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Community Pharmacy: Promoting Health and Wellbeing

Draft Report

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Contents

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Section 1: Introduction

1.1 BACKGROUND

The role of community pharmacies in public health promotion has become more prominent in recent years, and they are now increasingly seen as effective outlets for health professionals to provide services and disseminate information central to the public health agenda. Department of Health (2008) statistics show that 1.2 million health-related visits to community pharmacies take place every day with 78% of adults in England using them at least once a year.

The services being delivered by community pharmacies range from dispensing and advising on the use medicines, supporting independence and promoting good health and preventative behaviours (Department of Health 2016). It is through this last aspect that community pharmacies are seen to have the greatest potential to contribute to public health campaigns. The high volume of activity taking place in community pharmacies is indicative of their accessibility to local residents, allowing public health messages and resources to reach a larger number of people. Research also shows that they are also well-placed to tackle health inequalities, with one study by Todd *et al.* (2014) estimating that in areas of high deprivation nearly 100% of the population can walk to their local community pharmacy within 20 minutes.

The economic modelling described in this report will contribute to the development of guidelines recommending interventions that can be delivered by community pharmacies to improve public health.

1.2 OBJECTIVES

This work will contribute toward the achievement of the objectives set out in the NICE scope. The intention is to model the cost-effectiveness of a series of interventions commonly delivered in community pharmacies for multiple health areas outlined below. The types of interventions and health areas that will be evaluated have been outlined in the scope and have been informed by the NICE effectiveness review for this guideline. The key questions from the scope are as follows:

1)

a) How can information on health and wellbeing (including information provided as part of awareness raising campaigns) be provided in an effective way by community pharmacy staff? For example, are booklets containing self-help material effective?
b) Is providing information acceptable to users of community pharmacy services?
c) How can information on health and wellbeing (including information provided as part of awareness raising campaigns) be provided in a cost effective way by community

pharmacy staff? For example, are booklets containing self-help material cost effective?

2)
   a) What are the most effective ways for community pharmacy staff to offer advice or education to promote health and wellbeing to users of community pharmacy services?
   b) Is offering advice or education acceptable to users of community pharmacy services?
   c) What are the most cost effective ways of offering advice or education to promote health and wellbeing by community pharmacy staff?

3)
   a) What types of behavioural support for self-care to promote health behaviour change are effective in community pharmacies?
   b) Is offering behavioural support acceptable to users of community pharmacy services?
   c) What types of behavioural support for self-care to promote health behaviour change are cost effective in community pharmacies?

4)
   a) What is the most effective way for community pharmacies to refer or signpost people to other services or support?
   b) Is offering signposting and referral acceptable to users of community pharmacy services?
   c) What is the most cost effective way for community pharmacies to refer or signpost people to other services or support?

Section 2: Methods

2.1 MODELLING APPROACH

Developing *de novo* economic models for each of the 9 health areas covered by the scope was not feasible within the timeline of the guideline development; therefore, the approach we take is to identify existing cost-effectiveness models relating to the health area of interest, with a preference for those developed for previous NICE guidance. After updating them to reflect the best available data, the treatment effects extracted from the effectiveness studies of community pharmacy-based interventions can then be input into these models to estimate their cost and health impacts.

The modelling is, therefore, dependent upon two factors: (i) available evidence linking pharmacy-based interventions in a given health area to an appropriate outcome measure and (ii) cost-effectiveness models for that health area that are compatible with the outcome measure. The NICE evidence review identified sufficient evidence for two health areas: smoking cessation and weight management.

The method described above does not generate any economic evidence to support recommendations for the remaining health areas identified in the scope, including alcohol dependency, diabetes or cardiovascular disease. Effectiveness studies have been identified in the evidence review for these areas; however, the outcomes reported cannot be linked to long-term health outcomes. These include studies that only assess the feasibility of an intervention or that measure patient attitudes, knowledge or awareness. The principal issues with evidence for each of the excluded health areas identified by the evidence review are provided in Table 2.1.

Table 2.1: Health areas not included in modelling

	Reason for exclusion
Alcohol abuse	2 feasibility studies, 1 RCT showing no effect
Asthma	Unusable outcome measure (asthma severity or knowledge)
Chronic obstructive pulmonary disease	Unusable outcome measure (emergency department visits)
Cardiovascular disease	Unusable outcome measure (patient experience survey)
Diabetes	Unusable outcome measure (HbA1c level, BMI change)
Osteoporosis	No previous NICE model identified
General health	No previous NICE model identified

Note: 'Unusable outcome measure' can refer to the outcome measure(s) reported in each study being incompatible (i) for economic modelling generally or (ii) for the specific model used in previous NICE guidance.

Where there was effectiveness evidence that is insufficient for cost-effectiveness modelling, cost-consequence analysis, which presents the intervention costs alongside a dashboard of expected impacts, was considered. However, at the request of the Public Health Advisory Committee (PHAC), this was not conducted. Since the studies contained such a wide range of primary and secondary outcome measures, the Committee felt that a comparison was not likely to be useful in informing their recommendations. This report, therefore, details our approach toward modelling interventions for which cost-effectiveness evidence could be generated, namely behavioural support interventions for smoking cessation and weight management. The approaches for each are described in detail below.

2.2 SMOKING CESSATION

2.2.1 Model Overview

For smoking cessation interventions we use the decision model built to help inform NICE guidance currently in development (GID-PH94), which was, in turn, based on modelling for previous NICE guidelines (PH10 & PH45). A cohort model was developed in line with the NICE methods manual and an NHS and personal social services (PSS) perspective is adopted (National Institute for Health and Care Excellence 2014). A lifetime time horizon is adopted in order to capture all relevant costs and benefits. Discount rates of 3.5% for both costs and benefits are applied to future costs and outcomes as stipulated in the NICE manual for guideline development (2014). The principal measure of cost-effectiveness is the incremental cost-effectiveness ratio (ICER), expressed as the incremental cost per quality-adjusted life year (QALY) of an intervention when compared with no intervention. This is defined as the ratio of the difference in cost and the difference in QALYs between the treatment, tx, and comparator, cx:

$$ICER = \frac{Cost_{tx} - Cost_{cx}}{QALY_{tx} - QALY_{cx}}$$

If the ICER is below the cost-effectiveness threshold, for which NICE uses a range of £20,000 to £30,000, then an intervention is usually deemed cost-effective. The cost-effectiveness threshold reflects the opportunity cost of lost health from elsewhere in the healthcare system as funds are moved to the new intervention that arises in fixed-budget health care systems. We also summarise results using net monetary benefit:

$$NMB = \left(QALY_{tx} - QALY_{cx}\right)k - \left(Cost_{tx} - Cost_{cx}\right)$$

Where k is an estimate of the cost-effectiveness threshold. NMB provides the net QALY per person gained, and converts the health impacts in to a monetary value using k. NMB has the property an intervention will be cost-effective if it is greater than zero. We also provide disaggregated results that show both incremental costs and health-related quality of life (HRQL) benefits.

2.2.2 Model Structure

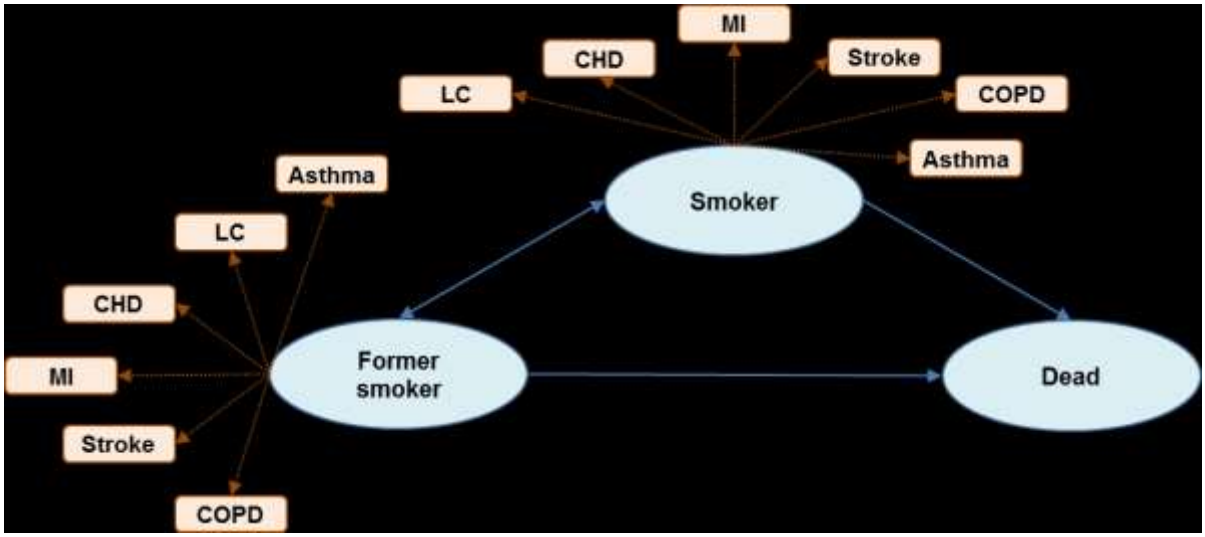
The Markov model structure is shown in Figure 2.1. A similar model structure has been used in past cost-effectiveness models for smoking interventions (PH10, PH45, (Taylor et al. 2011).

Individuals in the model are always in one of three states: 'smoker', 'former smoker' or 'dead. A hypothetical cohort enter the model in the 'smoker' state and, according to the effectiveness of the intervention, have a probability of quitting and moving to the 'former smokers' state. Conversely, former smokers have a probability of relapsing. People from either the 'smoker' or 'former smoker' health state can move to the 'dead' health state. It is noted that tobacco harm reduction is out of the scope of this project.

Each cycle, smokers and former smokers have a probability of 5 different long-term comorbidities occurring:

- Lung cancer (LC);
- Coronary heart disease (CHD);
- Chronic obstructive pulmonary disorder (COPD);
- Myocardial infarction (MI);
- Stroke.

Figure 2.1: Model structure



Note: LC = lung cancer, CHD = coronary heart disease, MI = myocardial infarction, COPD = chronic obstructive pulmonary disease, asthma = asthma exacerbation.

In addition, smokers and former smokers have a probability of experiencing an acute asthma exacerbation.

Two cohorts (one for the intervention and another for the comparator) then progress through the model. The proportion of the cohort in the 'former smoker' state is determined by the effectiveness of an intervention in motivating individuals to quit smoking. In each annual cycle individuals have a probability of death and probabilities of developing each of the comorbidities, which dependent upon are smoking status.

Costs are determined by two factors: the initial intervention cost and the numbers experiencing comorbidities, for whom a yearly cost is applied. The lifetime health of the cohort is calculated by subtracting the QALYs lost due to experiencing disease from the QALYs that would have experienced by all those alive without comorbidities.

Cohorts progressing through the model for an individual model run are all the same starting age by design. However, given that the kinds of interventions being considered could be offered to the whole adult population, we run the model for every year of age from 16 to 100, yielding 85 sets of incremental costs and QALYs. A weighted average of these is then taken to derive the population average ICER and net health benefit. The age weights represent the relative smoking population density and are taken from the Health Survey for England (pooled 2012 and 2013 datasets), which are shown in Appendix A.

The computational burden of this approach means that probabilistic sensitivity analysis, which captures the combined uncertainty of all parameters simultaneously through Monte-Carlo simulation, was not deemed practical. Instead, a wide range of deterministic sensitivity analyses are conducted to establish the robustness of the results. These show the change in net monetary benefit when the value of an individual parameter is varied.

2.2.3 Model Inputs

This section outlines the model inputs that have been used to populate the smoking cessation model and also highlights any areas in which there are data gaps.

2.2.3.1 Effectiveness

The NICE evidence review found a total of 8 studies that investigated the effectiveness of pharmacy-based smoking cessation interventions. Of these, 4 were found to measure the proportion of participants who had abstained from smoking at the last follow-up point in the study. Each of these interventions is described in Table 2.2. 3 relate to behavioural support interventions, in which counselling is offered to participants. The remaining intervention is one in which participants have their photograph taken and run through specialist software which shows the expected impact of smoking on their future appearance.

Table 2.2: Included studies for smoking cessation

Study	Intervention	Description
Maguire (2001)	Usual care (with private NRT)	'Normal pharmaceutical service'.
	Leaflet + Counselling + NRT (private)	Initial 10-30 minute interview with flip-chart visual aid and agreed verbal quit contract. Leaflet provided. Participants asked to return for four weekly follow-ups then three monthly follow-ups.
Burford (2013)	Usual care	Two minute smoking cessation advice.
	Photoageing software	Two minute smoking cessation advice followed by body dysmorphia questionnaire. Photograph taken and run through photoageing software.
Cramp (2007)	Counselling + NRT	Completed nicotine quiz and 'I quit' contract', then received written advice on NRT. Counselling provided 'as appropriate'.
Costello (2011)	1 counselling session + NRT	Initial 5-10 minute interview plus five weeks of NRT.
	3 counselling sessions + NRT	Initial 5-10 minute interview plus one week of NRT, followed by two further 5-10 minutes counselling sessions plus two weeks of NRT.

Note: NRT = nicotine replacement therapy

2 of the 4 studies matched the effectiveness input required by the model (quit rate at 12 months). In the remaining 2 studies, no adjustment is made to reflect the fact that shorter follow-up times are associated with a higher quit rate. This means that the quit rates for these studies are likely to be overestimated, since we would expect additional people to relapse between the end of the respective follow-up (6 months and 44 weeks) and 12 months. Lastly, 2 studies calculated quit rates using self-reported survey data rather than carbon monoxide validation. This will cause upward bias in the quit rates for these studies. Evidence on the relationship between smoking cessation and time from Coleman *et al.*[1] suggests that this difference is negligible between 44 and 52 weeks but reduces by 12.5% between 6 and 12 months. We therefore adjust the quit rates from Burford *et al.* by this figure in sensitivity analysis (from 1.3% and 13.8% to 1.1% and 12.1%). The quit rates and outcome measures extracted from the studies are included in the summaries below and in Table 2.3. Due to the heterogeneous nature of the interventions identified in the review, it was not appropriate to synthesize the results in a meta-analysis. We therefore evaluated interventions on a study-by-study basis, using the study arms as the intervention and comparator. Similarly a fully incremental analysis is not conducted given the heterogeneity in the study populations.

[1] Coleman T, Agboola S, Leonardi-Bee J, Taylor M, McEwen A, McNeill A. Relapse prevention in UK Stop Smoking Services: current practice, systematic reviews of effectiveness and cost-effectiveness analysis. Health Technol Assess. 2010;14(49):1-152, iii-iv

Table 2.3: Outcome measures and quit rates for smoking cessation studies

Study	Intervention	Outcome measure	Quit rate
Maguire *et al.* (2001)	Usual care (with private NRT)	Validated at 12 months	2.7%
	Leaflet + Counselling + NRT (private)		14.3%
Burford *et al.* (2013)	Usual care	Validated at 6 months	1.3%
	Photoageing software		13.8%
Cramp *et al.* (2007)	Counselling + NRT	Self-reported at 44 weeks	15.8%
Costello *et al.* (2011)	1 counselling session + NRT	Self-reported at 12 months	40.5%
	3 counselling sessions + NRT		46%

Note: As no quit rate was provided for the 'usual care' arm in the Cramp *et al.* study we assumed the comparator to be 'no intervention' and apply a natural background quit rate of 2% (West 2006).

2.2.3.2 Costs

Comorbidity costs

Comorbidities are incorporated into the model using the prevalent rather than the incident population. However, the prevalent population can cover a wide variety of patient types and resource use, such as cancer patients with metastatic disease compared with those in remission. We therefore sought estimates of annual national-level expenditure for each comorbidity and divided this by the estimates of the prevalent population to generate the yearly costs for a hypothetical average patient.

Table 2.4: On-going annual comorbidity costs per person (NHS)

Comorbidity	Cost	Year	Inflated cost	Source
Stroke	£4,826	2008	£5,577	NICE CG92 Full guideline (2010)
Lung cancer	£9,071	2012	£9,377	Cancer Research UK (2012)
MI	£975	2011	£1,025	Ali *et al.* (2011)
CHD	£1,311	2014	£1,356	British Heart Foundation. Cardiovascular Disease Statistics (Townsend *et al.* 2014)
COPD	£479	2007	£553	NICE CG101 Full guideline
Asthma exacerbation	£1,162	2014	£1,248	Leaviss *et al.* (2014)

Note: All costs are inflated using from their base year to current 2015/16 prices using the hospital and community health services index published by the Personal Social Services Research Unit (2015)

The annual costs associated with each comorbidity and the data sources used to calculate them are provided in

Figure **2.4**. The costs reflect the on-going annual costs of the average individual with condition, and are multiplied by the number of people with each comorbidity in each cycle. The comorbidity cost sources were reviewed to identify if social care costs were included, and if so whether these costs could be disaggregated. However, given that not all cost sources

reported the disaggregated costs it was not possible to report overall costs for social care separately and, therefore, results are reported for NHS and PSS as a whole.

