National Institute for Health and Care Excellence

Final

Tobacco: preventing uptake, promoting quitting and treating dependence: update

[H] Evidence reviews for opt-out stop smoking support

NICE guideline NG209

Evidence reviews underpinning recommendations 1.18.1 to 1.18.3 in the NICE guideline

November 2021

Final

These evidence reviews were developed by PH-IGD

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Contents

Opt-out stop smoking support

Review questions

Is opt-out provision of stop smoking support for pregnant women who smoke[a] effective and cost effective in increasing uptake of the support and increasing smoking cessation?

Is opt-out provision of stop smoking support acceptable to women who are pregnant? What are the barriers and facilitators to taking up the support?

Introduction

Smoking during pregnancy is associated with a variety of health risks for mother and baby, and is one of the focuses of the new Saving Babies Lives Care Bundle. Whilst NICE guideline PH26 (Smoking: stopping in pregnancy and after childbirth) recommended pregnant women who smoke or have quit within the last two weeks are referred via an opt-out system for specialist stop smoking support, this is not universally implemented[b]. This review aims to ascertain whether providing support on an opt-out basis can increase uptake of stop smoking support or increase smoking cessation among pregnant women. In addition, this review aims to explore the barriers and facilitators to taking up opt-out stop smoking support.

PICO table

The following table summarises the protocol for this review.

Table 1: PICO inclusion criteria

Population	Women who are pregnant and who smoke or have quit within the last two weeks. Women who have recently quit are also likely to be eligible for opt out provision under current practice.
Interventions	Opt-out provision of stop smoking support at any point during pregnancy. Stop smoking support is defined as: • Pharmacological support only • Behavioural support only • Pharmacological and behavioural support • E-cigarettes (alone or in combination with pharmacological and/or behavioural support)
Comparator	- No intervention - Usual practice - Opt-in referral systems - Other appropriate comparators, including active interventions.
Outcomes	**Quantitative outcomes (H.i.)** Critical outcomes

[a] Throughout, smoking refers to the use of all smoked tobacco products.
[b] Smoking in Pregnancy Challenge Group (2018) Review of the challenge

Smoking status at longest available follow-up prior to birth, and longest total follow-up. Measured as:

- Abstinence from smoking (relative risk)

Where continued abstinence is presented, this is preferred over point-prevalence abstinence. Point prevalence measures will only be used where no continuous measure is reported.

Where biochemically validated measures are available (i.e. saliva cotinine / carbon monoxide validation), these will be preferred to self-reported measures. Self-reported measures will only be used where no validated measure is reported.

- Take up of provision following opt-out (relative risk)

Important outcomes

- Adverse or unintended (positive or negative) effects.
- Health-related quality of life (using validated patient-report measures, for example EQ-5D).

Qualitative outcomes (H.ii.)

Qualitative evidence on opt-out referral systems for pregnant women who smoke will be examined where available. Evidence should relate to views of pregnant women who smoke or who used to smoke on:

- The acceptability of opt-out referral systems.

Cost/resource use associated with the intervention

The following outcomes will be extracted in reviews of the health economic evidence, where available:

- cost per quality-adjusted life year
- cost per unit of effect
- net benefit
- net present value
- cost/resource impact or use associated with the intervention or its components

Methods and process

This evidence review was developed using the methods and process described in Developing NICE guidelines: the manual (2018). Methods specific to this review question are described in the review protocol in Appendix C.

Declarations of interest were recorded according to NICE's 2018 conflicts of interest policy.

See the methods chapter for additional information on methods for the Tobacco guideline.

Identification of public health evidence

Included studies

NICE guideline PH26 previously considered some evidence (2 observational studies) on opt-out provision of stop smoking support among pregnant women, this was not evaluated as part of a complete formal evidence review. As such, the review presented here is a new review for this guideline. Both studies identified in NICE guideline PH26 were reassessed in relation to this review question and were subsequently excluded based on their study design (see Appendix J).

A systematic search was undertaken in April 2019 for relevant studies published since 1998 and in the English language. It was decided to search for studies in the past 20 years (from when protocols were written). This limit is applied because before this point it is likely that the context of stop smoking support would be too different to be relevant and applicable to the guideline. Website searches were conducted in line with the protocol. Further details on the search strategy are available in Appendix D.

