-23.4 to 41.4	0.587
2 months after	-8.1	-55.3 to 39.1	0.736	3.3	-24.8 to 31.4	0.819
3 months after	-1.9	-18.9 to 15.1	0.828	0.4	-24.5 to 25.4	0.972
6 months after	-2.8	-14.5 to 8.9	0.641	-0.2	-21.3 to 20.9	0.986
9 months after	-0.9	-9.2 to 7.4	0.832	1.3	-11.9 to 14.5	0.844
Permanent change	-1.4	-4.3 to 1.6	0.371	0.0	-9.5 to 9.6	0.994
	Wales			**Northern Ireland**		
	Estimate (%)	95% CI (%)	P-value	Estimate (%)	95% CI (%)	P-value
Q1 of SFL year	5.0	-52.0 to 61.9	0.864	-3.6	-27.1 to 20.0	0.765
1 month before	7.6	-73.7 to 88.8	0.855	-23.6	-71.0 to 23.8	0.330
2 months before	8.4	-75.5 to 92.3	0.844	-8.9	-25.4 to 7.6	0.292
3 months before	5.0	-52.0 to 61.9	0.864	-6.7	-20.7 to 7.4	0.353
6 months before	4.0	-24.6 to 32.6	0.784	-2.9	-12.6 to 6.7	0.550
9 months before	2.3	-13.5 to 18.2	0.773	-2.2	-10.7 to 6.3	0.612
1 month after	-3.5	-40.0 to 32.9	0.849	-0.1	-130.4 to 130.2	0.998
2 months after	-0.1	-29.8 to 29.7	0.997	-2.1	-59.6 to 55.5	0.944
3 months after	-2.7	-27.4 to 22.0	0.831	-3.3	-49.7 to 43.1	0.889
6 months after	-2.0	-15.8 to 11.9	0.780	-3.2	-34.9 to 28.4	0.841
9 months after	-2.2	-13.5 to 9.1	0.705	-4.5	-22.9 to 13.9	0.633
Permanent change	-1.6	-8.4 to 5.2	0.645	-2.1	-9.9 to 5.7	0.603

Recording of referral to stop smoking services

	England			Scotland		
	Estimate (%)	95% CI (%)	P-value	Estimate (%)	95% CI (%)	P-value
Q1 of SFL year	1.9	-169.6 to 173.5	0.982	10.4	-77.1 to 97.9	0.816
1 month before	18.0	-219.9 to 256.0	0.882	-9.0	-118.2 to 100.2	0.872
2 months before	7.3	-111.4 to 126.0	0.904	6.8	-98.9 to 112.5	0.900
3 months before	1.6	-69.8 to 73.0	0.966	10.4	-77.1 to 97.9	0.816
6 months before	1.5	-55.8 to 58.8	0.959	-3.1	-42.9 to 36.7	0.878
9 months before	2.0	-21.6 to 25.5	0.869	-2.8	-34.8 to 29.3	0.866
1 month after	2.9	-193.5 to 199.3	0.977	-52.3	-183.0 to 78.5	0.433
2 months after	-21.6	-95.7 to 52.5	0.568	-31.8	-114.9 to 51.3	0.453
3 months after	-16.5	-79.7 to 46.6	0.608	-22.8	-85.4 to 39.9	0.476
6 months after	-10.2	-44.3 to 23.9	0.557	-9.9	-50.4 to 30.7	0.634
9 months after	-6.4	-34.8 to 22.1	0.660	5.7	-2.1 to 13.5	0.151
Permanent change	-2.5	-23.3 to 18.3	0.812	0.5	-16.7 to 17.7	0.957
	Wales					
	Estimate (%)	95% CI (%)	P-value			
Q1 of SFL year	4.5	-24.8 to 33.9	0.762			
1 month before	-12.7	-92.1 to 66.8	0.755			
2 months before	-3.5	-48.6 to 41.7	0.880			
3 months before	4.5	-24.8 to 33.9	0.762			
6 months before	-1.5	-15.8 to 12.9	0.841			
9 months before	-1.6	-13.3 to 10.0	0.783			
1 month after	18.1	-64.7 to 100.9	0.668			
2 months after	-1.6	-48.5 to 45.3	0.947			
3 months after	-1.5	-36.6 to 33.7	0.935			
6 months after	-3.8	-21.2 to 13.6	0.668			
9 months after	-0.6	-14.1 to 12.9	0.935			
Permanent change	0.7	-9.1 to 10.4	0.896			