Intervention costs

Per person intervention costs are provided in

Table **2.5**. The costs are primarily calculated from resource use reported in each study, including the amount of contact time or the number of follow-up visits and counselling sessions. 1 study (Cramp *et al.* 2007) provided a full breakdown of all intervention costs, including pharmacist training and the operating costs. The sources for these costs, however, are not given. Per person costs were obtained by dividing total costs by the number participants and inflating them using the hospital and community health services index. For the 3 studies reporting resource use, our base case analysis conservatively assumes that the interventions are delivered by a trained pharmacist. A scenario analysis assumes that a pharmacy assistant delivers the intervention with equivalent effectiveness but at a lower cost. The cost-per-hour of each professional is obtained from the Personal Social Services Research Unit (2016).

Table 2.5: Smoking cessation intervention costs

Parameter	Components	Total cost (pharmacist)	Total cost (assistant)
Burford *et al.* (2013)			
Usual care	2 minutes of pharmacist time	£1.73	£0.77
Photoageing intervention	Cost of photoageing token. Average of 4.8 minutes of pharmacist time.	£6.46	£4.16
Cramp *et al.* (2007)			
Counselling + NRT	Training costs (letters, written material and lost leisure time) Operating costs (fees, NRT, printing and evaluation)	£166.28	N/A
Maguire *et al.* (2001)			
Usual care	10 minutes of pharmacist time	£8.63	£3.83
Counselling + leaflet	20 minutes of pharmacist time plus 4 additional follow-up sessions of 15 minutes.	£35.20	£15.64
Costello *et al.* (2011)			
1 counselling session + NRT	Average of 9 ½ minutes of pharmacist time.	£19.21	£14.65
3 counselling sessions + NRT	Average of 21 minutes of pharmacist time.	£29.23	£19.10

Notes:

1. Unit costs are taken from Personal Social Services Research Unit (2016). Per hour rates for pharmacist and pharmacy assistant are is £51.77 and £23.00, respectively.

2. Costs are inflated using the Health and Community Services Index from PSSRU (2016)

2.2.3.3 Utilities

Utilities are applied to smokers and former smokers. In order to estimate the effect of developing each comorbidity on HRQL, we undertook searches to identify estimates of the utility values associated with each of the five conditions contained in the model. These utility values, and their source are reported in Table 2.6. From these we calculate the associated disutility (the utility loss associated with living with the condition for one year). These are calculated by subtracting the disease-specific utility from that of someone in good health and are specific to smoking status. For example, we calculate the disutility of stroke for smokers by subtracting the stroke utility from the utility for smokers to obtain 0.85-0.48=0.37. The baseline utility values for smokers and former smokers control for the effect of one of the comorbidities in the model, CHD. This means that the baseline utilities reflect the disutility of all other comorbidities in the respective populations and that subtracting the disease-specific disutilities in the aforementioned process will introduce a degree of double counting. We, therefore, conduct a scenario analysis to determine cost-effectiveness under the conservative assumption that there are no QALY gains from comorbidities in the model.

We also assume that the effect on HRQL of experiencing multiple comorbidities, which some people invariably will, is additive. An alternative assumption is to apply only the highest disutility. This requires further assumptions to be made about the number of people that have more than one co-morbidity, given that it is not possible to determine this from the prevalence data. This second approach is, therefore, explored in scenario analysis.

Table 2.6: Utility values

Parameter	Utility value	Source
Stroke	0.7	Samsa *et al*. (ref[2])
Lung cancer	0.61	Bolin *et al.* (2009)
MI	0.80	Tengs and Wallace (2000)
CHD	0.76	Stevanovic (2016) (2016)
COPD	0.73	Rutten-van Molken *et al.* (2006)
Asthma exacerbation	0.52	Applied for one week. Szende *et al.* (2004)
Smoker	0.8486	Vogl *et al.* (2012)
Former smoker	0.8669	Vogl *et al.* (2012)

2.2.3.4 Comorbidity Epidemiology

As the cohort progresses through the model and grows older, their risk of developing comorbidities will also change. These risks are also dependent upon an individual's smoking status. We, therefore, required information on the prevalence of each condition by age and gender and the relationship between risk and smoking status, so these changing risks could be incorporated into the model.

The inputs informing the calculations of the prevalence of comorbidities by age, gender and smoking status are summarised in this section. Table 2.7 summarises the sources used for the prevalence of each comorbidity, whilst Table 2.8 provides the details on the relative risks of comorbidities by smoking status that are used in the model. The prevalence of smoking by

[2] Samsa et al. Performing Cost-Effectiveness Analysis by Integrating Randomized Trial Data with a Comprehensive Decision Model: Application to Treatment of Acute Ischemic Stroke. J Clin Epidemiol Vol. 52, No. 3, pp. 259–271, 1999

age and gender was extracted from the Health Survey for England (Health and Social Care Information Centre 2015).

Table 2.7: Sources for prevalence of comorbidities

Prevalence	Source/notes
Stroke	Bhatnagar *et al.* (2015)
Lung cancer	Maddams *et al.* (2009)
MI	Bhatnagar *et al.* (2015)
CHD	Liu *et al.* (2002).
COPD	Public Health England data set (not reported by gender).

Note:

1. MI = myocardial infarction; CHD = coronary heart disease; COPD = chronic obstructive pulmonary disease
2. Studies for stroke, lung cancer and MI reported prevalence for age 0-44 and this was not reported with any more granularity

Table 2.8: Relative risks (RR) of comorbidities

Comorbidity	RR (male smokers vs former smokers)	RR (female smokers vs former smokers)	Source/notes
Stroke	1.47	1.99	Myint *et al.* (2008)
Lung cancer	3.15	2.79	Pesch *et al.* (2012)
MI	1.44	2.63	Prescott *et al.* (1998)
CHD	1.45	1.21	Shields *et al.* (2013)
COPD	3.11	2.38	Lokke *et al.* (2006)

The sources above provide data on prevalence, by age, of each comorbidity in the general population (regardless of smoking status) (A), the relative risk of each co-morbidity by smoking status (smokers versus formers smokers (B) and smokers versus non-smokers (C)) and the prevalence of smoking (D). This can be used to calculate the prevalence of each co-morbidity for a current smoker (E), former smokers (F) and non-smokers (G), by ensuring that the following equation is satisfied:

$$(E \times D1) + (F \times D2) + (G \times D3) = A$$

Where E:F = the relative risk, B; G:F = the relative risk ratio C

This can be illustrated using the example of a 60-year-old male with lung cancer. The prevalence of lung cancer is provided in Table 2.9, the relative risk of lung cancer is shown in Table 2.8 and the prevalence of smoking is shown in Table 2.10.

Table 2.9: Prevalence of lung cancer (males)

Age	Prevalence
12 to 15	0.002%
16 to 24	0.002%
25 to 34	0.002%
35 to 44	0.002%
45 to 54	0.089%
55 to 64	**0.089%**
65 to 74	0.748%
75+	0.150%

Table 2.10: Prevalence of smoking (males)

Age	Non	Former	Smoker
16 to 24	67.99%	5.78%	26.23%
25 to 34	53.55%	17.23%	29.22%
35 to 44	51.78%	23.18%	25.04%
45 to 54	54.31%	24.72%	20.96%
55 to 64	**45.43%**	**37.26%**	**17.30%**
65 to 74	44.80%	41.74%	13.46%
75+	41.64%	53.28%	5.08%

Substitute the prevalence of smoking and the actual prevalence rate:

$$\left(E \times 0.17\right) + \left(F \times 0.37\right) + \left(G \times 0.45\right) = 0.089\%$$

Substitute the relative risks and calculate prevalence by smoking status using the RRs:

$$\left(E \times 0.17\right) + \left(E \times 0.37 \times 7.5\right) + \left(E \times 0.45 \times 23.6\right) = 0.089\%$$

$$E = \frac{0.089\%}{(0.17 + (0.37 \times 7.5) + (0.45 \times 23.6))}$$

(E) = 0.29%
(F)= 0.09%
(G) = 0.01%

This process was repeated for each age and gender for all co-morbidities.

Similar to Leaviss *et al.* (2014), mortality associated with asthma exacerbation was assumed to equal all-cause mortality (i.e. asthma exacerbations did not result in excess death). In addition, it was assumed that asthma exacerbations were transient in nature and resolved within 1 year. Given the low incidence of exacerbations and the small utility losses associated with them, this assumption was expected to have minimal impact on the outputs of the model.

Table 2.11 Incidence of asthma exacerbations

	Males		
Age	**Smokers**	**Long-term quitters**	**Short-term quitters**
12 to 15	0.08%	0.05%	0.05%
16 to 24	0.08%	0.05%	0.05%
25 to 34	0.08%	0.05%	0.05%
35 to 44	0.05%	0.05%	0.05%
45 to 54	0.05%	0.05%	0.05%
55 to 64	0.05%	0.05%	0.05%
65 to 74	0.07%	0.06%	0.06%
75+	0.07%	0.06%	0.06%
	Females		
Age	**Smokers**	**Long-term quitters**	**Short-term quitters**
12 to 15	0.08%	0.06%	0.06%
16 to 24	0.08%	0.06%	0.06%
25 to 34	0.08%	0.06%	0.06%
35 to 44	0.05%	0.05%	0.05%
45 to 54	0.05%	0.05%	0.05%
55 to 64	0.05%	0.05%	0.05%
65 to 74	0.06%	0.05%	0.06%
75+	0.06%	0.05%	0.06%

In the Leaviss *et al.* HTA report, asthma exacerbation incidence rates were reported for short-term and long-term quitters, which are reported in Table 2.11. The incidence data for short-term quitters was applied for 4 years after quitting in the model. However, the current model structure does not allow the incidence rates to be applied in this way and consequently the long-term rate is applied in the base case (which is not a conservative estimate but may be more accurate given the lifetime time horizon of the model).

Leaviss *et al.* report the incidence rates of asthma exacerbations for smokers and long-term quitters (applied to former smokers) by age and gender. The number of people in these health states is multiplied by the relevant incidence rate to determine the number of people that experience an asthma exacerbation each year.

2.2.3.5 Mortality

The inputs informing the calculations of the mortality rates by age, gender and smoking status are summarised in this section.

The mortality rates from Doll *et al.* (1994) were adjusted to reflect the general population mortality rates. This study followed a sample of 34,439 British doctors from 1951 through to 1991.To adjust the mortality to reflect that found in the general population the mortality per 1,000 men, by age band, was taken from the Doll study. Although a more recent paper which provides follow-up until 2001 has been produced in 2004 (Doll et al. 2004), the 1994 paper has been used because it provided annual mortality by smoking habits at age of death. The 2004 paper does not provide figures for those over 85 and for former smokers under 45 years. The Doll (2004) paper reports mortality beginning at the age of 35. In order to populate the age bands below this, an exponential distribution was applied and the mortality for the lower

age groups was calculated (Table 2.12). The Doll paper was used to calculate the odds ratio for smokers versus formers smokers and smokers versus non-smokers. The ONS Life Tables (2015) provide the 'real' mortality for each age. The prevalence of smoking for each age and gender was taken from the Health Survey for England (Health and Social Care Information Centre 2015) (Table 2.10).

Table 2.12: Mortality by smoking status

Age	Mortality per 1000 men		
	Non	Former	Smoker
16 to 24	0.2*	0.3*	0.6*
25 to 34	0.6*	0.8*	1.3*
35 to 44	1.6	2.0	2.8
45 to 54	4.0	4.9	8.1
55 to 64	9.5	13.4	20.3
65 to 74	23.7	31.6	47.0
75 to 84	67.4	77.3	106.0
85+	168.6	179.7	218.7

Note: * Data extrapolated using exponential function

The above information was used to calculate the actual mortality rates for smokers, former smokers and non-smokers using the process used to calculate comorbidity prevalence described above.

2.3 WEIGHT MANAGEMENT

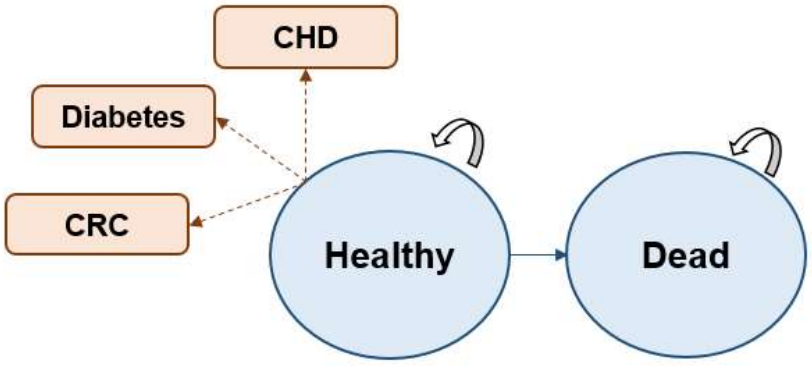
2.3.1 Model Overview

For weight management interventions we use a decision model built in 2014 (Lewis et al. 2014) to help inform the cost-effectiveness of a weight loss intervention that was based on modelling for previous NICE guidance (CG43). As with the smoking cessation model, the weight management model was developed in line with the NICE methods manual and adopts a NHS and personal social services (PSS) perspective (National Institute for Health and Care Excellence 2014). The model allows for various time horizons to be reported, and incorporates a lifetime time horizon in order to capture all relevant costs and benefits. Discount rates of 3.5% for both costs and benefits are applied to future costs and outcomes as stipulated in the NICE methods manual. The principal measures of cost-effectiveness are again the incremental cost-effectiveness ratio (ICER) and net monetary benefit.

2.3.2 Model Structure

The Markov model structure is shown in Figure 2.2. Patients enter the model in the 'healthy' state and, for each yearly cycle, are at risk of death (transitioning them to the 'dead' state) or of developing three comorbidities: diabetes, colorectal cancer (CRC) and coronary heart disease (CHD). These comorbidities were selected following a targeted review conducted during the previous analysis. Although other cancers may be associated with body mass index (BMI), we model only CRC as it is the principal cancer type that is both highly prevalent and strongly associated with BMI (Cancer Research UK 2014, Renehan et al. 2008).

Figure 2.2: Weight management model structure



Note: CRC = colorectal cancer, CHD = coronary heart disease.

Two cohorts (one for the intervention and another for the comparator) then progress through the model. Although starting off with the same BMI, the cohorts differ in mortality and comorbidity risks due to the effectiveness of each treatment in reducing BMI. As with the smoking cessation model, costs are determined by the intervention cost and the comorbidity-related costs. The lifetime health of the cohort is calculated by adding together the QALYs of those without comorbidities to those with them, with the latter group having been subject to reduced HRQL through disease-specific multipliers.

Cohorts progressing through any single model run are all the same age by design. However, given that the kinds of interventions being considered are for overweight individuals presenting at pharmacies, we run the model for every year of age from 16 to 100. The costs and QALYs for each age are then weighted by their relative density in the overweight population (defined as a BMI greater than 30 kg/m^2) and used to create weighted average estimates. The weights are taken from the Health Survey for England (pooled 2012 and 2013 datasets), and are shown in Appendix A. These are then used to estimate cost-effectiveness of each intervention relative to the comparator.

The computational burden of this approach means that probabilistic sensitivity analysis, which captures the combined uncertainty of all parameters simultaneously through Monte-Carlo simulation, was not deemed practical. Instead, a wide range of deterministic sensitivity analyses are conducted to establish the robustness of the results.

2.3.3 Model Inputs

This section outlines the model inputs that have been used to populate the weight management model and also highlights any areas in which there are data gaps.

2.3.3.1 Effectiveness

Table 2.13: Included studies for weight management

Study	Intervention	Description
Bush *et al.* (2014)	My Choice programme	12 weekly follow-up appointments plus a further three at 5, 7 and 9 months. Counselling involved 11 areas of advice, ending with a session of weight loss maintenance. Written advice provided and participants encouraged to keep food and exercise diary
Boardman *et al.* (2014)	Unnamed weight management programme	12 face-to-face visits at fortnightly then monthly intervals. Diet plans and exercise regimes agreed and reviewed with participants at each session.
Morrison *et al.* (2011)	Counterweight	Initial screening plus 6 further appointments and 3 follow-up visits at 6, 9 and 12 months. Behaviour change advice provided alongside eating plan.
Jolly *et al.* (2013)	Lighten Up	12 one-to-one sessions with trained pharmacist. Sessions included advice, goal setting and planning, motivation enhancement and behavioural assessment.

