Title: Are financial incentives cost-effective to support smoking cessation during pregnancy?

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DECLARATION OF INTERESTS

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ABSTRACT

Aims: To investigate the cost-effectiveness of up to £400 worth of financial incentives for smoking cessation in pregnancy as an adjunct to routine healthcare.**Design**: Cost-effectiveness analysis based on a phase II RCT and a cost-utility analysis using a lifetime Markov model. **Setting:** The RCT was undertaken in Glasgow, Scotland. The economic analysis is undertaken from the UK NHS perspective. **Participants:** 612 pregnant women randomised to receive usual cessation support +/- financial incentives of up to £400 vouchers ($609 USD), contingent on smoking cessation. **Measurements:** Comparison of usual support and incentive interventions in terms of cotinine validate quitters, Quality Adjusted Life Years (QALYs)and direct costs to the NHS. **Findings:** The incremental cost per quitter at 34-38 weeks pregnant was £1127 ($1716).This is similar to the standard look-up value derived from Stapleton & Wests published ICER tables (72), £1390 per quitter, by looking-up the CPIT trial incremental cost (£157) and incremental 6 month quit outcome (0.14). The lifetime model resulted in an incremental cost of £17 (95% CI: -£93, £107) and a gain of 0.04 QALYs (95% CI: -0.058, 0.145), giving an ICER of £482/QALY ($734/QALY). Probabilistic sensitivity analysis indicates uncertainty in these results, particularly regarding relapse after birth. The expected value of perfect information was £30 million (at a willingness to pay of £30,000/QALY), so given current uncertainty, additional research is potentially worthwhile. **Conclusion:** Financial incentives for smoking cessation in pregnancy are highly cost-effective, with an incremental cost per QALY of £482, which is well below recommended decision thresholds.

INTRODUCTION

Smoking during pregnancy is the leading preventable cause of morbidity and death amongst women and their babies (1;2), costing between £20-£87 million per annum in the UK (3), and over $367million (4) (£241million[1]) in the USA. Smoking in pregnancy accounts for up to 30% of low-birth weight babies and up to 14% of pre-term deliveries per annum and is associated with increased risks for ectopic pregnancy, premature rupture of membranes, stillbirth, low birth weight, and congenital anomalies such as cleft lip (6).

Despite these risks, 10 to 20% of pregnant women in Europe continue to smoke during pregnancy (7). In Scotland 18% of pregnant women smoke(8), and only 20% of them manage to quit during their pregnancy (9). A range of effective cessation services exist to support pregnant smokers (10;11), however, engagement with these services is poor as are successful quit attempts (9;12). Financial incentives have been proposed as a valuable addition to the behaviour change toolkit (13;14), with a wide body of experimental evidence supporting their success in abstinence from a range of addictive substances (15-19), including nicotine (20;21). In 2010 NICE reported there is little evidence to support use of financial incentives in a routine smoking cessation setting (11),while a Cochrane review (22) found financial incentives to be the 'single most effective intervention' for smoking cessation during pregnancy, based on four small trials conducted in the USA. Since then further trials have been published in support of financial incentives (23;24) (20;25-27). While the efficacy evidence on financial incentives is growing, as yet there has been little economic analysis of their value in addition to existing public health services, and no cost-effectiveness analyses on their value in smoking cessation during pregnancy. The healthcare system in the UK is a publicly funded National Health Service (NHS), primarily funded through taxes providing comprehensive healthcare to all UK residents; most of which is free at the point of use. A collectively financed healthcare system such as the NHS cannot afford to fund every new clinical and public health intervention, and

[1] 1USD=0.6566GBP, www.xe.com, 9th February 2015

therefore choices need to be made about funding allocation (28;29), aided by the recommended UK cost-effectiveness threshold of £20,000/QALY(30;). Indeed, many countries now require economic evidence prior to reimbursement (31). If financial incentives to aid smoking cessation are to be considered as an option in the UK and other high income countries, then cost-effectiveness analyses are integral to policy-making considerations. The current guidance for smoking cessation in pregnancy highlights the need for economic evidence on financial incentives for pregnant smokers (11). Therefore, this paper reports on an economic evaluation undertaken as part of a phase II randomised controlled trial (ISRCTN 87508788) (32;33) of 612 pregnant women in Glasgow, Scotland; to assess the cost-effectiveness of the offer of up to £400 of shopping vouchers in addition to routine care to help pregnant smokers quit. To our knowledge this is the first cost-effectiveness analysis of financial incentives for smoking cessation in pregnant women.