Time series analysis of rates of recording of advice and referral produce very similar results in all patients compared to just those identified as current smokers. In both cases, no significant changes in the rate of recording of either advice or referral are seen in any intervention period in any jurisdiction of the UK.

Prescribing of NRT

	England			**Scotland**		
	Estimate (%)	95% CI (%)	P-value	Estimate (%)	95% CI (%)	P-value
Q1 of SFL year	-0.3	-6.7 to 6.0	0.919	-3.0	-11.0 to 5.0	0.466
1 month before	**15.3**	**8.5 to 22.1**	**<0.001**	16.5	-15.2 to 48.2	0.308
2 months before	**12.2**	**6.7 to 17.7**	**<0.001**	7.8	-7.0 to 22.6	0.304
3 months before	**9.0**	**4.0 to 14.0**	**<0.001**	-3.0	-11.0 to 5.0	0.466
6 months before	**5.5**	**1.1 to 9.8**	**0.013**	4.5	-4.3 to 13.3	0.313
9 months before	4.2	-0.1 to 8.5	0.054	1.2	-6.3 to 8.7	0.751
1 month after	3.5	-15.1 to 22.1	0.712	3.3	-30.9 to 37.5	0.851
2 months after	-2.6	-7.8 to 2.7	0.341	-5.3	-15.1 to 4.6	0.298
3 months after	**-8.1**	**-3.6 to -12.5**	**<0.001**	-4.4	-12.7 to 4.0	0.306
6 months after	**-6.4**	**-2.4 to -10.3**	**0.002**	-5.2	-11.7 to 1.3	0.115
9 months after	**-5.4**	**-2.6 to -8.3**	**<0.001**	-3.0	-8.4 to 2.5	0.286
Permanent change	-1.8	-4.3 to 0.7	0.151	2.1	-1.2 to 5.4	0.217
	Wales			**Northern Ireland**		
	Estimate (%)	95% CI (%)	P-value	Estimate (%)	95% CI (%)	P-value
Q1 of SFL year	-3.5	-15.2 to 8.1	0.550	6.8	-13.7 to 27.2	0.516
1 month before	6.4	-16.1 to 29.0	0.576	17.6	-23.6 to 58.8	0.403
2 months before	3.8	-12.7 to 20.2	0.654	7.5	-8.5 to 23.4	0.358
3 months before	-3.5	-15.2 to 8.1	0.550	-0.5	-12.2 to 11.2	0.930
6 months before	2.4	-7.2 to 12.0	0.625	-2.9	-10.5 to 4.7	0.458
9 months before	-3.5	-10.3 to 3.4	0.319	-0.5	-12.2 to 11.2	0.930
1 month after	**14.3**	**0.4 to 28.2**	**0.044**	18.8	-3.7 to 41.3	0.101
2 months after	**9.3**	**2.5 to 16.0**	**0.007**	**12.4**	**4.7 to 20.2**	**0.002**
3 months after	5.6	-0.7 to 11.9	0.082	**7.4**	**1.4 to 13.4**	**0.015**
6 months after	-3.6	-8.9 to 1.6	0.177	-3.9	-9.2 to 1.3	0.141
9 months after	-3.2	-8.0 to 1.7	0.206	-3.5	-8.1 to 1.1	0.140
Permanent change	-1.4	-4.1 to 1.3	0.308	-0.5	-3.2 to 2.3	0.740