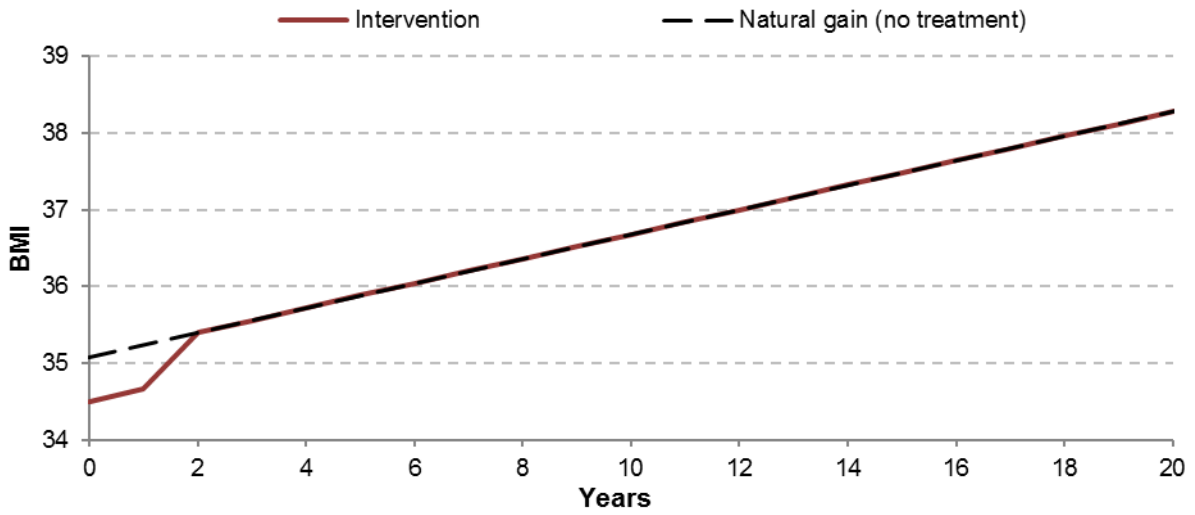
The NICE evidence review found a total of 5 studies that investigated the effectiveness of pharmacy-based weight management interventions. These are described in Table 2.13. Of these, 4 were found to measure the average reduction in either weight or BMI at the last follow-up point in the study. Only 1 out of the 4 studies used an outcome measure identical to that

used in the model – BMI change at 12 months. Where only weight loss is reported, the mean height in the study sample is combined with pre and post mean weight to calculate BMI change. Where the follow-up is less than 12 months, no adjustment is made to reflect the expectation that we might see larger BMI changes for shorter follow-up times; we instead assume that the change at 6 or 9 months remains at 12 months. The BMI change and outcome measures extracted from the studies are included in the summaries below and in Table 2.14.

Table 2.14: Mean body mass index (BMI) and weight change values for included weight management interventions

Study	Intervention	Outcome measure	Mean BMI change [kg/m^2](weight change)
Bush *et al.* (2014)	My Choice programme	BMI change at 9 months	-0.9
Boardman *et al.* (2014)	Unnamed weight management programme	Weight change at 6 months	-1.7 (-4.59kg)
Morrison *et al.* (2011)	Counterweight	Weight change at 12 months	-0.6 (-1.7kg)
Jolly *et al.* (2013)	Lighten Up	BMI change at 12 months	-0.3

Figure 2.3: Body mass index trajectory over time with and without the intervention



Note: 'Intervention' is an example programme that reduces BMI by 0.5 units after 1 year. Because the model is run in annual cycles, the loss is actually shown from the start of the intervention, although a 'half-cycle correction' is applied within the model structure, indicating that the drop in BMI would actually occur sometime *between* year 0 and year 1.

In the no treatment group and for the treatment group after the end of each weight management programme (assumed to be one year), a background natural annual change in BMI of 0.16 was applied, which was calculated as the average of the natural annual BMI change for men and women in the UK (Ara et al. 2012). Using the standard errors reported in their regression analyses, we found that the 95% confidence interval for this parameter was

0.109 to 0.21. The impact of this uncertainty is explored in univariate sensitivity analysis. It was assumed that the BMI of participants on each of the interventions would not go above the natural 'no intervention' BMI, which itself had a maximum cap of 60. We conservatively assume that in the year after individuals stop receiving the intervention, they return to the BMI level they would have had with no intervention. An example of this trajectory is shown in Figure 2.3.

2.3.3.2 Costs

Comorbidity costs

Comorbidities are incorporated into the model using the prevalent rather than the incident population. For each condition, total NHS expenditure from 2013/14 is inflated to 2015/16 prices using the Hospital and Community Services Index, then divided by an estimate of the prevalent population (NHS England 2015). Total NHS costs are extracted from Programme Budgeting Category data, which disaggregates expenditure by broad disease type. The relevant categories for the comorbidities in the model are 02c (lower gastrointestinal cancer), 04a (diabetes) and 10a (coronary heart disease). The sources used to estimate prevalence, along with the final annual per person costs that are used in the model, are reported in Table 2.15.

Table 2.15: On-going annual comorbidity costs per person (NHS)

Parameter	Cost	Base year	Inflated cost	Source
Diabetes	£1,016	2014	£1,061	NHS Programme Budgeting Category (PBC) Spending (2015) NICE CG189 Guideline (2014)
Colorectal cancer	£1,637	2014	£1,732	NHS PBC Spending (2015) Maddams *et al.* (2009)
CHD	£921	2014	£962	NHS PBC Spending (2015) British Heart Foundation (2014)

Note: All costs are inflated using from their base year to current 2015/16 prices using the Hospital and Community Health Services index published by the Personal Social Services Research Unit (2016).

Intervention costs

Per person intervention costs are provided in

Table **2.5**. The My Choice programme was costed by using reimbursement provided to pharmacists by the investigators for training, assessments and follow-up appointments. Per person costs were obtained by dividing total costs by the number participants and inflating them using the hospital and community health services index. The remaining studies reported resource use, including time spent training and delivering behavioural support. Our base case analysis conservatively assumes that the interventions are delivered by a trained pharmacist. A pair of scenario analyses assume that: (i) a pharmacy assistant delivers the intervention with equivalent effectiveness but at a lower cost and (ii) training costs are excluded from the intervention cost. The cost-per-hour of each professional is obtained from the Personal Social Services Research Unit (2016).

Table 2.16: Weight management intervention costs

Study/Intervention	Components	Per person cost (pharmacist)	Per person cost (assistant)
Bush *et al.* (2014			
My Choice	Costed in the study.	£129.74	N/A
Boardman *et al.* (2014)			
Unnamed WMP	Pharmacist training. 123 minutes of pharmacist time.	£125.89	£55.93
Morrison *et al.* (2013)			
Counterweight	Pharmacist training 130 minutes of pharmacist time.	£132.06	£58.67
Jolly *et al.* (2011)			
Lighten Up	Pharmacist training. 120 minutes of pharmacist time	£123.43	£54.84

Note:
1. WMP = weight management programme.
2. Unit costs are taken from Personal Social Services Research Unit (2016). Per hour rates for pharmacist and pharmacy assistant are is £51.77 and £23.00, respectively.
3. Prices inflated using the Hospital & Community Health Services index (Personal Social Services Research Unit 2016).

2.3.3.3 Utilities

Quality of life was modelled as a function of BMI. An average was taken of the utility of males and females in each of a number of BMI groups from Macran (2004), as shown in Table 2.16.

Table 2.17: Relationship between body mass index and health-related quality of life

BMI Group	<21 kg/m^2	21-25 kg/m^2	26-30 kg/m^2	31-39 kg/m^2	>39 kg/m^2
EQ-5D score	0.86	0.87	0.84	0.80	0.78

This study calculated EQ-5D scores from a survey of 11,783 people from the general population in the UK. By assuming these scores referred to the mid-point of each BMI group, we used them to generate a continuous function of the relationship between BMI and utility, which could be applied to the BMI of the cohort in each cycle and was as follows:

$$Utility = (BMI^2 \times -0.000191) + (BMI \times 0.006954) + 0.798435$$

Quality of life decrements were also associated with the development of comorbidities. As in NICE Clinical Guideline 43, a multiplier of 0.8861 was used for diabetes, 0.8670 for CHD (Ara and Brennan 2007) and 0.9500 for CRC (Lewis *et al*. 2002). For example, an individual with a BMI of 35 would have a utility value of 0.808; the same individual, if they developed diabetes, would have a utility value of 0.81 multiplied by 0.8861, or 0.70. The baseline utility values (for no comorbidities) by BMI do not control for the impact of the comorbidities included in the model, and consequently incorporate the disutility associated with the presence of these

comorbidities in study population from which they are estimated. Applying the comorbidity-specific multipliers in the aforementioned process will, therefore, introduce a degree of double counting. We therefore conduct a scenario analysis to determine cost-effectiveness under the conservative assumption that there are no QALY gains from comorbidities in the model.

2.3.3.4 Comorbidity Epidemiology

The prevalence of each of the 3 comorbidities was modelled by age and BMI. Firstly, data on the relationship between these comorbidity risks and BMI were obtained from the literature (McQuigg et al. 2008) and (Bhaskaran et al. 2014). Exponential functions were fitted to the data for diabetes and CHD and a linear function to the CRC data to estimate the continuous relationship between the odds of having a comorbidity and BMI relative to a BMI of 25. Figure 2.4 to Figure 2.6 demonstrates how these functions fit to the odds ratios extracted from the literature. The equations describing the fitted functions for each comorbidity are the following:

$$Odds\ of\ diabetes = 0.0806 \times exp^{0.1028 \times BMI}$$
$$Odds\ of\ CRC = -1.349 + 0.093 \times BMI$$
$$Odds\ of\ CHD = 0.2191 \times exp^{0.062 \times BMI}$$

These odds ratios are then applied to prevalence estimates for the non-overweight population that were calculated using general population prevalence using the same methods described in Section 2.2.3.4.

Figure 2.4: Continuous function relating body mass index and odds of diabetes

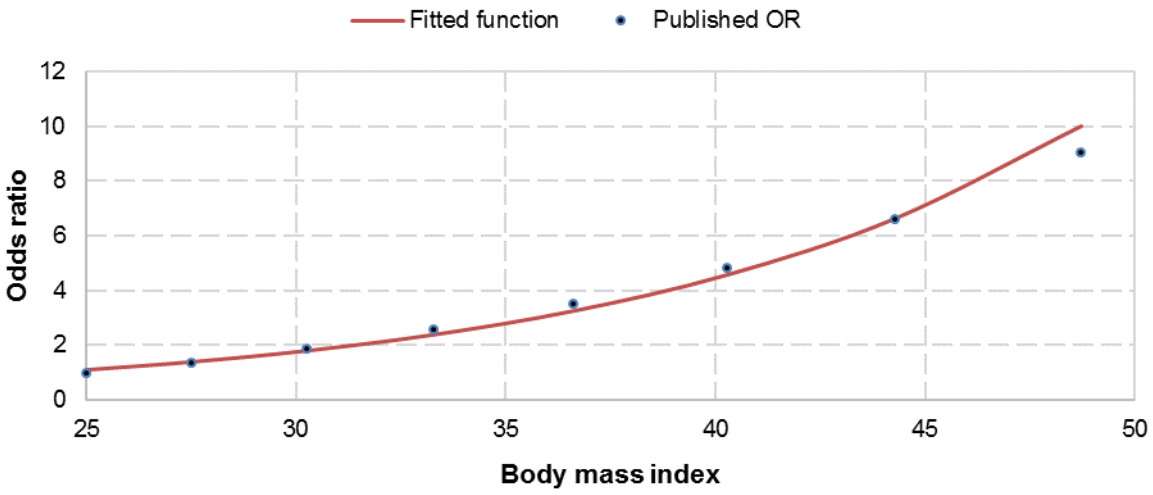


Figure 2.5: Continuous function relating body mass index and odds of colorectal cancer

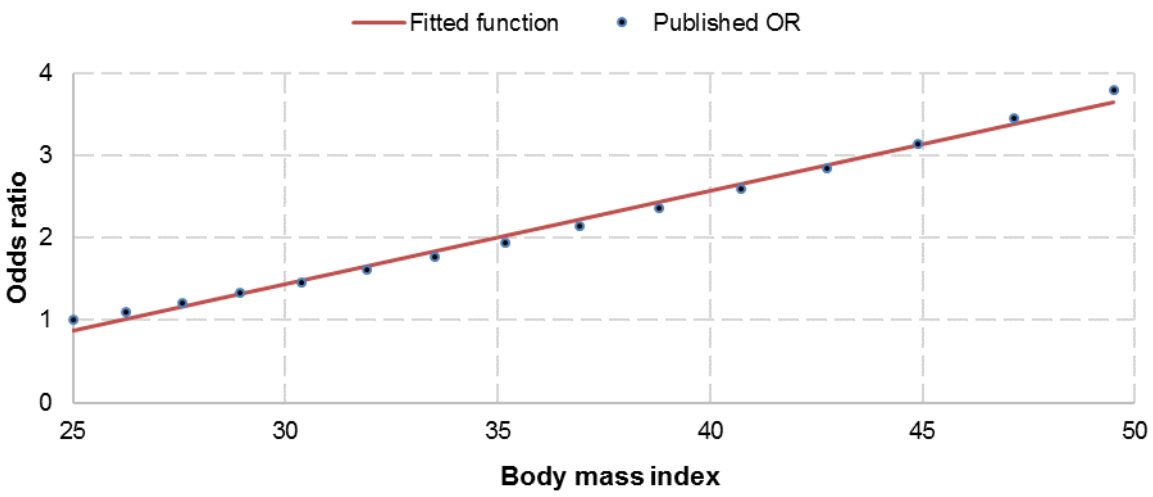
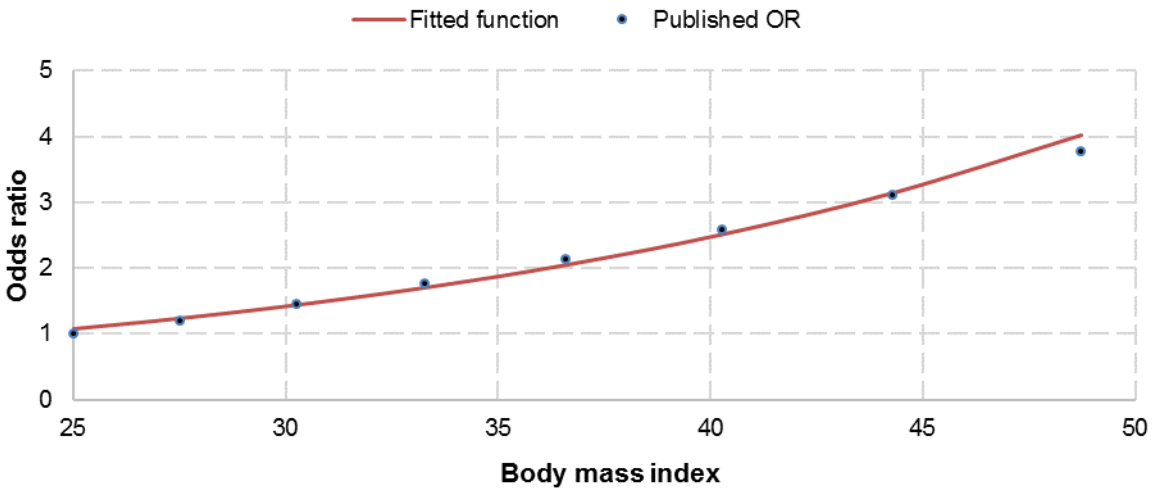


Figure 2.6: Continuous function relating body mass index and odds of coronary heart disease



2.3.3.5 Mortality

Mortality was modelled as a function of both age and BMI. Mortality by single years of age were extracted from life tables for England (Office for National Statistics 2016). We then used the results of meta-analysis by Aune *et al*. (2016) that estimated the non-linear dose-response relationship between BMI and all-cause mortality. A polynomial function was fitted to the discrete relative risk estimates to estimate the continuous relationship between BMI and mortality risk, yielding the following equation, shown in

Figure **2.7**:

$$Relative\ risk\ of\ mortality = 3.9276 - 0.2254 \times BMI + 0.0043 \times BMI^2$$

The set of discrete odds ratios the function are fitted to are relative to a BMI of 23. However, the Health Survey for England indicates that the mean BMI in the English population, which is reflected in the mortality data, is 27. We therefore re-estimate the odds ratio in each annual cycle in the model relative to 0.98, the odds ratio of a BMI of 27 relative to 23. For example, for individuals with a BMI of 35, the adjusted odds ratio will be 1.29/0.98 = 1.31.

Figure 2.7: Continuous function relating body mass index and odds of coronary heart disease

Section 3: Results

The results in this section are representative of the whole smoking and overweight populations, and are reported for a lifetime time horizon from the perspective of the NHS. The principal results are the point estimates of cost-effectiveness, represented by the ICER and NMB. An extensive set of sensitivity analyses are also provided to demonstrate the robustness of the cost-effectiveness results. Throughout the results, net health benefit is calculated using a threshold of £20,000 per QALY, except during the threshold scenario analysis.

3.1 SMOKING CESSATION

3.1.1 Intervention Cost-Effectiveness Results

All smoking cessation interventions 'dominated' the comparator treatment, indicating that each programme provides additional health benefits and cost savings to the health sector. ICERs are not estimated, as they would be negative and not interpretable. Interventions were ranked in terms of NMB based on the incremental probability of quit success over the comparator. The counselling programme evaluated in Cramp *et al.* (2007), which had an incremental probability of 13.8% over no intervention, had the highest NMB of £2,968 per person. The intervention in Costello *et al*. (2011), which compared 3 sessions of behavioural support counselling to 1 session, yielded an incremental quit probability of 5.5% and an NMB of £1,239 per person.