METHODS

This economic evaluation was undertaken alongside the Cessation in Pregnancy Incentives Trial (CPIT) (ISRCTN 87508788); which was a large single centre, single blinded, randomised, controlled parallel group trial, undertaken in Glasgow, Scotland. The trial recruited 612 (609 after three patients withdrew consent post randomisation) self-reported smokers who had a carbon monoxide (CO) reading of at least 7ppm at maternity booking, were aged 16 years and over, less than 24 weeks pregnant and resident in NHS Greater Glasgow and Clyde (GGC), following the published CPIT trial protocol (32). The control arm (n=303) received routine care consisting of routine referral to the NHS GGC Stop Smoking Services (SSS) which offer specialist pregnancy cessation advice in a one hour face-to-face appointment, followed by four weekly telephone support calls and 'free to the user' Nicotine Replacement Therapy (NRT) via local pharmacies for 10 weeks. The intervention arm (n=306) received routine care, as described above, with the addition of up to £400 vouchers (Love2shop) for engaging with the SSS (£50 for attending the first face-to-face appointment and setting a quit date) and for quitting during pregnancy (£50 for achieving a 4-week CO validated quit,

£100 for achieving a 12 weeks CO validated quit; and £200 for a CO validated quit at 34-38 weeks pregnancy). Further details of the intervention, level and contingency of the incentives, randomisation, methods and outcomes for the trial are reported elsewhere (33;34).

The cost-effectiveness analysis was undertaken from the UK NHS perspective for cost year 2013, adhering to good practice guidelines (30;35). The analysis was undertaken in two parts: a within-trial analysis which utilised data on resource use and quit outcomes to report the incremental cost per late pregnancy quitter; followed by a lifetime analysis which adapted a previously published probabilistic decision analytic model (36;37) to assess the incremental cost per quality adjusted life year (QALY) gained. The analyses are described below, with further details provided in the supplementary report.

Within trial analysis

The primary effectiveness endpoint for the trial was the number of cotinine validated quitters at 34-38 weeks pregnancy. The analysis used an intention-to-treat approach and all clients who were lost to follow-up were considered to have relapsed (33).

The direct healthcare costs for each arm of the trial are attributed to three areas: cessation support (face-to-face and telephone), NRT and financial incentives (Table 1). Unit cost information (Table 2) was combined with the trial resource use data and the mean cost per client in each arm was estimated (35). Patient level data on resource use included: duration of first contact (face-to-face support and/or first phone contact); number and duration of support calls post quit-date; number of clients accepting a four week supply of NRT at week 1, and week 5; and in the intervention arm, the number of clients receiving financial incentives at the pre-specified time points. Administration costs such as postage and packaging for vouchers (sent via special delivery) were included. Unit cost information was taken from routine sources such as the British National Formulary (38), the Personal Social Services Research Unit (39) and from the trial sources (value of the vouchers, postage and

packaging charges). Costs are in UK pounds sterling for price year 2012/13. The basecase analysis does not incorporate additional research and start-up costs.

INSERT TABLES 1 & 2 NEAR HERE

Lifetime analysis

A health economic model we previously developed (36;37) was adapted to incorporate the trial information, capturing the short and longer-term costs and health gains of cessation for the mother[2]. The model uses a Markov design to simulate the lifetime likelihood and impact of cessation, expressing the long-term health benefits of quitting smoking in terms of QALYs and the potential long-term reduction in costs to the health service of cessation. The model accounts for any relapse to smoking post-trial; in the six month period following birth, and for up to eight years post-quit (which will have cost and life expectancy impacts in the long term). Post-birth hospitalisation costs for premature and low birth weight babies were included, and long-term cost of treating smoking related diseases was incorporated in a scenario analysis.

INSERT FIGURE 1 NEAR HERE

Figure 1 depicts the Markov model, which simulates the options for a cohort of pregnant smokers undertaking a quit attempt. The model consists of four main Markov states that a smoker can move to once they undertake a quit attempt: Ex-smoker, Smoker (relapsed), Non Smoking Related Death and Smoking Related Death. After a quit attempt, a woman will either be successful and become an ex-smoker, or relapse and remain a smoker. The direction of the arrows indicate possible transitions between the states. For example, ex-smokers who were successful in the quit attempt can still relapse later in life to become smokers again. It is assumed however that no further quit attempts are undertaken, so there is no transition from the smoker relapsed state to the smoker quit attempt or ex-smoker states. Ex-smokers can remain an ex-smoker, relapse to become a smoker again, die

[2] As the phase II CPIT trial found no difference in low birth weight or premature births between study arms (33), the lifetime economic modelling was undertaken only for the mothers.

from non-smoking related causes or die from smoking related causes. Clients in the smoking relapse state remain here until they die from either a smoking or non-smoking related cause.