Prescribing of bupropion

	England			**Scotland**		
	Estimate (%)	95% CI (%)	P-value	Estimate (%)	95% CI (%)	P-value
Q1 of SFL year	0.6	-16.9 to 18.2	0.943	11.9	-19.2 to 43.0	0.454
1 month before	**41.7**	**22.0 to 61.5**	**<0.001**	-0.6	-71.3 to 70.1	0.987
2 months before	**17.8**	**9.4 to 26.2**	**<0.001**	6.9	-39.8 to 53.5	0.773
3 months before	**13.8**	**5.3 to 22.2**	**0.001**	11.9	-19.2 to 43.0	0.454
6 months before	**10.9**	**1.9 to 19.9**	**0.018**	5.9	-7.5 to 19.4	0.386
9 months before	4.8	-1.6 to 11.3	0.141	4.7	-7.4 to 16.7	0.449
1 month after	2.5	-27.4 to 32.3	0.872	-26.3	-170.6 to 118.0	0.721
2 months after	**-19.4**	**-5.5 to -33.2**	**0.006**	-17.4	-112.7 to 78.0	0.721
3 months after	**-19.0**	**-5.4 to -32.6**	**0.006**	-13.8	-81.0 to 53.3	0.686
6 months after	**-16.3**	**-4.7 to -27.9**	**0.006**	-6.9	-31.5 to 17.7	0.582
9 months after	**-12.9**	**-5.4 to -20.3**	**0.001**	-4.3	-17.1 to 8.4	0.505
Permanent change	-3.3	-7.9 to 1.2	0.154	-3.5	-7.2 to 0.3	0.070

	Wales			Northern Ireland		
	Estimate (%)	95% CI (%)	P-value	Estimate (%)	95% CI (%)	P-value
Q1 of SFL year	13.3	-4.5 to 31.1	0.142	27.4	1.7 to 53.2	0.037
1 month before	7.8	-48.7 to 64.4	0.786	-24.5	-142.1 to 93.1	0.683
2 months before	11.3	-17.1 to 39.7	0.435	-12.5	-102.3 to 77.4	0.785
3 months before	13.3	-4.5 to 31.1	0.142	-1.5	-52.1 to 49.1	0.953
6 months before	**14.2**	**1.9 to 26.5**	**0.023**	**20.6**	**8.9 to 32.3**	**0.001**
9 months before	**8.7**	**2.4 to 14.9**	**0.007**	**14.5**	**5.3 to 23.7**	**0.002**
1 month after	-18.7	-77.8 to 40.4	0.535	-39.1	-120.4 to 42.1	0.345
2 months after	-17.6	-61.6 to 26.5	0.434	**-25**	**-1.2 to -48.7**	**0.039**
3 months after	-12.8	-41.5 to 15.9	0.381	**-30.2**	**-13.3 to -47.2**	**<0.001**
6 months after	-8.5	-17.4 to 0.3	0.059	-13.5	-27.5 to 0.5	0.059
9 months after	**-8.4**	**-3.7 to -13.0**	**<0.001**	-10.7	-23.2 to 1.8	0.093
Permanent change	**-4.2**	**-2.9 to -5.5**	**<0.001**	-5.4	-12.2 to 1.4	0.120