The results also indicate which model inputs have the largest impact on the results. The health sector cost savings are largely driven by reducing the prevalence of stroke, lung cancer and COPD. These three comorbidities account for over 80% of the cost savings associated with cessation. The effect on asthma exacerbations was minimal, accounting for just 0.03% of savings. A different picture is offered when it comes to the heal gains. Reductions in mortality were responsible for over 80% of the QALY changes associated with quitting. In terms of comorbidities, reductions in COPD generated the largest gains of around 14%. Reductions in MI, CHD and asthma exacerbations all contributed less than 1% to the total health gain. The detailed cost-effectiveness results are presented in Tables 3.1a to 3.4a, whilst the number of patients in various categories at 5 and 10 years are shown in Tables 4.1b to 4.4b. Finally, results of the sensitivity analyses are shown in Figures 4.1 to 4.4.

Table 3.1a: Counselling + leaflet + private NRT vs. usual care[a] (Maguire *et al.* 2001)

	Intervention	Comparator	Incremental
Intervention costs	£35	£9	£27
Stroke costs	£4,776	£4,911	-£135
Lung cancer costs	£886	£942	-£57
MI costs	£671	£692	-£21
CHD costs	£2,789	£2,830	-£41
COPD costs	£1,188	£1,269	-£81
Asthma costs	£14	£14	£0
Total costs	**£10,360**	**£10,667**	**-£308**
QALYs no complications	17.27	17.17	0.094
QALYs stroke	-0.13	-0.14	0.003
QALYs lung cancer	-0.02	-0.02	0.001
QALYs MI	-0.04	-0.04	0.000
QALYs CHD	-0.20	-0.20	0.000
QALYs COPD	-0.27	-0.28	0.016
QALYs asthma	-0.0001	-0.0001	0.000
Total QALYs	**16.61**	**16.50**	**0.12**
ICER			**Dominant**
Net monetary benefit			**£2,608**

Note: All values are per person estimates.

[a] In this study, the 'usual care' pharmaceutical service included NRT as appropriate.

Table 3.2b: Counselling + leaflet + private NRT vs. usual care[a] (Maguire *et al.* 2001)

	5 years			10 years		
	Int.	**Comp.**	**Incr.**	**Int.**	**Comp.**	**Incr.**
Smokers	784.29	890.45	-106.16	678.58	770.43	-91.85
Former smokers	189.05	82.19	+106.86	255.69	161.99	+93.70
Dead	26.84	27.55	-0.71	65.91	67.77	-1.85
Stroke	22.38	23.43	-1.06	26.79	27.89	-1.10
Lung cancer	2.87	3.11	-0.24	3.34	3.60	-0.26
CHD	61.33	63.07	-1.74	71.96	73.66	-1.69
COPD	84.61	91.76	-7.15	87.35	94.34	-7.00
MI	18.11	18.98	-0.868	21.54	22.46	-0.917

Table 3.3a: Photoageing software vs. usual care[a] (Burford *et al.* 2001)

	Intervention	Comparator	Incremental
Intervention costs	£6	£2	£5
Stroke costs	£4,782	£4,927	-£145
Lung cancer costs	£888	£949	-£61
MI costs	£672	£695	-£23
CHD costs	£2,791	£2,835	-£44
COPD costs	£1,192	£1,279	-£87
Asthma costs	£14	£14	-£0.094
Total costs	**£10,345**	**£10,700**	**-£355**
QALYs no complications	17.26	17.16	0.102
QALYs stroke	-0.13	-0.14	0.003
QALYs lung cancer	-0.02	-0.02	0.001
QALYs MI	-0.04	-0.04	0.000
QALYs CHD	-0.20	-0.20	0.000
QALYs COPD	-0.27	-0.28	0.017
QALYs asthma	-0.0001	-0.0001	0.000
Total QALYs	**16.61**	**16.48**	**0.12**
ICER			**Dominant**
Net monetary benefit			**£2,834**

Note: All values are per person estimates

[a] In this study, usual care included two minutes of smoking cessation advice from the pharmacist.

Table 3.4b: Photoageing software vs. usual care[a] (Burford *et al.* 2001)

	5 years			10 years		
	Int.	**Comp.**	**Incr.**	**Int.**	**Comp.**	**Incr.**
Smokers	788.87	903.26	-114.39	682.54	781.52	-98.98
Former smokers	184.45	69.29	+115.16	251.65	150.68	+100.97
Dead	26.88	27.64	-0.77	66.00	67.99	-1.99
Stroke	22.42	23.56	-1.14	26.84	28.02	-1.19
Lung cancer	2.88	3.14	-0.26	3.35	3.63	-0.28
CHD	61.40	63.28	-1.88	72.03	73.86	-1.83
COPD	84.92	92.62	-7.71	87.65	95.19	-7.54
MI	18.15	19.08	-0.935	21.58	22.57	-0.988

Table 3.5a: 3 counselling sessions + NRT (Costello *et al.* 2011) versus advice + NRT (Costello *et al.* 2011)

	Intervention	Comparator	Incremental
Intervention costs	£73	£63	£10
Stroke costs	£4,408	£4,472	-£64
Lung cancer costs	£731	£758	-£27
MI costs	£614	£624	-£10
CHD costs	£2,677	£2,696	-£19
COPD costs	£968	£1,006	-£38
Asthma costs	£14	£14	£0
Total costs	**£9,485**	**£9,633**	**-£148**
QALYs no complications	17.53	17.48	0.045
QALYs stroke	-0.13	-0.13	0.001
QALYs lung cancer	-0.02	-0.02	0.001
QALYs MI	-0.03	-0.03	0.000
QALYs CHD	-0.20	-0.20	0.000
QALYs COPD	-0.22	-0.23	0.008
QALYs asthma	-0.0001	-0.0001	0.000
Total QALYs	**16.93**	**16.87**	**0.05**
ICER			**Dominant**
Net monetary benefit			**£1,239**

Note: All values are per person estimates

Table 3.6b: 3 counselling sessions + NRT (Costello *et al.* 2011) versus advice + NRT (Costello *et al.* 2011)

	5 years			10 years		
	Int.	**Comp.**	**Incr.**	**Int.**	**Comp.**	**Incr.**
Smokers	494.19	544.52	-50.33	427.58	471.13	-43.55
Former smokers	481.10	430.43	+50.67	511.76	467.33	+44.43
Dead	24.91	25.24	-0.34	60.85	61.73	-0.88
Stroke	19.50	20.00	-0.50	23.78	24.30	-0.52
Lung cancer	2.22	2.34	-0.11	2.63	2.76	-0.12
CHD	56.57	57.40	-0.83	67.33	68.14	-0.80
COPD	65.06	68.45	-3.39	68.23	71.54	-3.32
MI	15.74	16.15	-0.411	19.03	19.47	-0.435

Table 3.7a: Counselling + NRT (Cramp *et al.* 2007) vs. no intervention

	Intervention	Comparator	Incremental
Intervention costs	£166	£0	£166
Stroke costs	£4,759	£4,919	-£160
Lung cancer costs	£878	£946	-£67
MI costs	£669	£693	-£25
CHD costs	£2,784	£2,832	-£49
COPD costs	£1,178	£1,274	-£96
Asthma costs	£14	£14	£0
Total costs	**£10,447**	**£10,679**	**-£231**
QALYs no complications	17.28	17.17	0.112
QALYs stroke	-0.13	-0.14	0.003
QALYs lung cancer	-0.02	-0.02	0.002
QALYs MI	-0.04	-0.04	0.000
QALYs CHD	-0.20	-0.20	0.000
QALYs COPD	-0.26	-0.28	0.019
QALYs asthma	-0.0001	-0.0001	0.000
Total QALYs	**16.63**	**16.49**	**0.14**
ICER			**Dominant**
Net monetary benefit			**£2,967**

Note: All values are per person estimates. A 'natural' quit rate of 2% is used for no intervention.

Table 3.8b: Counselling + NRT (Cramp *et al.* 2007) vs. no intervention

	5 years			10 years		
	Int.	**Comp.**	**Incr.**	**Int.**	**Comp.**	**Incr.**
Smokers	770.56	896.86	-126.29	666.71	775.98	-109.27
Former smokers	202.87	75.74	+127.13	267.81	156.34	+111.47
Dead	26.75	27.60	-0.84	65.67	67.88	-2.20
Stroke	22.24	23.50	-1.25	26.65	27.96	-1.31
Lung cancer	2.84	3.12	-0.28	3.31	3.61	-0.31
CHD	61.10	63.17	-2.07	71.74	73.76	-2.02
COPD	83.68	92.19	-8.51	86.44	94.77	-8.32
MI	18.00	19.03	-1.032	21.42	22.51	-1.091

3.1.2 Tornado diagrams

The results of the sensitivity analysis are summarised below in a series of tornado diagrams. For each parameter the base case is replaced with a high and low value to show the effect on net monetary benefit.

Figure 3.1: Counselling + leaflet + private NRT vs. usual care (Maguire et al. 2001)

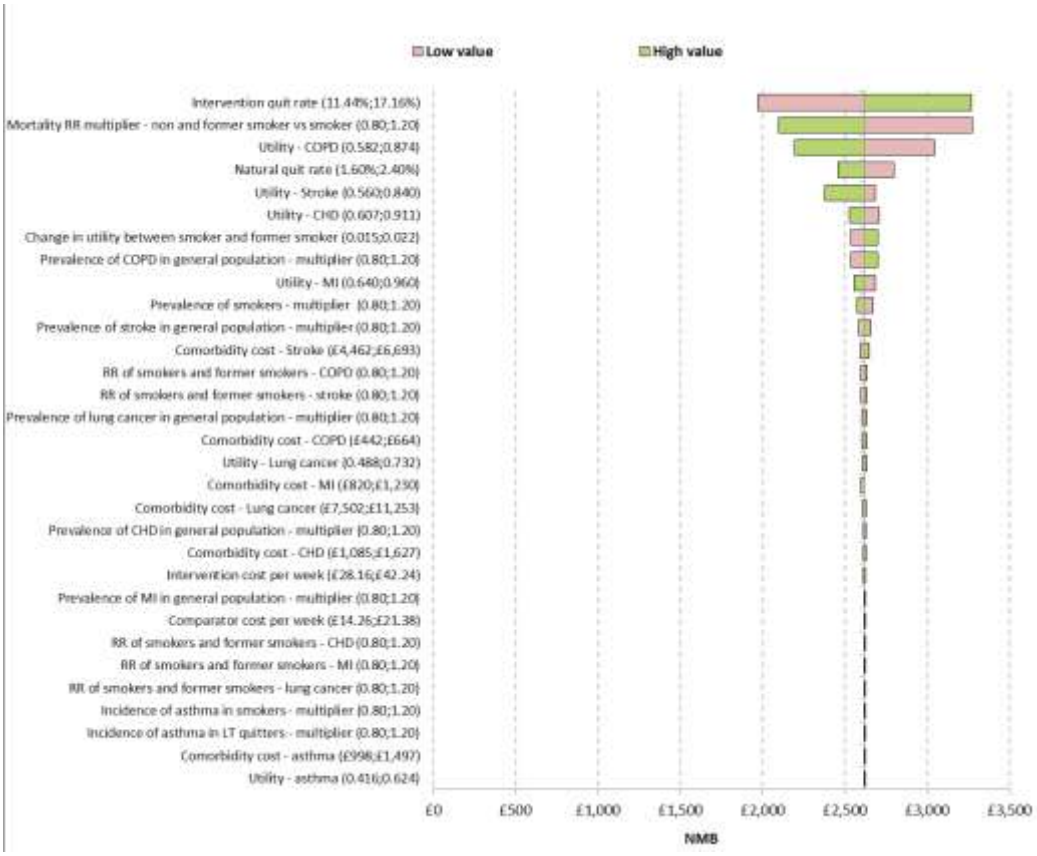


Figure 3.2: Photoageing software vs. usual care (Burford et al. 2001)

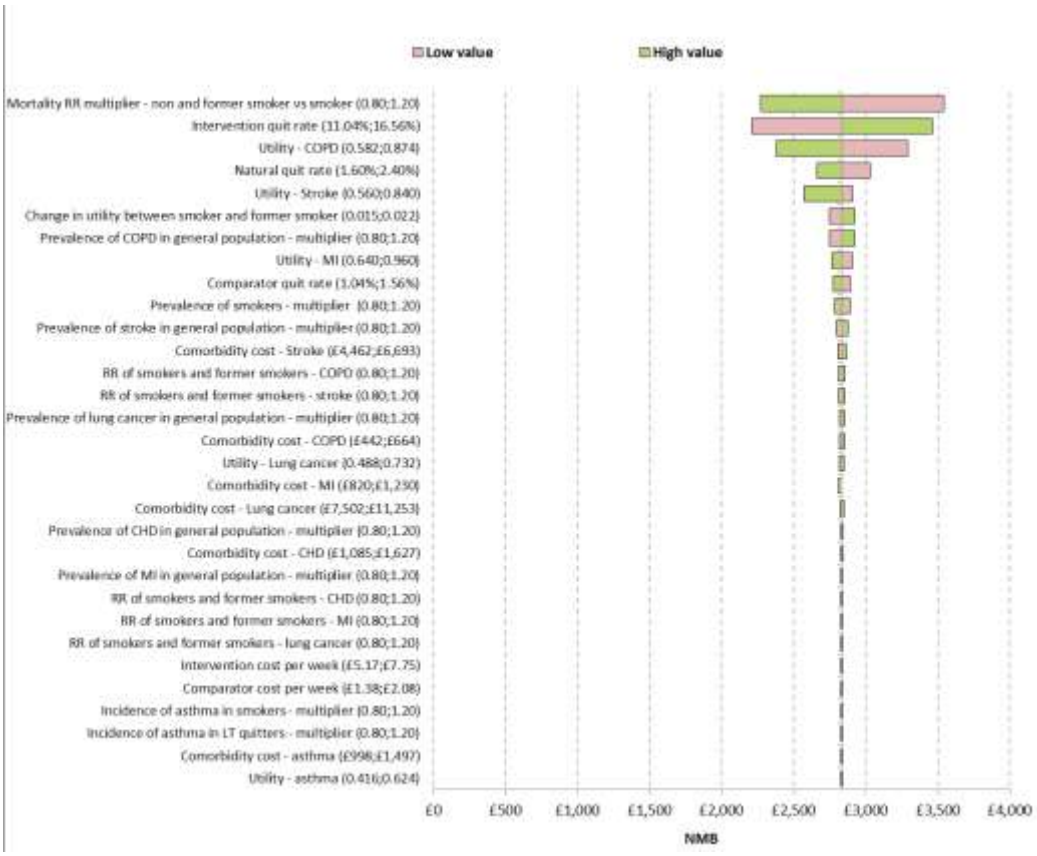


Figure 3.3: 3 counselling sessions + NRT (Costello et al. 2011) versus advice + NRT (Costello et al. 2011)