The model begins with a cohort of 1000 pregnant smokers, with a mean age of 28 years (average age from the trial) and runs in annual cycles until the entire cohort has died. The model is run for the routine care arm and for the financial incentives arm over the patient lifetime to calculate the mean cost, life expectancy and QALYs for each cohort. The first year of the model includes the arm specific trial costs and outcomes (up to 38 weeks pregnancy), followed by a six month post-trial period to allow for post-birth hospital costs for low birth weight babies and possible smoking relapse in mothers. Table 3 details the model input parameters and their sources, including standard errors and the distribution used in the probabilistic analysis. Costs and outcomes incurred beyond the first year were discounted at 3.5% as per recommended guidelines (24). Further details of the model, parameters, probabilistic analysis and assumptions are provided in the supplementary report.

INSERT TABLE 3 NEAR HERE

Sensitivity analyses

The model was analysed probabilistically (30;40) using a 1000 iteration Monte Carlo simulation to characterise uncertainty in the input parameters, and estimate confidence limits around the cost and effectiveness outcomes. Table 3 details the standard errors and distributions for the probabilistic analysis. An expected value of perfect information (EVPI) analysis (41;42) was carried out assuming an eligible population of 31,330 pregnant smokers in the UK per annum who would be referred to specialist smoking cessation services (9) over a conservatively assumed intervention lifetime of five years, discounted at 3.5%.

The model was re-run under six alternative scenario analyses to explore the impact of varying some of the assumptions using (1) the self-reported 6- month postnatal relapse rates (12 months post quit)followed-up post trial , (2) a worst case assumption on postnatal relapse (80% for the Incentives arm), (3) incorporating a cost for future smoking related disease, (4) no discounting, (5) adjusting the

analysis to account for gaming that was evidenced in the trial), (6) the trial self-reported quit rates at 34-38weeks as opposed to cotinine validated quit rates.

Finally, the amount of incentive and the corresponding impact on size of effect was considered in sensitivity analysis, given the growing evidence that substantially increasing incentive amount can impact on effect size from both the broader drug abstinence and smoking cessation fields (25)(43)(44). Scenarios 7 & 8 re-calculate cost-effectiveness using: (7) double the original incentive amount - a maximum of £800 vouchers (daily equivalent £4), (8) a maximum of £1800 vouchers (daily equivalent £10). Further information regarding the sensitivity analyses and evidence base are detailed in the supplementary report.

RESULTS

Table 4A and Figure 2 detail the base case outcomes.

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The within-trial analysis gave an incremental cost per late pregnancy quitter of £1127 compared to routine care. The lifetime model resulted in an incremental cost of £17 (95% CI: -£93, £107) ($26[3]) and a gain of 0.04 QALYs (95% CI: -0.058, 0.145), giving an ICER of £482/QALY ($734/QALY). These results are highly cost-effective and similar to cost-effectiveness ratios found for a range of smoking cessation interventions (45;46)(72). Figure 2 shows the distribution of incremental cost and QALY outcomes from the probabilistic analysis on a cost-effectiveness plane. The majority of values fall in the north eastern quadrant, with an ICER of £482/QALY, well below the UK threshold of £20,000/QALY (30). However, uncertainty is present– primarily due to relapse rates post trial- which is demonstrated in Figure 2 where outcomes pass through the origin into all four quadrants.

INSERT FIGURE 2 NEAR HERE

[3] 1USD=0.6566GBP, www.xe.com, 9th February 2015

The cost-effectiveness acceptability of the Incentives in comparison to the Control was calculated over a range of willingness to pay thresholds. At a willingness to pay of £20,000 to £30,000/QALY, Incentives had a 72% likelihood of being cost-effective compared to the Control. The probability of cost-effectiveness is detailed in Table 4B for the basecase and eight alternative scenario analyses. Table 4B shows the incentives arm is a highly cost-effective option over a range of alternative model assumptions. Only in the extreme worst case scenario 2 (assuming 80% relapse for Incentives, 30% relapse for Control post trial) was the control arm the optimal option, with a probability of 70%. Increasing the value of financial incentives offered is likely to be a cost-effective strategy as demonstrated in scenarios 7 & 8; however ICER values increase substantially compared to baseline, due to diminishing returns on the level of effect. The EVPI analysis (figure 3) indicated that given current uncertainty, the value of further information is £30million. Therefore additional research to improve evidence on quit rates and relapse rates post birth and post incentive is likely to be worthwhile.

Discussion

This economic evaluation has shown that financial incentives are highly likely to be cost-effective for pregnant smokers in encouraging engagement and successful cessation during pregnancy with existing stop smoking services. Financial incentives in addition to routine care for pregnant women were found to be cost-effective at £482/QALY ($734/QALY)which is well below recommended cost-effectiveness thresholds in high income countries (30;49;50). This is comparable to and in some cases lower than ICERs reported for more general smoking cessation interventions (45;46;51;52), particularly those for pregnancy (53-55) .