Prescribing of all smoking cessation medications

	England			Scotland		
	Estimate (%)	95% CI (%)	P-value	Estimate (%)	95% CI (%)	P-value
Q1 of SFL year	2.3	-18.4 to 23.1	0.827	4.6	-7.2 to 16.4	0.444
1 month before	**23.5**	**18.1 to 29.0**	**<0.001**	12.4	-6.7 to 31.6	0.203
2 months before	**16.8**	**11.7 to 21.8**	**<0.001**	6.3	-6.3 to 18.9	0.325
3 months before	**12.2**	**6.8 to 17.5**	**<0.001**	4.6	-7.2 to 16.4	0.444
6 months before	**10.3**	**5.0 to 15.6**	**<0.001**	4.1	-3.6 to 11.8	0.300
9 months before	**6.4**	**1.0 to 11.8**	**0.021**	1.1	-5.4 to 7.6	0.734
1 month after	15.3	-3.7 to 34.3	0.114	0.4	-46.1 to 47.0	0.985
2 months after	-0.1	-8.9 to 8.7	0.988	-7.9	-17.8 to 2.0	0.117
3 months after	-6.1	-13.3 to 1.1	0.096	-3.9	-11.7 to 3.8	0.321
6 months after	-5.6	-12.3 to 1.2	0.106	-3.4	-9.8 to 3.0	0.299
9 months after	**-5.5**	**-1.0 to -10.0**	**0.016**	-2	-8.0 to 4.0	0.514
Permanent change	-1.9	-4.9 to 1.1	0.218	-0.5	-2.9 to 1.9	0.688
	Wales			**Northern Ireland**		
	Estimate (%)	95% CI (%)	P-value	Estimate (%)	95% CI (%)	P-value
Q1 of SFL year	-2.9	-9.1 to 3.2	0.349	9.7	-161.0 to 180.3	0.912
1 month before	5.9	-8.9 to 20.7	0.436	22.3	-22.3 to 66.8	0.327
2 months before	1.8	-8.5 to 12.2	0.729	15.1	-16.0 to 46.2	0.340
3 months before	-2.9	-9.1 to 3.2	0.349	10.8	-17.6 to 39.2	0.454
6 months before	1.8	-10.6 to 14.3	0.772	6.4	-3.3 to 16.1	0.197
9 months before	3.3	-5.6 to 12.1	0.468	5.1	-1.9 to 12.2	0.151
1 month after	14.4	-12.1 to 40.9	0.288	14.7	-5.2 to 34.7	0.148
2 months after	0.6	-6.6 to 7.8	0.871	**11.1**	**0.9 to 21.4**	**0.034**
3 months after	4.2	-3.3 to 11.8	0.273	6.6	-1.0 to 14.2	0.087
6 months after	0.5	-5.6 to 6.5	0.880	0.1	-5.8 to 6.0	0.967
9 months after	-1.8	-7.1 to 3.6	0.519	-1.5	-5.9 to 2.8	0.487
Permanent change	-1.5	-4.6 to 1.6	0.340	-0.6	-3.2 to 2.0	0.674

The estimates of changes in NRT, bupropion and all prescribing in all patients are very similar in magnitude, direction and significance to the changes in prescribing seen in current smokers only.

8.14. TIME SERIES ANALYSIS OF DATA FROM APRIL 2004 ONWARDS

Recording of smoking status

	England			Scotland		
	Estimate (%)	95% CI (%)	P-value	Estimate (%)	95% CI (%)	P-value
Q1 of SFL year	5.9	-13.3 to 25.0	0.549	-2.1	-18.8 to 14.6	0.807
1 month before	-1.6	-21.7 to 18.7	0.883	**25.2**	**14.0 to 36.5**	**<0.001**
2 months before	3.8	-22.8 to 30.3	0.780	**19.5**	**10.5 to 28.5**	**<0.001**
3 months before	**-7.5**	**-2.7 to -12.4**	**0.002**	-2.1	-18.8 to 14.6	0.807
6 months before	-0.9	-6.8 to 5.1	0.774	4.4	-18.8 to 27.6	0.710
9 months before	1.3	-5.1 to 7.7	0.691	-0.8	-18.8 to 17.2	0.933
1 month after	2.5	-17.6 to 22.7	0.807	6.4	-10.1 to 22.9	0.446
2 months after	-1.6	-38.1 to 34.9	0.932	1.9	-79.7 to 83.5	0.964
3 months after	-2.7	-35.5 to 30.1	0.872	7.6	-6.1 to 21.2	0.277
6 months after	-5.9	-13.7 to 1.9	0.138	-2.8	-28.8 to 23.2	0.831
9 months after	-3.8	-10.9 to 3.3	0.294	8.6	-1.4 to 18.6	0.093
Step change	-0.9	-4.9 to 3.1	0.648	5.9	-0.4 to 12.2	0.065
	Wales			**Northern Ireland**		
	Estimate (%)	95% CI (%)	P-value	Estimate (%)	95% CI (%)	P-value
Q1 of SFL year	1.4	-7.2 to 10.0	0.750	**8.5**	**1.1 to 16.0**	**0.024**
1 month before	12.8	-0.7 to 26.3	0.063	**-46.5**	**-18.3 to -74.7**	**0.001**
2 months before	5.4	-4.7 to 15.5	0.295	-2.1	-16.9 to 12.6	0.777
3 months before	1.4	-7.2 to 10.0	0.750	0.9	-9.7 to 11.6	0.861
6 months before	**2.8**	**0.0 to 5.5**	**0.050**	7.0	-0.1 to 14.0	0.054
9 months before	**8.6**	**2.2 to 15.0**	**0.008**	3.3	-1.3 to 7.8	0.160
1 month after	**-10.6**	**-1.5 to -19.6**	**0.023**	-0.7	-80.6 to 79.2	0.986
2 months after	**-7.7**	**-0.6 to -14.9**	**0.035**	-2.5	-39.1 to 34.1	0.892
3 months after	-4.9	-11.3 to 1.5	0.136	-2.7	-22.5 to 17.2	0.792
6 months after	-4.4	-9.8 to 1.0	0.112	-2.3	-13.2 to 8.7	0.683
9 months after	-2.3	-6.8 to 2.2	0.313	-1.8	-9.8 to 6.1	0.654
Step change	-1.0	-3.1 to 1.1	0.350	-1.3	-4.8 to 2.2	0.466