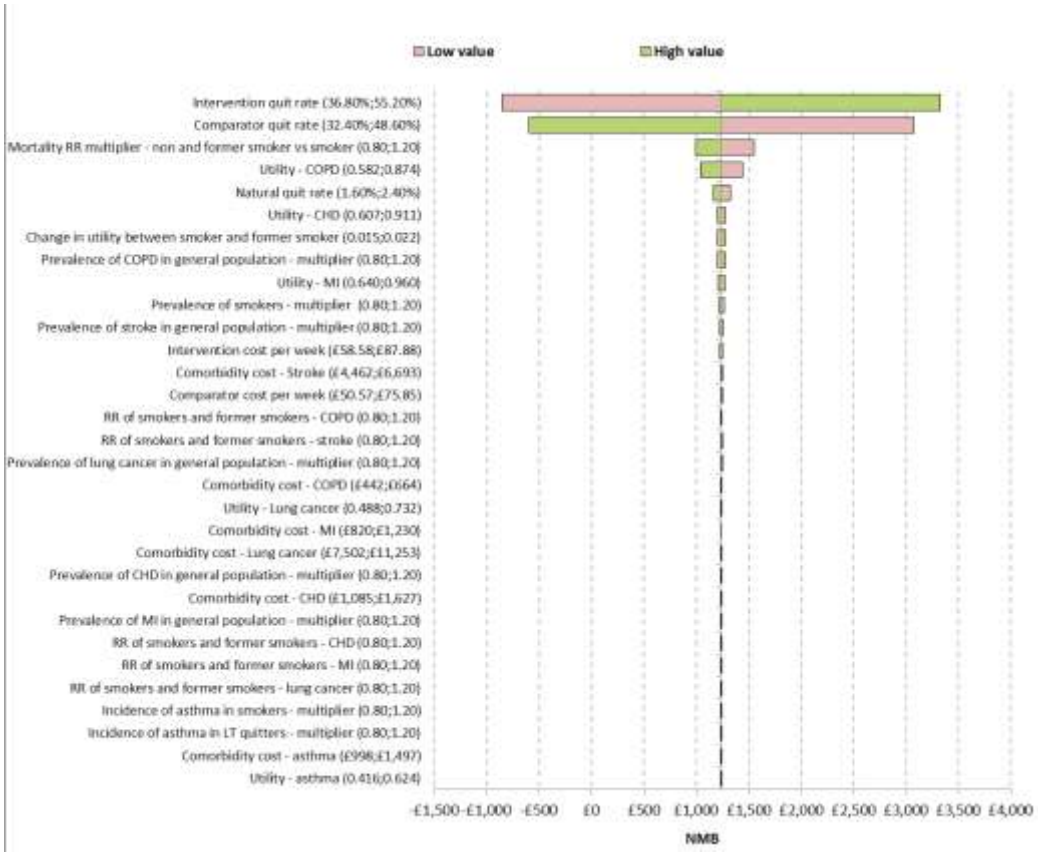
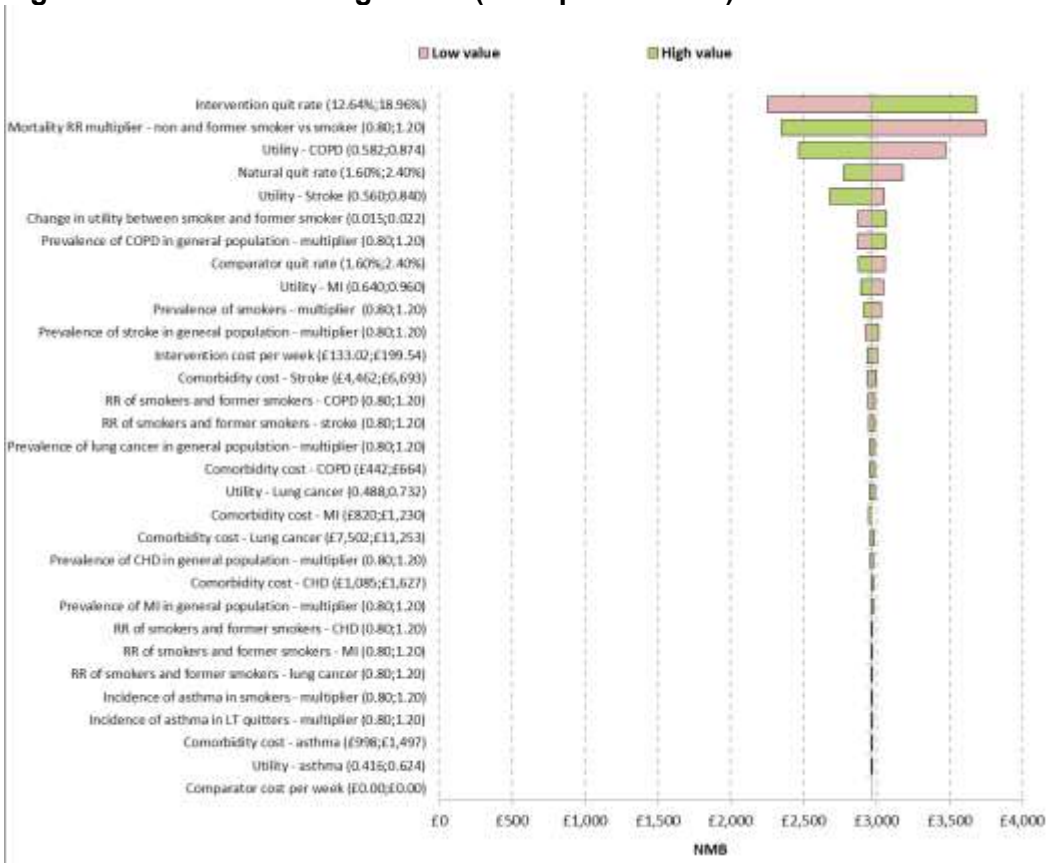


Figure 3.4: Counselling + NRT (Cramp et al. 2007) vs. no intervention



3.1.3 Scenario Analysis

The results from our three scenario analyses are presented in Table 3.9. When we assume that the pharmacy assistant delivers the intervention, at a lower cost with equal effectiveness, net monetary benefit increases in proportion to the amount of labour time involved in the intervention. For instance, the NMB of the counselling intervention in Maguire *et al.*, which involved around 40 minutes of additional labour time, increased by £15 when assuming that assistants delivered the intervention. This is compared to a difference of £1 for the photoageing intervention, which required approximately 5 minutes. As all interventions are already highly cost-effective, assuming cheaper delivery costs does not alter the direction of our results.

The second scenario we investigate is how cost-effectiveness changes when it is pessimistically assumed that comorbidity disutility is already reflected in the utility scores by BMI, such that the QALY gains associated with comorbidity reduction are not counted. For each intervention, NMB decreases but remains positive: all remain over £1,000 per person, indicating they are still highly cost-effective. An example of the changes in the cost-effectiveness results that comes from changing this assumption is shown in Table A.2. Two further sensitivity analyses support the robustness of the results: (i) removing training costs from the Cramp *et al.* study increased net monetary benefit from £2,968 to £2,977; adjusting down the quit rates to reflect additional relapse between 6 and 12 months for the Burford *et al.* results decreased NMB from £2,834 to £2,479.

Table 3.9: Summary of cost-effectiveness results for smoking cessation under alternative scenarios

	Net monetary benefit				
Intervention	**Base case**	**Assistant costs**	**No comorbidity QALYs**	**Highest disutility**	**Maximum intervention cost**
Counselling, leaflet, NRT (Maguire *et al.*, 2001)	£2,608	£2,623	£2,196	£2,497	£2,749
Photoageing software (Burford *et al.*, 2013)	£2,834	£2,836	£2,390	£2,715	£2,884
Counselling, NRT (Costello *et al.*, 2011)	£1,239	£1,245	£1,044	£1,187	£1,329
Counselling, NRT (Cramp *et al.*, 2007)	£2,968	N/A	£2,477	£2,836	£3,260

Note:

1. Assistant costs = intervention delivered by pharmacy assistant instead of pharmacist, at lower cost and equal effectiveness; no comorbidity QALYs = separately estimated QALY gains associated with reducing comorbidity prevalence are not included; highest disutility = only comorbidity with highest disutility is applied to patients with multiple conditions
2. Maximum intervention cost applies to the base case analysis and is the highest per person cost an intervention can be in order to remain cost-effective

Assistant costs are not applied to Cramp *et al.* (2007). As this study does not report average labour time, no adjustment can be made to the base case

Lastly, we show how the cost-effectiveness results for the counselling intervention in Maguire *et al*. (2001) change when we relax the structural assumption that comorbidity disutility is

additive. In this analysis we assumed that only the highest comorbidity disutility was applied, and found that NMB decreased by £111. This was driven by the fact that disutilities for MI, CHD and COPD were not applied to as many of the population (see Table A.2).

3.1.4 Sensitivity Analysis

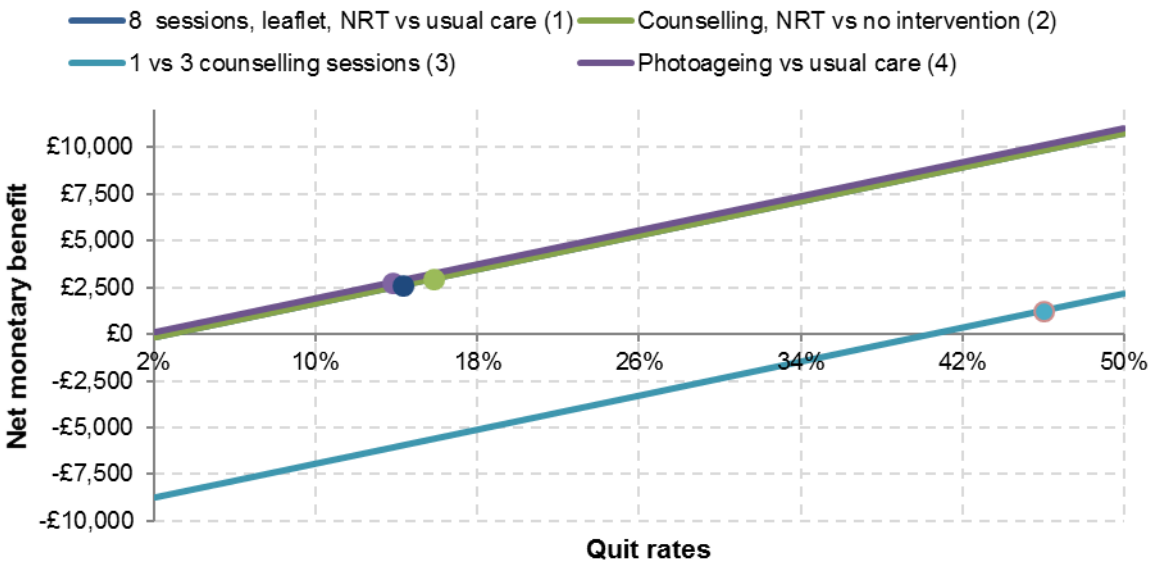
Univariate sensitivity analyses of five key model inputs are presented in Figure 3.5 to Figure 3.9. For the intervention quit rate, the programmes remain cost-effective until the quit rate becomes less than the comparator treatment. This occurs at around 2% for all interventions except the counselling intervention from Costello *et al*. (2007), for which the comparator arm (1 counselling session) had a quit rate of 40.5%.

The intervention cost sensitivity analysis indicates the maximum cost that the intervention can be in order for it be cost-effective. This is represented by where the line crosses 0, which does not occur within the intervention cost ranges presented in

Figure **3.6**. The thresholds are instead provided in Table 3.9.

The remaining parameters that are varied in sensitivity analysis all relate to the comorbidity utility values used to calculate the disutilities. Our results are robust to all possible ranges of utility score for each comorbidity, with NMB remaining above £1,000 in all circumstances.

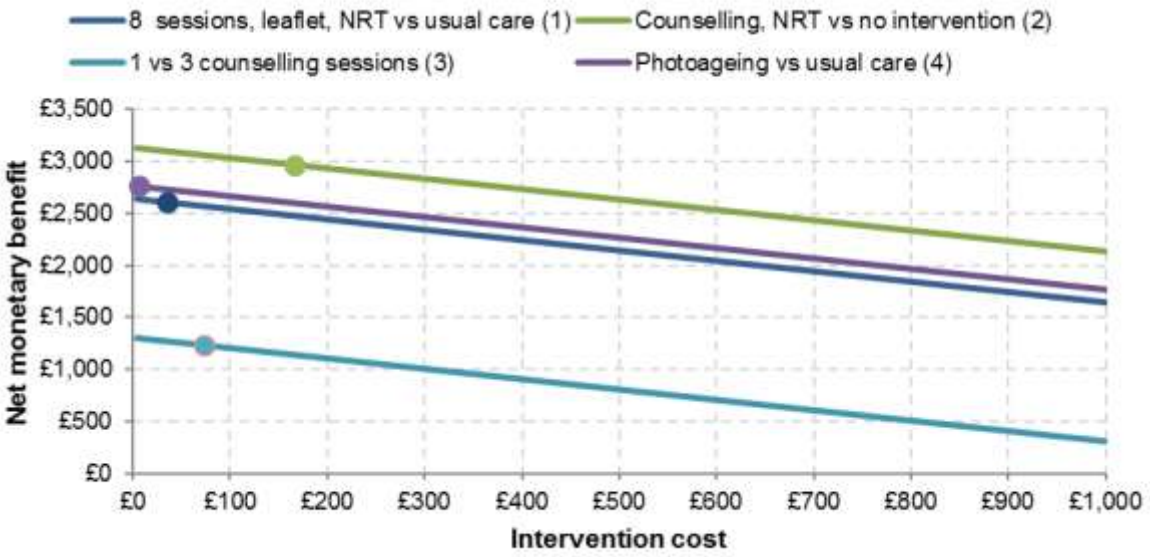
Figure 3.5: Quit rate sensitivity analysis



Notes:

1. (1) = Maguire et al. (2001); (2) = Burford et al. (2013); (3) Costello et al. (2011); (4) Cramp et al. (2007)
2. The quit rates here refer only to the intervention arm. However, it is the differences in the quit rates that drives cost-effectiveness; for each study, net monetary benefit becomes negative when the difference becomes negative.
3. Markers indicate the base case values for each study

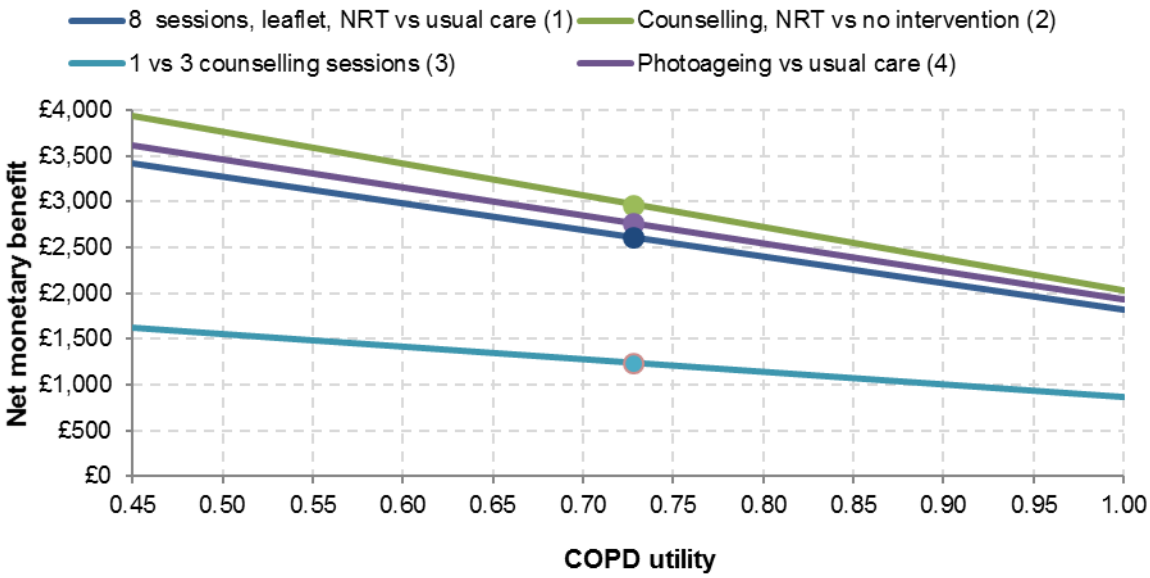
Figure 3.6: Intervention cost sensitivity analysis



Notes:

1. (1) = Maguire et al. (2001); (2) = Burford et al. (2013); (3) Costello et al. (2011); (4) Cramp et al. (2007)
2. Markers indicate the base case values for each study

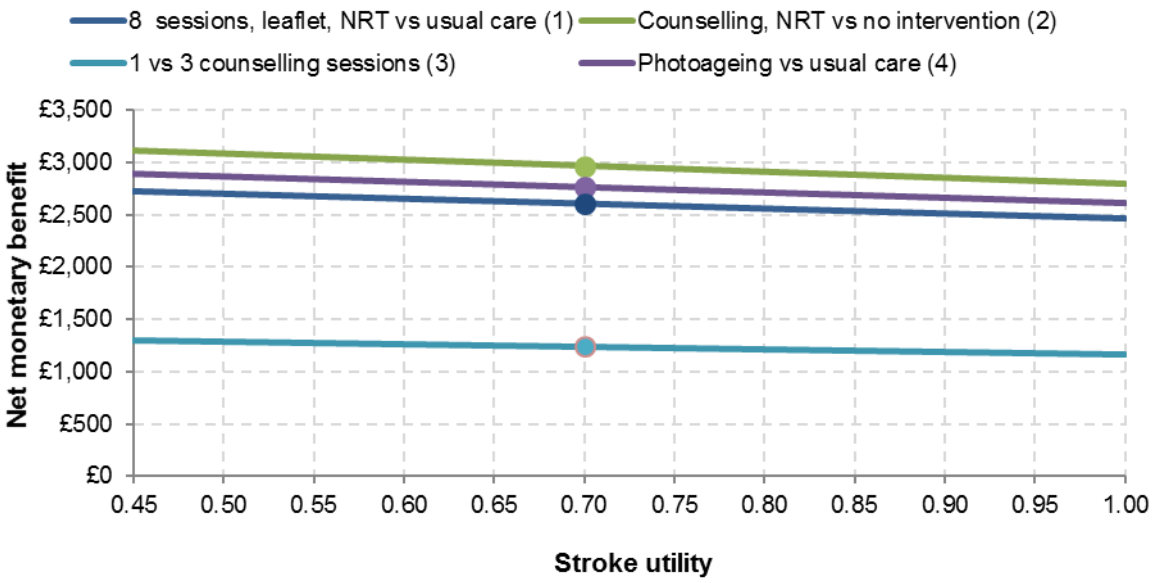
Figure 3.7: COPD utility sensitivity analysis



Notes:

1. (1) = Maguire et al. (2001); (2) = Burford et al. (2013); (3) Costello et al. (2011); (4) Cramp et al. (2007)
2. Markers indicate the base case values for each study