The incremental cost per quitter outcomes from our analysis correspond with values from the standardised ICER tables for smoking cessation studies endorsed by Stapleton & West to promote consistency and comparability between smoking cessation studies (72). Looking-up the CPIT trial incremental cost (£157) and incremental 6 month quit outcome (0.14) in their published tables (72),

predicts an approximate ICER value of £1390 per quitter (72), a close similarity to our ICER of £1127 per 34-38 week CO validated quitter.

Considering the wider evidence base for financial incentives supporting abstinence from a range of different abused drugs (16;43) and for healthy behaviours in general (47) the positive findings from the CPIT Trial (33) are unsurprising (48), and this paper adds additional evidence regarding the cost-effectiveness to support implementation in practice. . Following a NICE guidelines report (19) which recommended implementation of incentives for community substance abuse treatment centres in the UK; this paper further supports the cost-effective case for implementation. The basecase results for the economic analysis are highly encouraging; however, they are subject to uncertainty regarding post birth relapse, once the incentive has stopped. The uncertainty intervals around the mean cost and QALY outcomes in Table 4A, and Figure 2 demonstrate the extent of this uncertainty. . The trial did not incorporate follow-up beyond birth and only self-reported quit rates at 6 months postpartum were available. These relapse rates were encouraging:33% relapse for Incentives and 54% in the Control respectively(32), but without CO validation they are potentially biased, particularly for the Incentives arm where women may feel obliged to report a sustained quit post-trial. Therefore, literature on CO validated quits post-partum was consulted (20; 64) (56)(26), and a conservative approach adopted, assuming post-birth relapse rates which favoured the Control arm(60% relapse for Incentives, 30% relapse in the Control, as detailed in Table 3) (26)(64). Scenario 1 of the sensitivity analyses reports outcomes when we adopt the post-trial self-reported rates, giving an improved ICER of £164/QALY ($250/QALY) and a 99% probability that Incentives are the cost-effective option. In future trials, CO-validated evidence post-birth and post incentive would be beneficial and strengthen the evidence base. A future trial which measured longer-term relapse rates could also explore the cost-effectiveness of financial incentive for relapse prevention post birth, given the demonstrated success of financial incentives in the short term.

arms (34)(28)

A possible unintended consequence of financial incentives is the possibility of 'gaming'; whereby women could be untruthful about their smoking status, especially at the time of the primary outcome assessment where 50% of the incentive is offered. The CPIT and economic analysis tested for this type of 'gaming' (33) and found approximately 20% of women were untruthful about their smoking status, in both arms. This is higher than a recent single arm study on financial incentives in England, which found only 4% of participants gamed to gain cessation vouchers (26). Scenario 5 of our sensitivity analysis (Table 4B) adjusted for gaming (adjusting quit rates to exclude gamers, but keeping the costs incurred by them) and found incentives remained cost-effective, but with an increased ICER of £1443/QALY ($2198/QALY). This ICER remains well below the thresholds in high income countries (24;39;40), so even accounting for gaming, would be considered cost-effective.

Many high income countries offer a variety of specialist cessation interventions during pregnancy (1;2;6;49;50) yet in the UK only 25% of pregnant women make a quit attempt, and only 8% have been found to (via self-report) quit(58). The CPIT trial found a significant increase in quit when offered Incentives(22.5%) than Control (8.6%), a cessation improvement that is larger than that seen in most behavioural, (59) or pharmaceutical (60) pregnancy cessation trials. Previous systematic reviews of varied intervention strategies (59) highlight that current recommendations to help smokers quit during pregnancy (11) are not very effective. There is a growing evidence base showing financial incentives to have positive effects on health behaviours (11;13)(15-19), particularly in the smoking cessation arena (20,21). Likis et al. (61) recently reported that out of a range of interventions for smoking cessation during pregnancy, financial incentives demonstrated the strongest effect. Despite this evidence base, few studies have considered the cost-effectiveness of financial incentives, and none have assessed this for smoking cessation during pregnancy. If financial

incentives to aid smoking cessation are to be considered as an option in high income countries, then economic analyses are essential to policy-making considerations.

Policy Implications

Identifying pregnant women who smoke, engaging with them and supporting them to quit smoking during pregnancy is a key international tobacco policy priority (11;62) and this study provides evidence on the cost-effectiveness of financial incentives as a means to achieving cessation during pregnancy.

Godfrey et al. (3) found the cost of smoking during pregnancy is £8 - £64 million per annum ($367million (4) in the USA). They estimate that low cost cessation interventions (costing between £13 and £37 per pregnant smoker) could yield positive cost savings, but recommend further research on enhanced investment in smoking cessation interventions. Our sensitivity analysis (scenarios 7 & 8) show that enhanced incentives offering up to £800 and £1800 per quitter could potentially be cost-effective, while the base case analysis on the CPIT trial (33) provides evidence that financial incentives up to £400 in addition to routine care are a highly cost-effective way to encourage quit attempts and achieve cessation in pregnancy.