When data from January 2000 onwards was analysed, significant short-lived reductions in the rate of recording either before or after the introduction of smokefree legislation were seen in all four parts of the UK. When analysis is restricted to data from April 2004 onwards, a similar magnitude of decline in recording is seen in England in the three months before the smoking ban was introduced. However, some differences in the estimated effects of smokefree legislation in the other countries are apparent. For example, in Scotland a 25.2% increase in the rate of recording in the month before legislation was introduced is estimated from the shorter time series, though no significant effect is seen when all data are modelled. Similarly, significant increases in the rate of recording are seen six and nine months before the Welsh smoking ban when data from April 2004 onwards is modelled, though no significant effect is seen from analysis of data from the whole study period.

Recording of cessation advice

	England			Scotland		
	Estimate (%)	95% CI (%)	P-value	Estimate (%)	95% CI (%)	P-value
Q1 of SFL year	1.9	-12.2 to 16.0	0.788	-2.3	-343.9 to 339.3	0.990
1 month before	9.0	-93.6 to 111.5	0.864	1.3	-41.5 to 44.1	0.953
2 months before	3.1	-31.0 to 37.3	0.857	-0.4	-42.2 to 41.4	0.986
3 months before	-3.4	-16.3 to 9.6	0.610	-2.3	-343.9 to 339.3	0.990
6 months before	-0.6	-9.0 to 7.9	0.894	17.3	-7.0 to 41.6	0.163
9 months before	3.1	-7.8 to 13.9	0.581	**-7.6**	**-0.8 to -14.5**	**0.029**
1 month after	-7.1	-77.9 to 63.7	0.844	-5.6	-498.4 to 487.1	0.982
2 months after	-8.3	-52.6 to 36.0	0.715	-8.4	-190.4 to 173.7	0.928
3 months after	-8.9	-42.3 to 24.5	0.600	-11.8	-75.6 to 52.1	0.718
6 months after	**-7.8**	**-0.4 to -15.3**	**0.040**	-16.4	-33.8 to 1.0	0.065
9 months after	-4.8	-11.0 to 1.5	0.135	**-13.7**	**-5.8 to -21.7**	**0.001**
Step change	-1.3	-4.9 to 2.3	0.479	-1.8	-6.7 to 3.1	0.465
	Wales			**Northern Ireland**		
	Estimate (%)	95% CI (%)	P-value	Estimate (%)	95% CI (%)	P-value
Q1 of SFL year	-0.3	-10.5 to 9.9	0.951	4.0	-7.6 to 15.6	0.500
1 month before	22.5	-187.6 to 232.6	0.834	**-21.6**	**-5.2 to -38.0**	**0.010**
2 months before	5.1	-9.6 to 19.7	0.496	0.1	-8.1 to 8.4	0.979
3 months before	-0.3	-10.5 to 9.9	0.951	-2.3	-10.3 to 5.6	0.567
6 months before	16.8	-2.1 to 35.7	0.082	6.5	0.3 to 12.6	0.038
9 months before	2.9	-6.1 to 11.9	0.528	2.4	-1.2 to 6.0	0.192
1 month after	-14.6	-82.8 to 53.5	0.674	8.1	-237.9 to 254.2	0.948
2 months after	0.3	-37.1 to 37.6	0.989	1.8	-30.6 to 34.3	0.913
3 months after	-17.5	-41.8 to 6.8	0.158	1.2	-30.1 to 32.5	0.939
6 months after	1.2	-16.5 to 18.8	0.897	-1.2	-22.3 to 19.9	0.910
9 months after	1.3	-14.4 to 17.0	0.870	-2.8	-18.6 to 13.1	0.734
Step change	-3.4	-13.9 to 7.1	0.527	-1.3	-5.7 to 3.1	0.568