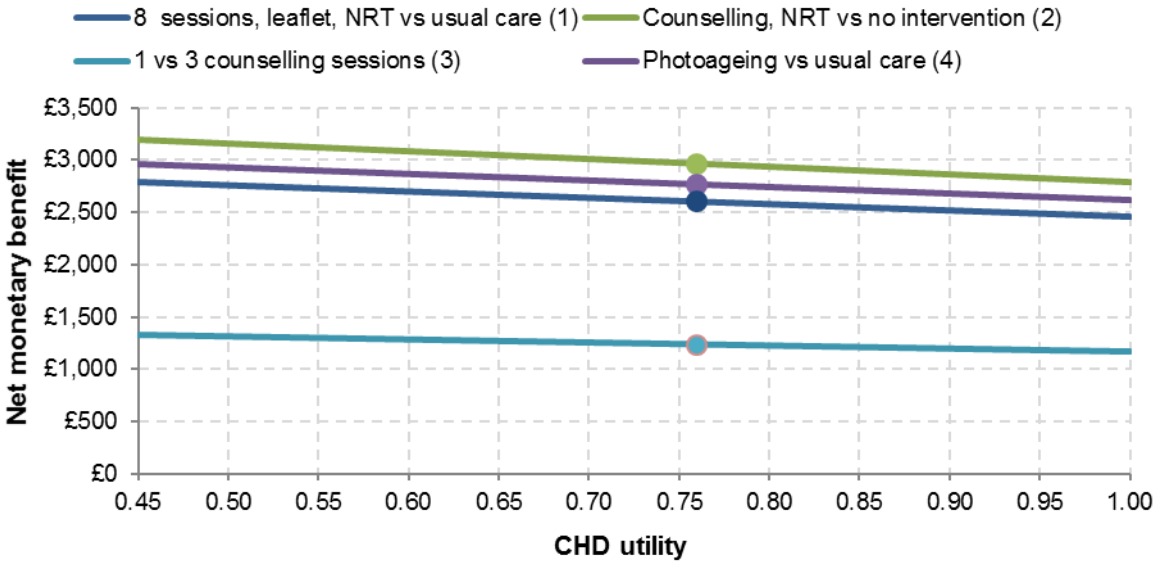
Figure 3.8: Stroke utility sensitivity analysis



Notes:

1. (1) = Maguire et al. (2001); (2) = Burford et al. (2013); (3) Costello et al. (2011); (4) Cramp et al. (2007)
2. Markers indicate the base case values for each study

Figure 3.9: CHD utility sensitivity analysis



Notes:

1. (1) = Maguire et al. (2001); (2) = Burford et al. (2013); (3) Costello et al. (2011); (4) Cramp et al. (2007)
2. Markers indicate the base case values for each study

3.2 WEIGHT MANAGEMENT

3.2.1 Intervention cost-effectiveness results

In our base case analysis, all four of the weight management programmes we identified are cost-effective at a threshold of £20,000 per QALY. The most cost-effective programme is the unnamed programme evaluated in Boardman *et al.* (2014), which provided a mean BMI reduction of 1.7 units at a cost of £126 per person, yielding an ICER of £3,309 per QALY. The highest ICER of £19,845 per QALY is seen for the Lighten Up programme, in which a mean BMI reduction of 0.3 costs £124 per person.

Unlike with smoking cessation interventions, the weight management programmes do not dominate no intervention, as the intervention costs are not compensated for by health sector cost savings from averting comorbidities. The most effective intervention (the unnamed weight management programme in Boardman *et* al. (2014)), for instance, had a mean BMI reduction of 1.7 and was associated with an average cost saving of £56 per participant, well below the cheapest intervention cost of £124 per person included in this evaluation. Diabetes is the most influential comorbidity, accounting for over 80% of the cost savings and QALY gains associated with new treatments.

Table 3.10: My Choice weight management programme (Bush *et al.* 2014)

	My Choice	No treatment	Incremental
Cost of intervention	£130	£0	£130
Cost of diabetes	£8,199	£8,226	-£27
Cost of colorectal cancer	£655	£656	-£1
Cost of CHD	£2,590	£2,595	-£4
Total cost	**£11,575**	**£11,477**	**£98**
QALYs no complications	13.57	13.56	0.009
QALY loss diabetes	0.814	0.816	-0.0025
QALY loss CRC	0.015	0.015	-0.00002
QALY loss CHD	0.281	0.282	-0.0004
Total QALYs	**12.46**	**12.45**	**0.012**
ICER			**£7,955**
Net monetary benefit			**£148**
NMB (no comorbidity QALYs)			**£89**

Note: All values are per person estimates

Table 3.11: Unnamed weight management programme (Boardman *et al.* 2014)

	Unnamed WMP	No treatment	Incremental
Cost of intervention	£126	£0	£126
Cost of diabetes	£8,180	£8,226	-£46
Cost of colorectal cancer	£654	£656	-£2
Cost of CHD	£2,587	£2,595	-£8
Total cost	**£11,547**	**£11,477**	**£70**
QALYs no complications	13.58	13.56	0.016
QALY loss diabetes	0.812	0.816	-0.0043
QALY loss CRC	0.015	0.015	-0.00003
QALY loss CHD	0.281	0.282	-0.0007
Total QALYs	**12.47**	**12.45**	**0.021**

ICER	**£3,309**
Net monetary benefit	**£354**

Note: All values are per person estimates

Table 3.12: Counterweight weight management programme (Morrison *et al.* 2013)

	Counterweight	No treatment	Incremental
Cost of intervention	£132	£0	£132
Cost of diabetes	£8,206	£8,226	-£20
Cost of colorectal cancer	£655	£656	-£1
Cost of CHD	£2,591	£2,595	-£3
Total cost	**£11,585**	**£11,477**	**£108**
QALYs no complications	13.57	13.56	0.007
QALY loss diabetes	0.814	0.816	-0.0019
QALY loss CRC	0.015	0.015	-0.00001
QALY loss CHD	0.281	0.282	-0.0003
Total QALYs	**12.46**	**12.45**	**0.009**

ICER	**£11,668**
Net monetary benefit	**£77**

Note: All values are per person estimates

Table 3.13: Lighten Up weight management programme (Jolly *et al.* 2011)

	Lighten Up	No treatment	Incremental
Cost of intervention	£124	£0	£124
Cost of diabetes	£8,214	£8,226	-£12
Cost of colorectal cancer	£656	£656	£0
Cost of CHD	£2,593	£2,595	-£2
Total cost	**£11,586**	**£11,477**	**£109**
QALYs no complications	13.57	13.56	0.004
QALY loss diabetes	0.815	0.816	-0.0011
QALY loss CRC	0.015	0.015	-0.00001
QALY loss CHD	0.282	0.282	-0.0002
Total QALYs	**12.46**	**12.45**	**0.005**

ICER	**£19,845**
Net monetary benefit	**£0.85**

Note: All values are per person estimates

3.2.2 Tornado Diagrams

Figure 3.10: My Choice weight management programme (Bush et al. 2014)

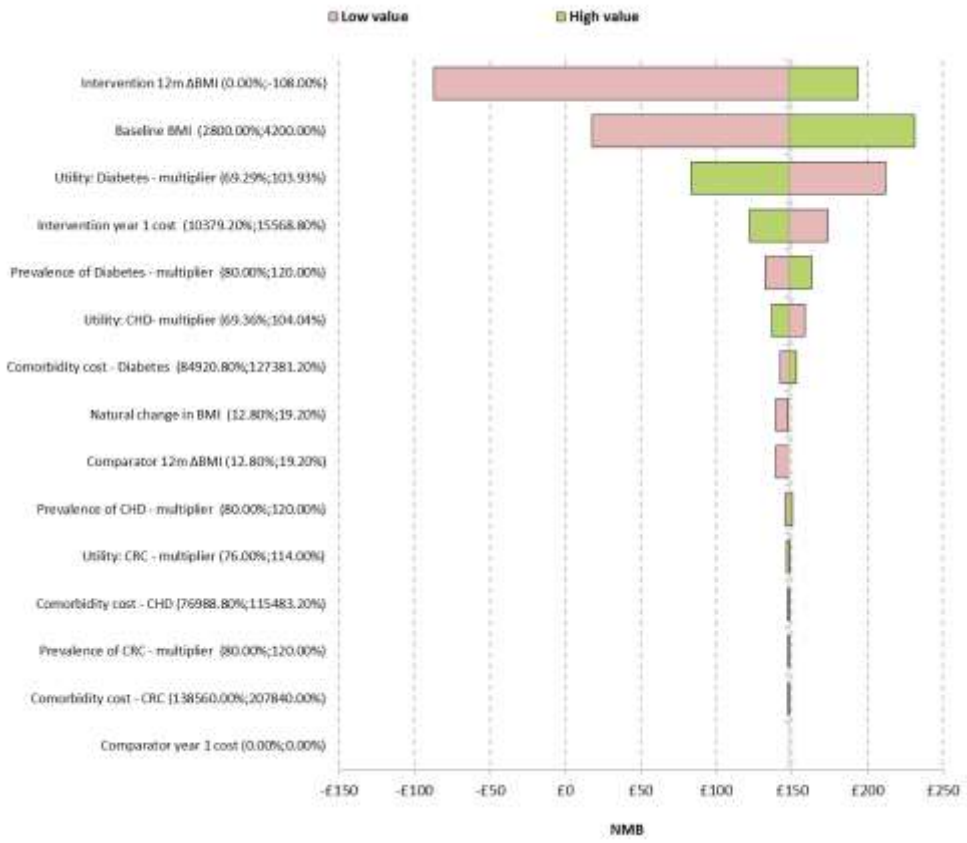


Figure 3.11: Unnamed weight management programme (Boardman et al. 2014)

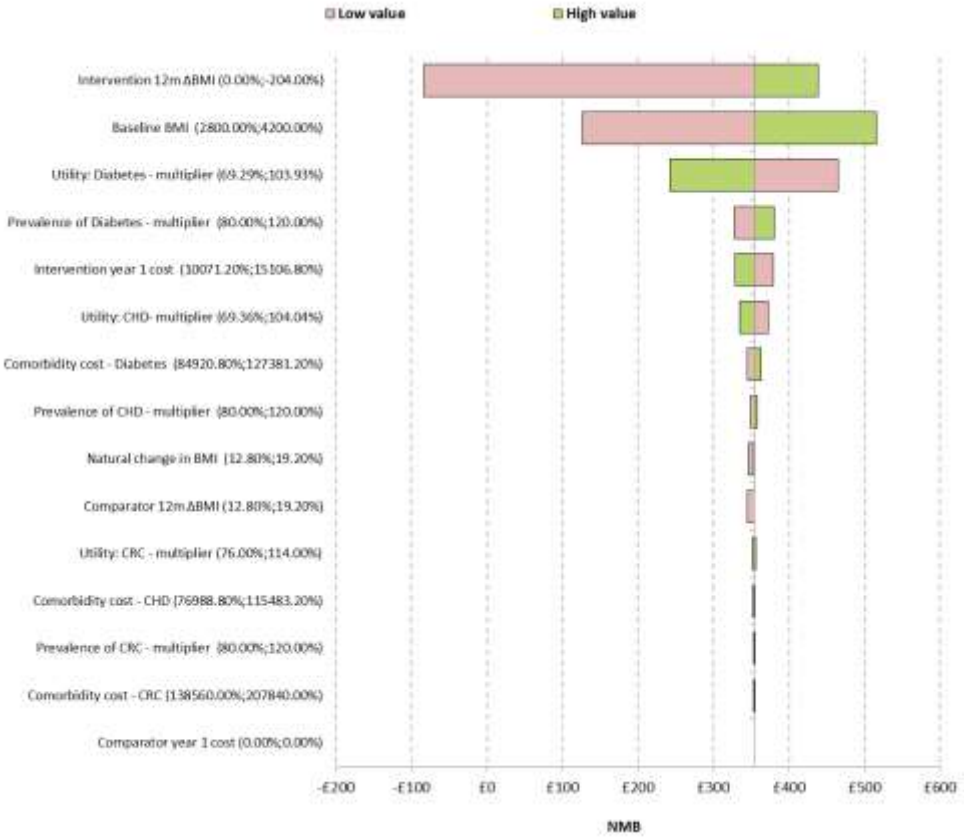


Figure 3.12 Counterweight weight management programme (Morrison et al. 2013)

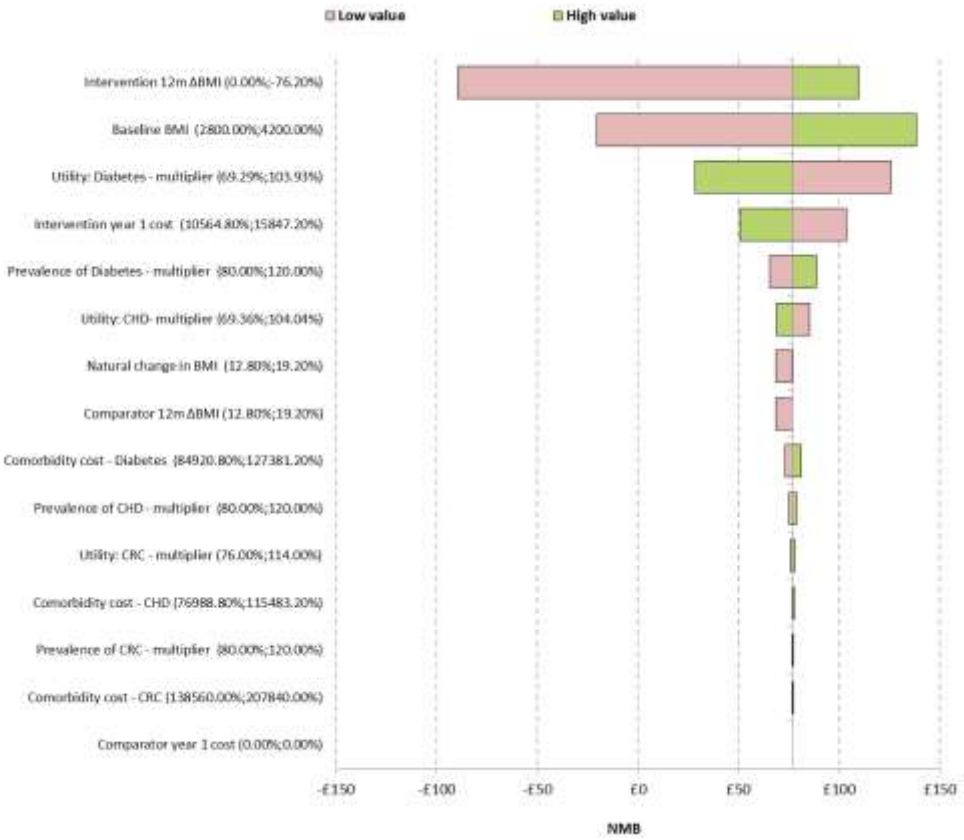
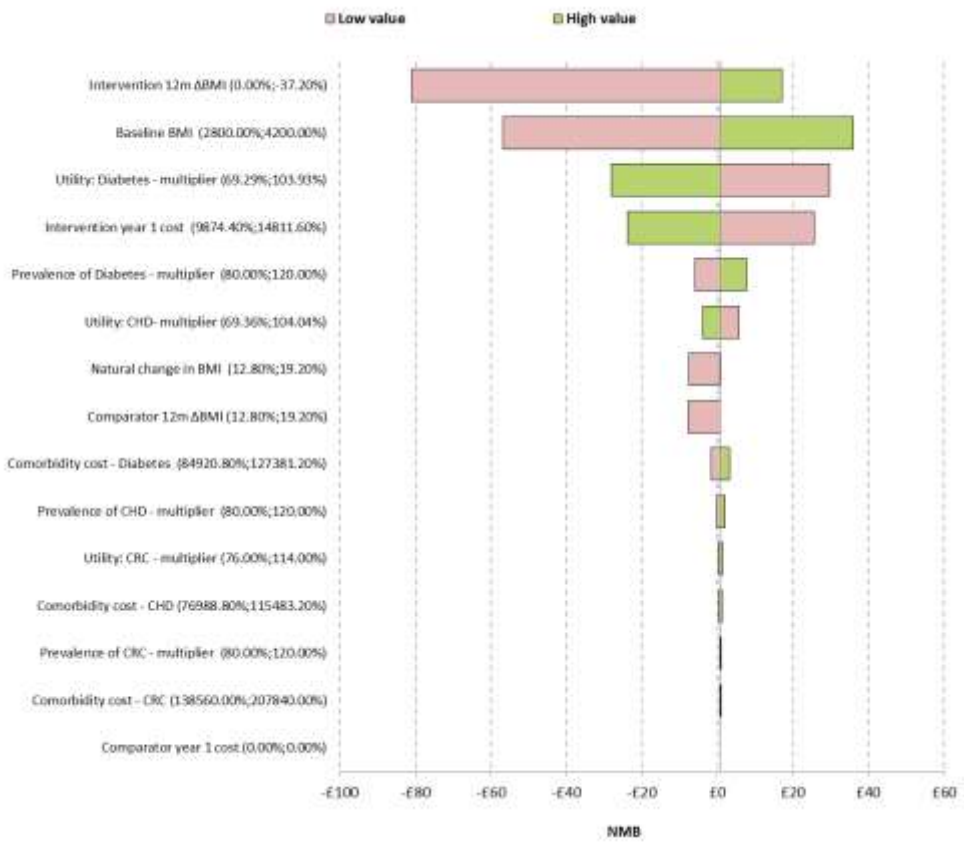


Figure 3.13: Lighten Up weight management programme (Jolly et al. 2011)



3.2.3 Scenario Analysis

Results from the scenario analyses we conduct are shown in Table 3.14 and Figure 3.14. When we assume that a pharmacy assistant instead of a pharmacist delivers interventions (at reduced cost and equal effectiveness), NMB increases for all interventions, improving their cost-effectiveness by around £70 per person. As all interventions are already cost-effective, this assumption does not change the direction of any of our results. When we assume that comorbidity disutility is accounted for in our baseline utility scores by BMI (thereby excluding the separately estimated disutility), NMB decreases for all interventions, from £101 for the unnamed programme in Boardman *et al*. (2014) to £26 for the Lighten Up programme. Although incurring the smallest absolute change amongst our interventions, this scenario makes the Lighten Up programme not cost-effective, with an NMB of minus £25. When training costs are excluded for the Boardman, Morrison and Jolly interventions, NMB increases from £354, £77 and £1 to £374, £97 and £21, respectively.