This research paper provides economic evidence based on a phase II RCT to support the use of financial incentives in addition to routine smoking cessation services for pregnant women. Our findings address the gap in cost-effectiveness evidence (10) (11), showing financial incentives are a potentially cost-effective way to help women who smoke to engage with cessation services, and quit when they are pregnant.

Strengths and weaknesses

The key strengths of this study are the RCT design and cost-effectiveness analysis. The resource use and outcome data was informed from an RCT, and to our knowledge this is the first cost-effectiveness analysis of financial incentives for pregnant smokers.

Key limitations are in the exploratory (phase II) nature of the trial, in that it was limited to one geographical location in Glasgow, Scotland. This sample is potentially representative of large city populations; however, routine cessation services for pregnant women vary throughout the UK.. Another limitation relates to the uncertainty of the data on relapse post birth (once financial incentives have stopped). The self-report postnatal data following the CPIT trial was encouraging, however, it could be subject to intervention group bias. If these findings remained the same in a cotinine validated follow-up, then the QALYs difference between the trial arms is likely to be real. However, given current uncertainty, the expected value of perfect information analysis showed that it is worthwhile to undertake further research.

This work strengthens the evidence base on potential cost-effectiveness of financial incentives and thus is extremely valuable for policy makers, both in the UK and in other high income countries in Europe and the USA.

CONCLUSION

Existing interventions for pregnant smokers are not highly effective; however, this study provides substantial evidence on the cost-effectiveness of a financial incentives intervention to add to existing cessation support. This study shows financial incentives to be highly cost-effective with an incremental cost-effectiveness ratio (ICER) of £482/QALY ($734/QALY) which is well below recommended thresholds.

WHAT THIS PAPER ADDS

- This is the first cost-effectiveness analysis of financial incentives for smoking cessation in pregnant women
- This study shows that financial incentives are highly likely to be cost-effective
- CO validated evidence regarding sustained quit once the incentive has ended and relapse post birth is needed to strengthen the evidence base.

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Tables & Figures

Table 1: Resource Use Information

Resource			Incentives	Control
Vouchers			Number*	Number*
Vouchers postage & packaging			504	NA
Additional vouchers re-posted			30	NA
1st Incentive: 1st face to face contact £50			248	NA
2nd incentive: 4 wks post quit £50			96	NA
3rd Incentive: 12 weeks post quit £100			79	NA
4th Incentive: 34-38 wks £200 CO validated			81	NA
Cessation Support	Duration	std error	Number*	Number*
1st phone contact (minutes)	10.00	5.10	210	225
1st face-face support (minutes)	50.00	15.31	248	236
1st post quit-date phone call only (minutes)	15.00	7.65	1	1
1st & 2nd post quit-date phone calls	15.00	7.65	3	7
1st, 2nd & 3rd post quit-date phone calls	15.00	7.65	9	26
1st, 2nd 3rd & 4th post quit-date phone calls	15.00	7.65	21	38
1st, 2nd, 3rd, 4th & 5th post quit-date calls	15.00	7.65	212	160
Unknown (assume mean 4.8 calls)†			5	6
Unknown (assume no calls)††			55	68
Nicotine Replacement Therapy			Number*	Number*
NRT 4 week prescription wk 1			158	155
NRT 4 week prescription wk 5			61	38
NRT 4 week prescription wk 10			32	15

*Number of participants in each arm of CPIT trial receiving which resources
†attended 1st face to face meeting – assume mean 4.8 calls
†† did not attend 1st face to face meeting – assume zero post quit date calls

Table 2: Unit Cost Information

Cost Area	Unit Costs	Source
Smokefree Pregnancy advisor (Band 5) cost per hour	£35.00	Curtis, L 2013
NRT: Nicorette 16hr patch (1st line) cost per week	£9.97	BNF 2013
Low Birth weight: Special Care Baby Unit cost per case	£8,602.00	ISD, 2012
Vouchers postage & packaging	£7.48	CPIT trial
Additional vouchers re-posted (postage only 2013)	£7.46	CPIT trial
1st Incentive: 1st face to face contact £50	£50.00	CPIT trial
2nd incentive: 4 wks post quit £50	£50.00	CPIT trial
3rd Incentive: 12 weeks post quit £100	£100.00	CPIT trial
4th Incentive: CO validated 34-38 wks £200	£200.00	CPIT trial