No significant changes in the rate of recording of cessation advice in current smokers were seen in any intervention period in any jurisdiction of the UK based on analysis of data from January 2000 onwards. However, some significant declines in the recording of advice are estimated using the shorter time series.

Recording of referral to stop smoking services

	England			Scotland		
	Estimate (%)	95% CI (%)	P-value	Estimate (%)	95% CI (%)	P-value
Q1 of SFL year	35.9	-56.8 to 128.7	0.447	25.6	-29.8 to 81.0	0.366
1 month before	23.2	-88.9 to 135.3	0.685	21.2	-31.2 to 73.5	0.428
2 months before	6.7	-45.1 to 58.6	0.799	36.8	-29.8 to 103.4	0.278
3 months before	-6.8	-80.5 to 66.8	0.856	25.6	-29.8 to 81.0	0.366
6 months before	26.6	-15.3 to 68.5	0.214	-19.1	-51.1 to 12.9	0.241
9 months before	**34.1**	**16.3 to 51.9**	**<0.001**	9.3	-28.4 to 47.1	0.628
1 month after	28.5	-41.2 to 98.1	0.423	-20.9	-70.0 to 28.3	0.406
2 months after	-6	-85.4 to 73.5	0.883	-14.8	-62.1 to 32.5	0.540
3 months after	-12	-91.3 to 67.3	0.767	-36.6	-104.4 to 31.2	0.290
6 months after	-30.1	-78.9 to 18.8	0.228	**-79.4**	**-29.6 to -129.2**	**0.002**
9 months after	-6.1	-92.3 to 80.0	0.889	-30.4	-85.0 to 24.2	0.275
Step change	-14.3	-90.8 to 62.2	0.714	-46.7	-134.3 to 40.9	0.296

	Wales		
	Estimate (%)	95% CI (%)	P-value
Q1 of SFL year	11.0	-16.3 to 38.2	0.430
1 month before	-17.1	-53.9 to 19.6	0.361
2 months before	-7.5	-28.7 to 13.6	0.485
3 months before	11.0	-16.3 to 38.2	0.430
6 months before	-11.1	-36.0 to 13.9	0.385
9 months before	-4.9	-27.9 to 18.1	0.677
1 month after	23.1	-22.5 to 68.8	0.320
2 months after	-1.0	-26.9 to 24.9	0.939
3 months after	-2.2	-21.5 to 17.1	0.825
6 months after	-4.3	-13.7 to 5.2	0.375
9 months after	-1.1	-8.8 to 6.7	0.785
Step change	0.7	-4.3 to 5.7	0.792

No significant changes in the rate of recording of referrals to smoking cessation services were seen in any intervention period in any jurisdiction of the UK based on analysis of the whole time series. However, when data from April 2004 onwards is analysed, an increase in referral in England is estimated to have occurred in the nine month period before the introduction of the smoking ban, and a decrease in Scotland in the six month period after legislation was enacted.

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