A range of intervention cost and effectiveness scenarios are presented in Figure 3.14. This demonstrates the relationship between cost and effectiveness and indicates the minimum BMI changes required given an intervention cost and the maximum cost given a BMI change that are required in order for an intervention to be cost-effective. When the cost is £50 per person, a mean BMI reduction of just 0.25 units is required. At £100 and £200 per person this rises to 0.2 and 0.6 units, respectively. Alternatively, for an intervention that reduces BMI by 1 unit, cost per person can be as high as £300 and remain cost-effective. A full breakdown of these results is provided in Table A.1.

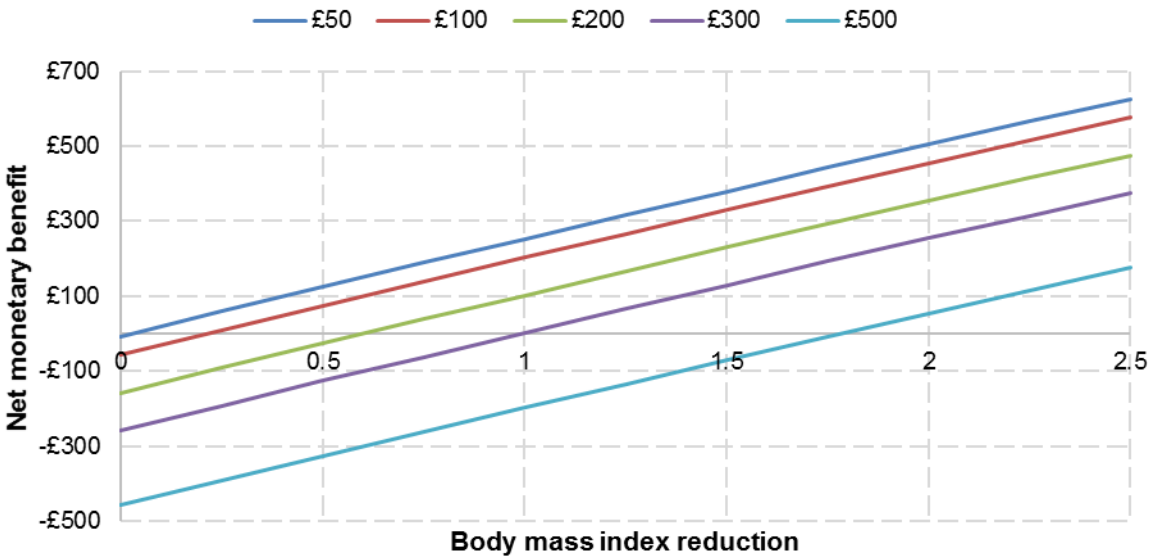
Table 3.14: Summary of cost-effectiveness results for weight management

	Net monetary benefit			
Intervention	**Base case**	**Assistant costs**	**No comorbidity QALYs**	**Maximum intervention cost**
My Choice (Bush et al., 2014)	£148	N/A	£89	£277
Unnamed programme (Boardman et al., 2014)	£354	£424	£252	£479
Counterweight (Morrison et al., 2011)	£77	£150	£33	£209
Lighten up (Jolly et al., 2009)	£0.85	£70	-£25	£124

Note:

1. Assistant costs = intervention delivered by pharmacy assistant instead of pharmacist, at lower cost and equal effectiveness; no comorbidity QALYs = separately estimated QALY gains associated with reducing comorbidity prevalence are not included
2. Assistant costs are not applied to the My Choice programme. As this study does not report average labour time, no adjustment can be made to the base case.
3. Maximum intervention cost applies to the base case analysis and is the highest per person cost an intervention can be in order to remain cost-effective

Figure 3.14: Intervention cost and effectiveness scenario analysis



Note: Each line represents an intervention cost. Combinations with a net monetary benefit greater than 0 are cost-effective at the cost-effectiveness threshold of £20,000 per QALY

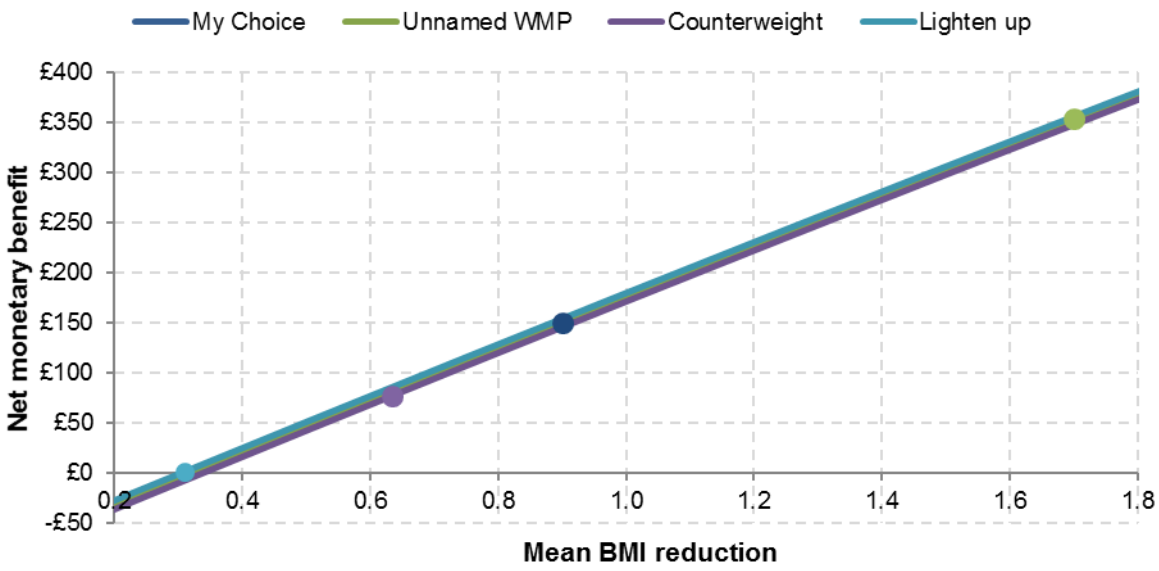
3.2.4 Sensitivity Analysis

The results from the univariate sensitivity analyses are presented in Figure 3.17 to Figure 3.19. Following on from the scenario analysis of intervention effectiveness in the previous section, we show, in Figure 3.17, the minimum level of effectiveness that each programme can be in order to be cost-effective. The cheapest programme, Lighten Up, remains cost-

effective down to a mean BMI reduction of 0.3 units. Similarly, with intervention cost we find that the most effective interventions remain cost-effective at high per person costs. My Choice and the unnamed programme from Boardman *et al*. (2014) remain cost-effective beyond costs of £250 per person. However, Lighten Up is only just cost-effective: its current intervention cost of £124 is almost exactly at the threshold for cost-effectiveness.

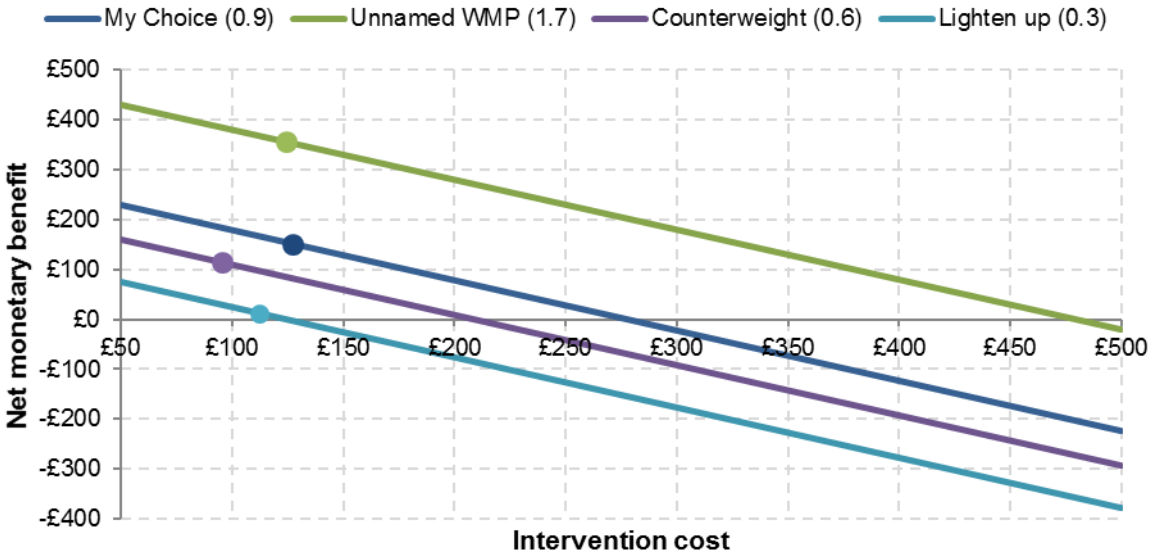
Sensitivity analyses are conducted on 3 additional parameters identified a priori as being influential on model results. The impact of the baseline BMI of the participant population is shown in Figure 3.17. For 3 of the 4 interventions, NMB remains positive for populations with an average BMI of 30, the clinical threshold for obesity. However, for Lighten Up to be cost-effective, the participants need to have an average BMI of 35 or above. A similar pattern is observed when the natural annual BMI increase is varied (**Error! Reference source not found.**); here, Lighten Up requires this value to be greater than approximately 0.15 per year, which lies within its 95% confidence interval. The final parameter we investigate is utility multiplier we apply to participants with diabetes, shown in Figure 3.19. The same trend is again observed, with the cost-effectiveness of Lighten Up only affected by the parameter values. In this instance, NMB becomes negative when the multiplier is greater than 0.87.

Figure 3.15: Intervention BMI change at 1 year sensitivity analysis



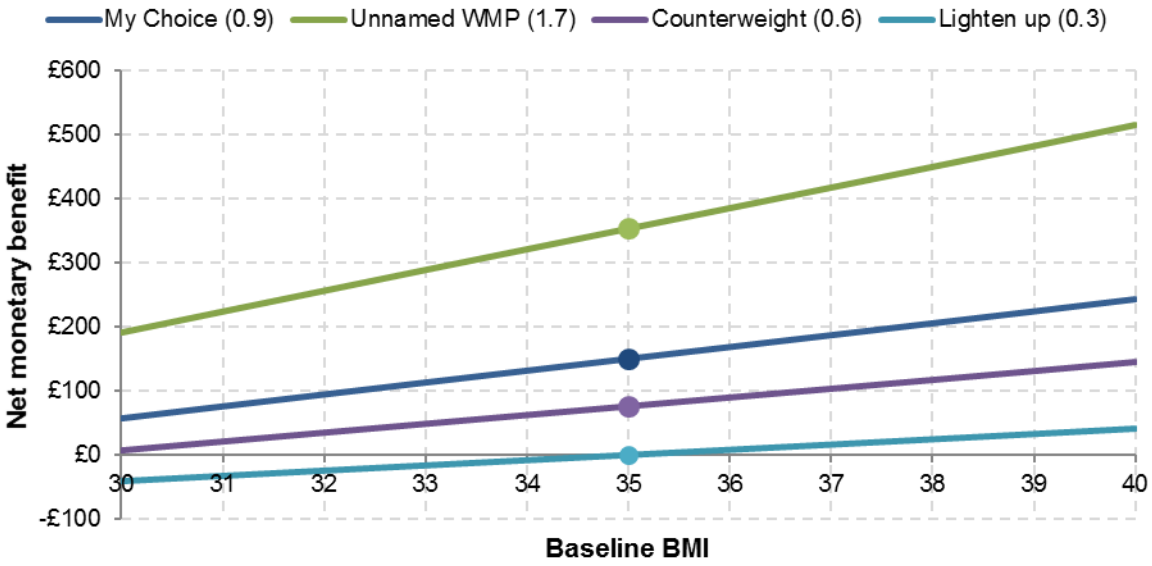
Note: Markers indicate the base case values for each study

Figure 3.16: Intervention cost-per-patient sensitivity analysis



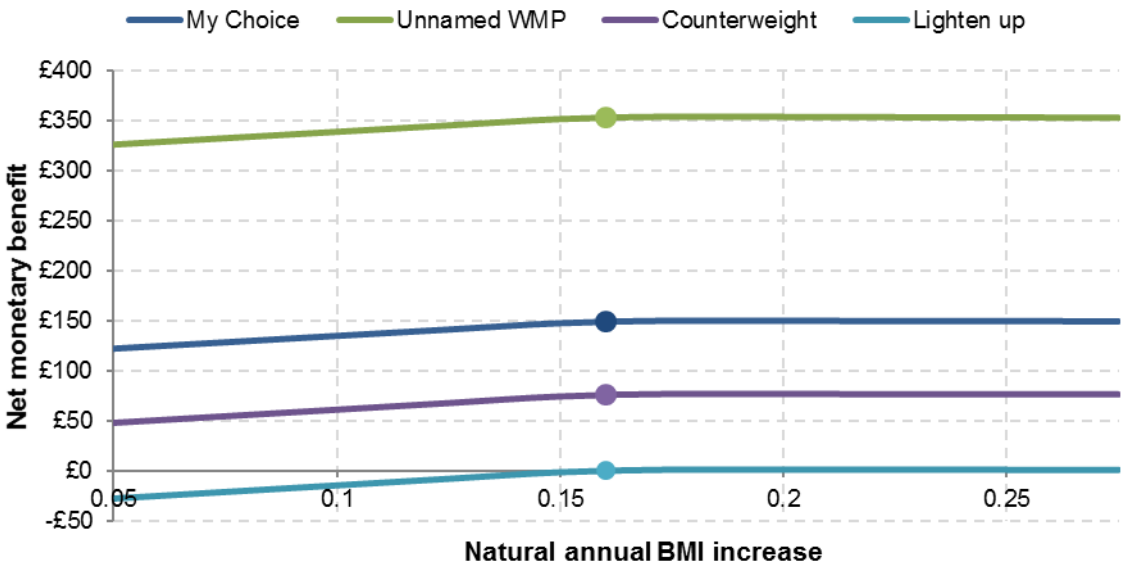
Note: Markers indicate the base case values for each study. Bracketed numbers indicate the mean BMI reduction at 1 year for each programme

Figure 3.17: Baseline BMI sensitivity analysis



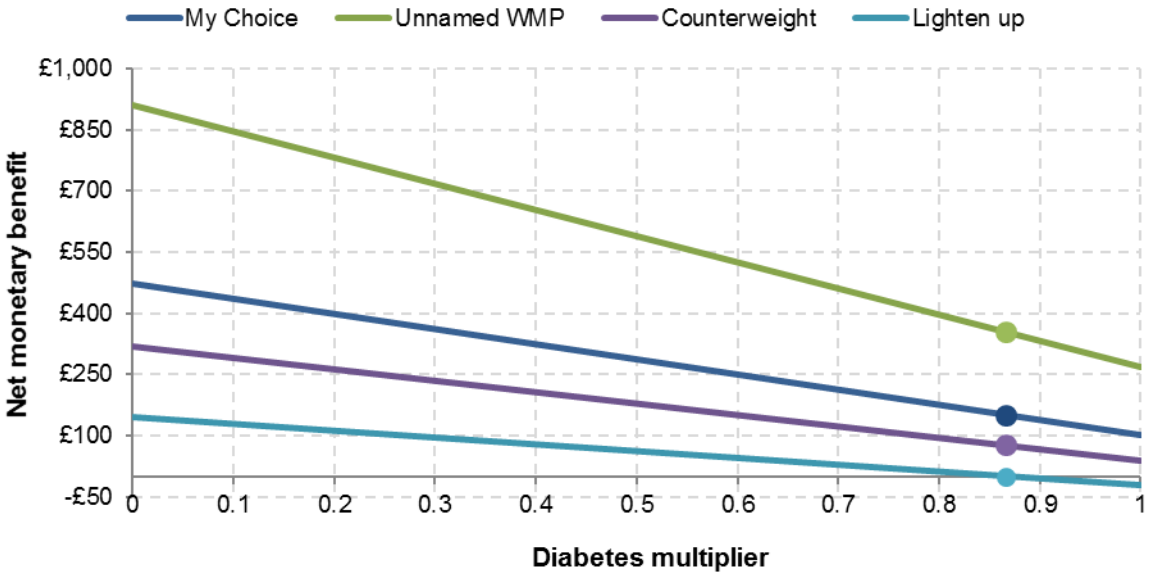
Note: Markers indicate the base case values for each study. Bracketed numbers indicate the mean BMI reduction at 1 year for each programme

Figure 3.18: Annual BMI increase sensitivity analysis



Note: Markers indicate the base case values for each study

Figure 3.19: Diabetes utility multiplier sensitivity analysis



Note: Markers indicate the base case values for each study

Section 4: Discussion

The economic modelling presented in this report demonstrates that behavioural interventions to support smoking cessation and weight management delivered in a community pharmacy setting are expected to be cost-effective. All 8 interventions that were evaluated yielded deterministic ICERs under the £20,000 per QALY that is used by NICE to determine cost-effectiveness, even under the assumption that pharmacists, with their more expensive wage rates, delivered the whole intervention. In the case of smoking interventions, all interventions were shown to be dominant. This result is driven by two factors: (i) low intervention costs of less than £50 per person and (ii) large relative risk reductions associated with quitting smoking. The latter means that a larger proportion of the population avoid comorbidities and avoid NHS the respective treatment costs, which far outweigh the cost of the intervention. Whilst the same relationship is observed with respect to BMI reduction in the weight management results, the higher intervention costs and smaller risk reductions mean that the interventions still pose a net cost to the NHS.