Table 3: Lifetime Model parameter inputs

Parameters	Value	std error	distribution	source
Trial Outcomes				
34-38week quit Incentive (cotinine validated)	0.225	0.0239	beta	(33)
34-38week quit Control (cotinine validated)	0.086	0.0161	beta	(33)
P very low & low birth weight - quitters	0.03	0.0180	beta	(33)
P very low & low birth weight - smokers	0.15	0.0156	beta	(33)
Cessation Support				
Duration 1st phone call (mins)	10.00	5.1020	gamma	(33)
Duration 1st face–to-face support (mins)	50.00	15.3061	gamma	(33)
Duration post quit date phone calls (mins)	15.00	7.6531	gamma	(33)
Relapse Rates				
P Relapse 3 months post birth Incentive	0.60	0.1800	beta	(20;26)
P Relapse 3 months post birth Control	0.30	0.0600	beta	(64),AA
Annual P Relapse yrs 1-5 post quit	0.05	NA	NA	(65)
Annual P Relapse yrs 6-8 post quit	0.03	NA	NA	(65)
Unit Costs				
NRT, 1st line (cost/week)	£9.97	NA	NA	(66)
Smokefree Pregnancy advisor (cost/hr)	£35.00	NA	NA	(39)
Incentive voucher postage & packaging	£7.48	NA	NA	(33)
Incentive voucher 1st & 2nd	£50.00	NA	NA	(33)
Incentive voucher 3rd	£100.00	NA	NA	(33)
Incentive voucher 4th	£200.00	NA	NA	(33)
NHS cost for low & very low birth weight†	£8,602	£1,720	gamma	(67)
Cost smoking related disease - basecase	£0	£0	NA	AA
Cost smoking related disease†† - scenario	£32,658	£6,532	gamma	(68)
Mortality rates				
Scottish female smoking related mortality**	mortality tables		NA	(69;70)
Scottish female mortality excluding smoking**	mortality tables		NA	(69;70)
Utilities				
female smoker age 25-34	0.92	0.0024	beta	(71)
female smoker age 35-44	0.89	0.0027	beta	(71)
female smoker age 45-54	0.78	0.0043	beta	(71)
female smoker age 55-64	0.69	0.0048	beta	(71)
female smoker age 65-74	0.75	0.0051	beta	(71)
female smoker age 75+	0.67	0.0051	beta	(71)
female non smoker age 25-34	0.93	0.0027	beta	(71)
female non smoker age 35-44	0.92	0.0024	beta	(71)
female non smoker age 45-54	0.87	0.0036	beta	(71)
female non smoker age 55-64	0.82	0.0041	beta	(71)
female non smoker age 65-74	0.78	0.0043	beta	(71)
female non smoker age 75+	0.72	0.0045	beta	(30;71)
Discount Rate				
outcomes & costs (beyond yr 1)	0.035	NA		(24)

P=probability, AA = Author assumption

*Scenario analysis 1 uses self-reported 3 month relapse rates; † Mean cost Special Care Baby Unit, inpatient cost per case

†† Scenario Analysis 3: mean cost £32,658 per smoking related death

**Lifetables for Scottish Females, age adjusted population death rates per 1000

Table 4: 4A - Basecase analysis results, 4B - Scenario analyses results

	Table 4A Economic Analysis	Arm	Mean Cost	Mean effect	Incremental Cost	Incremental effect	Incremental cost-effectiveness ratio (ICER)	
				quit		quit		
	Within trial	Control	£85	0.09	£157	0.14		
	(incremental cost per quitter)	Incentives	£243	0.23	*(£155, £162)*	*(0.08, 0.19)*	£1,127	per quitter
				QALY		QALY		
	Lifetime	Control	£1,265	19.101	17	0.036		
	(incremental cost per QALY)	Incentives	£1,282	19.137	*(-£93, £107)*	*(-0.058, 0.145)*	£482	per QALY
	Table 4B **Scenario Analyses**	**Arm**	**Mean Cost**	**Mean QALYs**	**Incremental Cost**	**Incremental QALYs**	**ICER**	**Prob CE £30K/Q***
	Base-case analysis	Control	£1,265	19.10				
		Incentives	£1,282	19.14	£17	0.036	**£482**	0.72
1	Self-reported postnatal relapse	Control	£1,245	19.08	£21	0.13	**£164**	0.99
	Incentives 33%, Control 54%	Incentives	£1,267	19.21	*(-£87, £101)*	*(0.018, 0.228)*		
2	Incentive arm higher Postnatal	Control	£1,257	19.10	£20	-0.017	**Usual Care**	0.30
	Risk Relapse (80%, se 0.18)	Incentives	£1,277	19.09	*(-£101, £99)*	*(-0.092, 0.15)*	**Dominates**	
3	Include cost for	Control	£25,397	19.10				
	smoking related disease	Incentives	£24,820	19.14	-£577	0.039	**Incentives**	0.73
	(£32,658, se £6532)				*(-£2382, £821)*	*(-0.05, 0.15)*	**Dominates**	
4	Discount rate 0%	Control	£1,254	40.02	£20	0.117	**£167**	0.75
		Incentives	£1,274	40.14	*(-£90, £100)*	*(-0.187, 0.459)*		
5	Gaming: exclude 20% quitters	Control	£1,273	19.09				
	Probability 34-38 week quit:	Incentives	£1,320	19.12	£47	0.033	**£1,443**	0.74
	Incentives 18%, Control 7%				*(-£47, £111)*	*(-0.036, 0.121)*		
6	Use self reported quit rates	Control	£1,137	19.21			**Incentives**	
	Probability quit 34-38 weeks:	Incentives	£1,121	19.21	-£16	0.003	**Dominates**	0.49
	Incentives 39%, Control 21%				*(-£153, £86)*	*(-0.14, 0.196)*		
7	Increase incentive max £800	Control	£1,256	19.10	£152	0.062	**£2461**	0.64