The scenario analyses indicate the combinations of intervention cost and effectiveness would render an intervention cost-effective. For smoking, costs need to reach implausible levels due to the substantial health gains and cost savings associated with quitting smoking explained above. For example, an intervention that induced an additional 2% of smokers to quit (compared to some alternative) could cost up to £473 in order to be effective. For weight management, cost-effectiveness is less certain. An intervention generating an average BMI reduction of 0.5 units will only be cost-effective up to an intervention cost of approximately £175 per person. Both models also use baseline utility scores (by smoking status and BMI) that do not properly control for all of the other comorbidities included in the model. When adopting a more pessimistic assumption that no separate comorbidity disutilities are included in the results, 7 out of 8 interventions remain cost-effective. Of the comorbidities included in the models, those with the highest prevalence and the strongest relationship with smoking or weight had the biggest influence on results. For smoking, these were stroke and COPD, whilst for weight management, diabetes was the biggest driver. However, in both instances, the impact on all-cause mortality had a greater impact on cost-effectiveness than comorbidities.

The sensitivity analyses indicate that the results for the smoking cessation interventions are more robust than those for weight management. Alongside intervention cost and quit rate, the 3 parameters selected (CHD, stroke and COPD utility) were those that a preliminary analysis indicated would have the biggest influence on net monetary benefit. However, it is shown that even when no disutility is experienced for any one of these comorbidities, all interventions are still highly cost-effective.

The same conclusions do not apply to the weight management model. For example, sensitivity analysis indicated the Lighten Up intervention, which had relatively high costs and a BMI reduction of 0.3, had an ICER of £19.845, a fraction below the £20,000 threshold. This programme would no longer be cost-effective if the average BMI of the participants was

marginally lower or if the HRQL impact of diabetes was smaller. However, interventions maintained cost-effectiveness despite variation in these parameters if the BMI reduction was greater than 0.5. Therefore, our results indicate that when the mean BMI reduction is smaller than 0.5, interventions should be targeted at increasingly overweight populations.

As with all economic modelling, simplifying assumptions were made within both models that influence the results. The smoking model, for instance, does not explicitly include multiple quit attempts beyond the initial intervention in the first year. However, the incorporation of a background 'net' quit rate into the model mitigates this limitation. Sensitivity analysis showed that this input has some impact on the results but would need to change significantly in order for the direction of results to change. Nor does the model account for the fact that a certain proportion of quitters will be expected to relapse over time. Accounting for this would reduce the cost-effectiveness of the interventions modelled in this study. Our scenario analysis shows that even modest improvements in quit success are highly cost-effective, which may be more reflective of long-term abstinence.

Within the weight management model, a critical structural assumption made in the base case analysis is that individuals in the intervention arm regain the weight they initially receive after two years, such that their BMI reverts to what it would have been without the intervention. The fact that all of the interventions were cost-effective despite this conservative assumption provides strong evidence for the conclusion that weight management programmes, given a sufficient level of relatively short-term effectiveness, are a cost-effective use of public health resources.

Caution must also be taken when interpreting the evidence for intervention effectiveness used in both models. Although these were taken from the best sources available as identified by the NICE team, there is also a great deal of heterogeneity between studies in terms of the characteristics of the participants and interventions. As only severely limited and caveated conclusions could be drawn from a fully incremental analysis (in which all interventions are compared with one another), we do not conduct one here. For the smoking cessation studies, each intervention was compared with "usual care", which varied considerably from study to study. For weight management, the plausibility of the assumption that usual care is no intervention at all is also debatable. Lastly, the joint uncertainty of the input parameters is not quantified in either model through a probabilistic sensitivity analysis. This was, as we have noted previously, due to computational restraints, as the models combine results simulated over age groups.

Whilst these limitations provide a note of caution when interpreting the economic evidence presented in this report, the base case results suggest that behavioural interventions provided in community pharmacies to support weight management and smoking cessation constitute a highly cost-effective use of public health resources.

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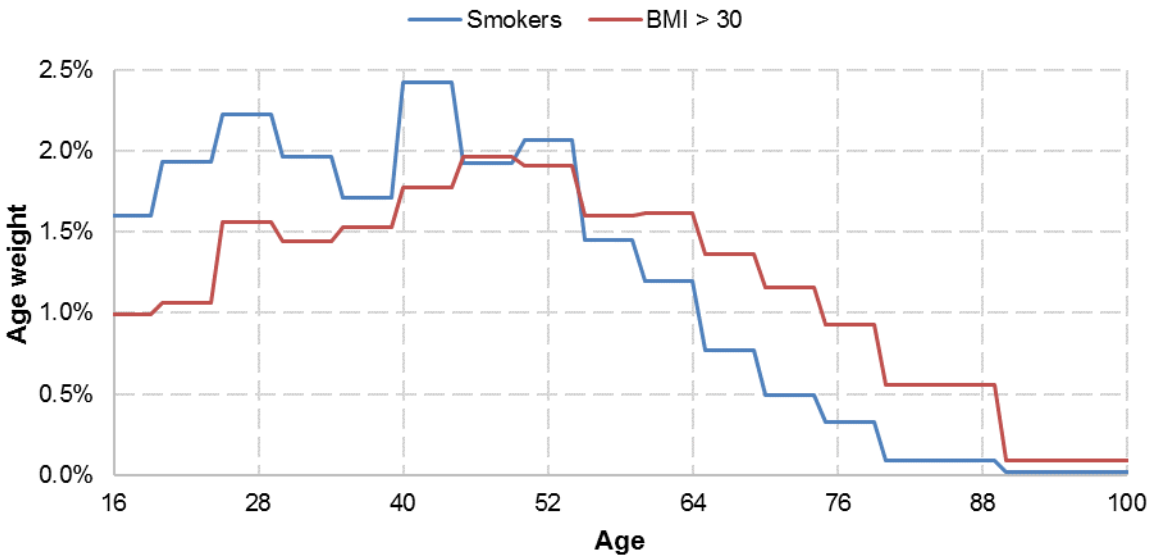
APPENDIX A

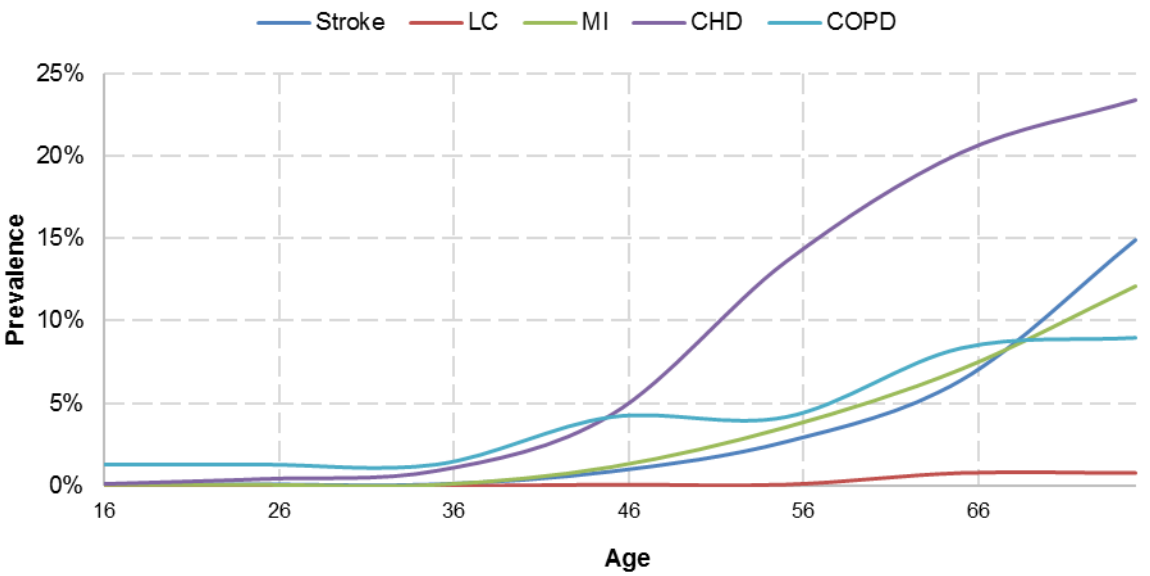
Mortality and Epidemiology Data

Figure A.1: Population densities by year of age used to weight cost-effectiveness results



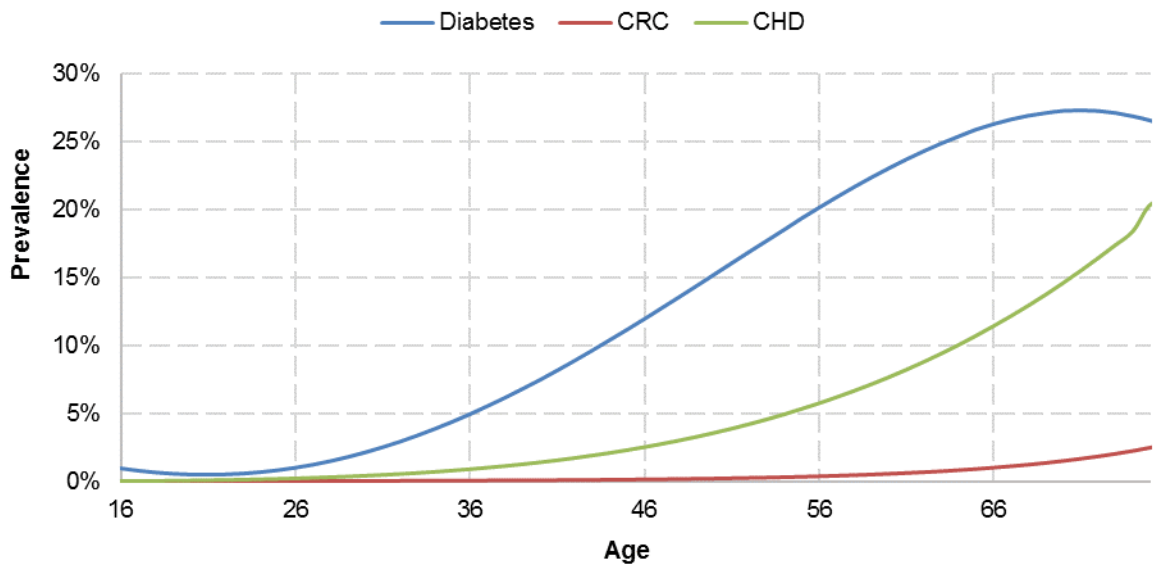
Note: BMI = Body mass index

Figure A.2: Smoking comorbidity prevalence by age



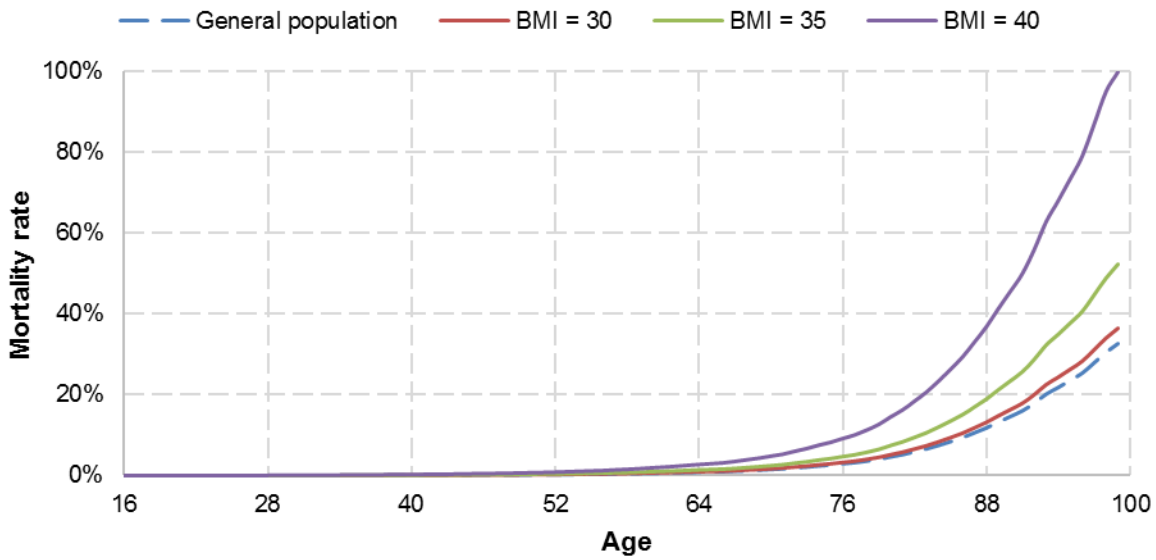
Note: LC = lung cancer, CHD = coronary heart disease, MI = myocardial infarction, COPD = chronic obstructive pulmonary disease

Figure A.3: Weight management comorbidity prevalence by age



Note: CHD = coronary heart disease, CRC = colorectal cancer

Figure A.4: Mortality risk by age and body mass index



Note: BMI = Body mass index

APPENDIX B

Scenario Analyses

Table A.1: Net monetary benefit of combinations of intervention effectiveness (BMI reduction) and cost for weight management interventions

	Intervention cost										
BMI reduction at 1 year	**£50**	**£100**	**£150**	**£200**	**£250**	**£300**	**£350**	**£400**	**£500**	**£600**	**£750**
0.0	-£7	-£57	-£108	-£158	-£208	-£258	-£308	-£358	-£458	-£558	-£708
-0.25	£59	£9	-£41	-£92	-£142	-£192	-£242	-£292	-£392	-£492	-£642
-0.5	£124	£74	£24	-£26	-£76	-£126	-£176	-£226	-£326	-£426	-£577
-0.75	£189	£139	£89	£39	-£11	-£61	-£111	-£161	-£262	-£362	-£512
-1.0	£253	£203	£153	£103	£53	£3	-£47	-£97	-£197	-£297	-£447
-1.25	£317	£267	£217	£167	£117	£67	£17	-£34	-£134	-£234	-£384
-1.5	£380	£330	£280	£230	£180	£130	£80	£30	-£71	-£171	-£321
-1.75	£442	£392	£342	£292	£242	£192	£142	£92	-£8	-£108	-£258
-2.0	£504	£454	£404	£354	£304	£254	£204	£154	£54	-£46	-£196
-2.25	£565	£515	£465	£415	£365	£315	£265	£215	£115	£15	-£135
-2.5	£626	£576	£526	£476	£426	£376	£326	£276	£176	£76	-£74

Notes:

1. Interventions are cost-effective if net monetary benefit is greater than 0. Shaded cells indicate combinations that are not cost-effective.

2. A cost-effectiveness threshold of £20,000 per QALY is used to estimate net monetary benefit.

Table A.2: Change in comorbidity disutility for counselling vs. usual care (Maguire et al., 2001) when only highest disutility is applied

	Intervention	Comparator	Incremental
Stroke disutility	0.000	0.000	0.000
Lung cancer disutility	-0.003	-0.003	0.000
MI disutility	-0.015	-0.016	0.001
CHD disutility	-0.049	-0.051	0.003
COPD disutility	-0.025	-0.027	0.002
Asthma disutility	0.000	0.000	0.000
Total QALYs	**-0.091**	**-0.097**	**0.006**

Net monetary benefit	-£110.54

Note: When only the highest disutility is applied, the comorbidity disutilities for both the intervention and comparator are reduced. Smaller incremental disutilities are observed for myocardial infarction (MI), coronary heart disease (CHD) and chronic obstructive pulmonary disease (COPD). This translates into a smaller net monetary benefit.