	Prob quit 34-38 week: 0.28:	Incentives	£1,408	19.16	*(£81, £538)*	*(-0.03, 0.184)*		
8	Increase incentive max £1800	Control	£1,256	19.10	£579	0.133	**£4360**	0.59
	Prob quit 34-38 week: 0.43:	Incentives	£1,835	19.23	*(£236, £982)*	*(-0.04, 0.362)*		

* probability that Incentives Arm is cost-effective at a threshold of £30,000/QALY

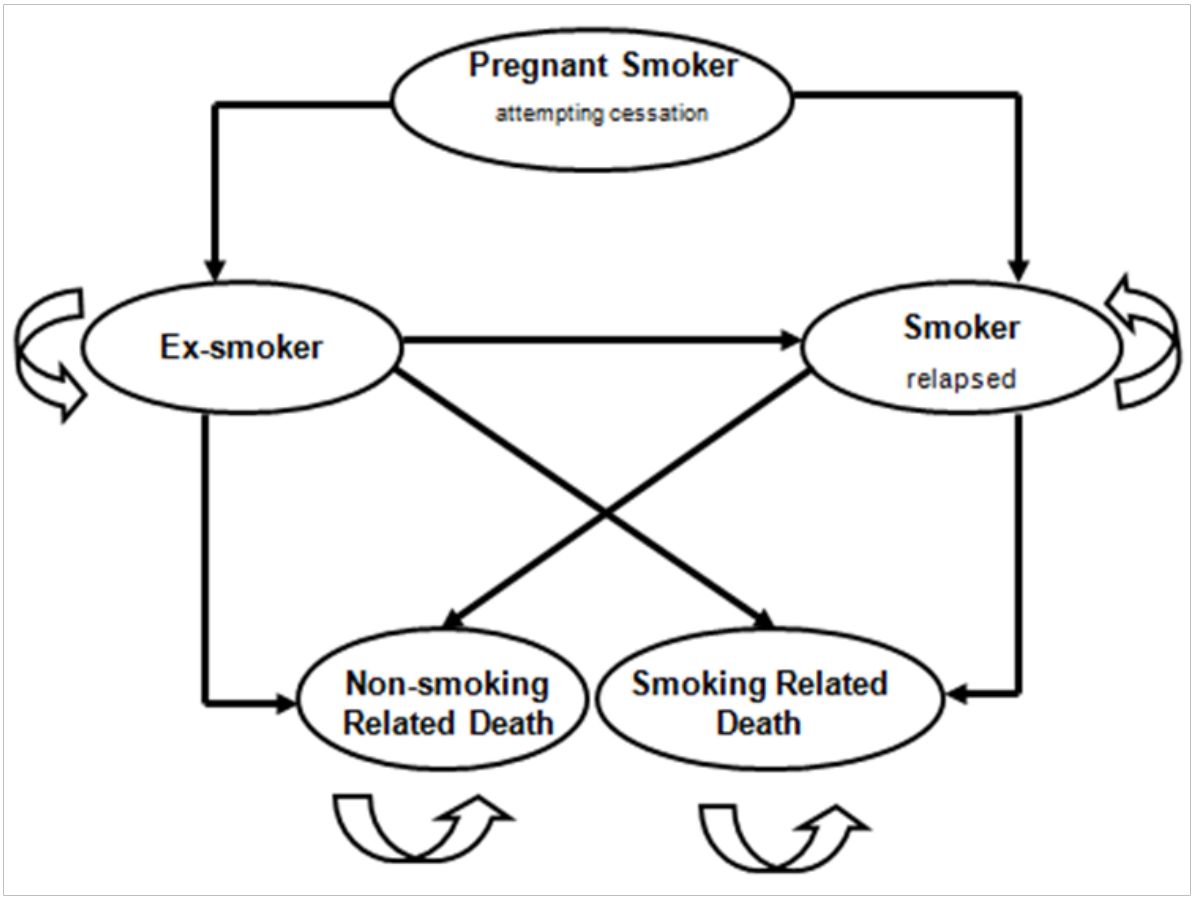

Figure 1: Markov Model

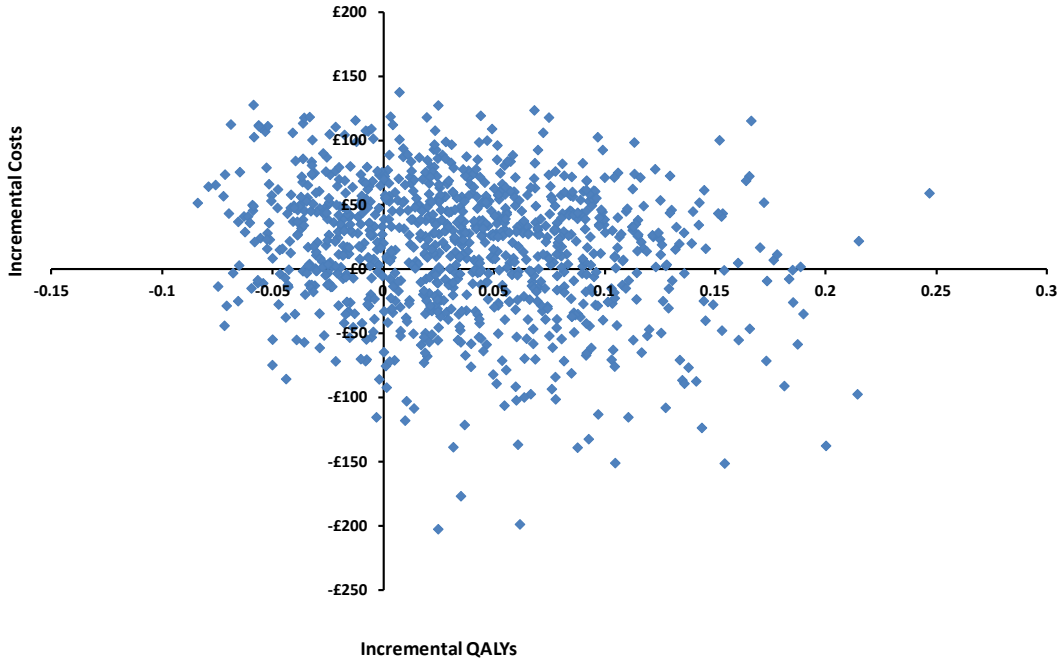

Figure 2: Cost-effectiveness plane – Financial Incentives versus Control

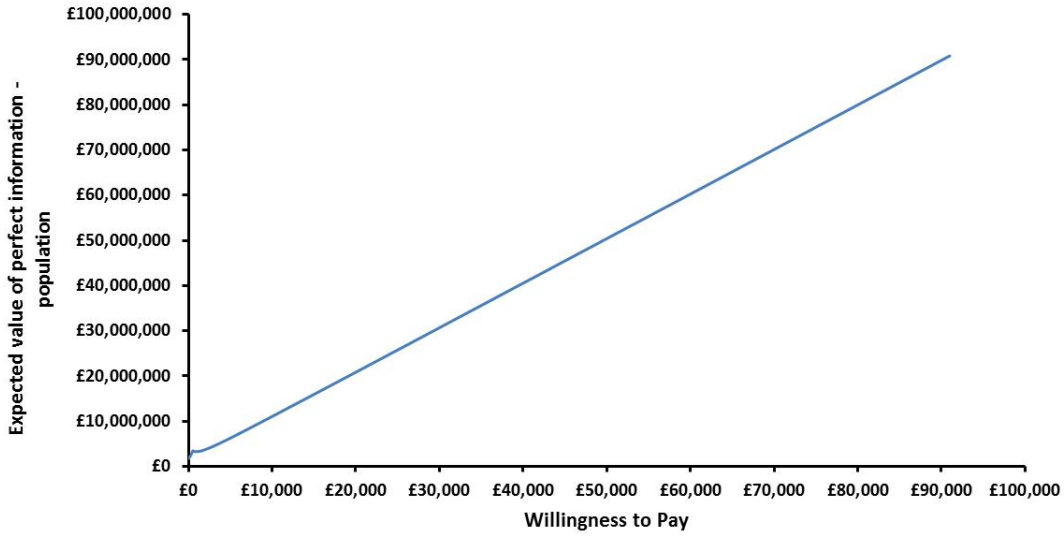

Figure 3: Expected Value of Perfect Information – population level