After removal of duplicates 1,096 unique database results were identified. 14 papers from this search and one paper identified from PH26 with potential to answer the review questions were ordered for full-text review. Of these, 5 papers (5 studies) met the inclusion criteria for this review. 2 studies have an uncontrolled before and after design, 1 study is an interrupted time series analysis, 1 study is qualitative and 1 includes a mixed methods approach (qualitative component of relevance to this review question).

A joint website search was completed for review questions on opt-out stop smoking support and incentives during pregnancy. Website searches identified a further 7 results that were screened separately. No includes from website searches were identified.

Excluded studies

Of the 15 papers retrieved at full-text review, 10 were excluded. See Appendix J for a full list of excluded studies and the reasons for exclusion.

Table 2: Summary of quantitative public health studies included in the evidence review

Study	Setting	Population	Intervention	Comparator	Outcome(s)
Bauld 2012 Uncontrolled before and after study	West Midlands, UK 2 NHS areas: 1 hospital based, 1 community based	Pregnant women who smoke 780 participants	Opt-out provision of stop-smoking support, including carbon monoxide (CO) testing.	Time comparison (before intervention implementation: opt-out provision)	• Abstinence from smoking during pregnancy
Bell 2018 Interrupted time series analysis	North East England, UK 8 NHS trusts and 12 local authority areas	Pregnant women who smoke 10,594 participants	BabyClear complex intervention Intervention included skills training for staff, carbon monoxide monitoring with routine	Time comparison (before intervention implementation: opt-out provision)	• Abstinence from smoking during pregnancy

Study	Setting	Population	Intervention	Comparator	Outcome(s)
			opt-out referral for smoking cessation support, an explicit referral pathway and follow up protocol.		
Campbell 2017 Uncontrolled before and after study	Nottinghamshire, UK 2 antenatal clinics in NHS trust	Pregnant women who smoke 1,060 maternal smokers	Opt-out provision of stop-smoking support, including CO testing.	Time comparison (before intervention implementation: opt-out provision)	- Abstinence from smoking during pregnancy - Take up of provision following opt-out

Table 3: Summary of qualitative public health studies included in the evidence review

Study	Setting	Population	Intervention	Outcome(s)
Bauld 2017 Mixed methods study (qualitative element of relevance to this review question)	Scotland, UK NHS site	Pregnant women who smoke(d) 21 participants	Opt-out provision of stop-smoking support, including CO monitoring.	Themes around acceptability of automatic referral and CO monitoring.
Sloan 2016 Qualitative study	UK Hospital trust	Pregnant or post-partum women who smoke(d) 18 participants	Opt-out provision of stop-smoking support, including CO testing.	Themes around expectations, acceptability and impact of opt-out referral pathway.

See Appendix B for full evidence tables.

Synthesis and appraisal of public health studies included in the evidence review

Evidence appraisal

- This review addresses an intervention question. Non-randomised evidence using before and after studies was therefore assessed using the Effective Practice and Organisation of Care (EPOC) RoB tool, according to the NICE Manual.
- All GRADE ratings start at 'high' and are downgraded as appropriate.
- All qualitative studies were assessed using the CASP checklist and confidence was assessed using GRADE CERQual.

See Appendix A for full GRADE and GRADE CERQual tables.

See Methods document for details of rationale for GRADE judgements.

Table 4: Minimal important differences (MIDs) agreed

Outcome	Importance	MID
Abstinence from smoking during pregnancy	Critical	Statistical significance
Take up of provision following opt-out	Critical	10% increase or decrease (RR 0.91, 1.10)

Data synthesis

3 quantitative studies were identified for inclusion in this review.

All 3 studies measured change in abstinence from smoking after versus before implementation of opt out provision of stop smoking support. Two studies measured abstinence as self-reported 4-week quit rates and 1 study defined abstinence as quitting by delivery (see GRADE profile 1). One study also measured change in abstinence from smoking by maternal age and socioeconomic position (See GRADE profiles 2 and 3).

One study reported on the outcome take up of provision following opt-out, defined as setting a quit date with stop smoking service support (see GRADE profile 4).

Economic evidence

Included studies

A joint search was used to identify evidence for the cost effectiveness elements of review questions H, I and J. This search incorporated elements from the original effectiveness searches and an agreed cost effectiveness filter. The joint systematic search was undertaken in July 2019 for studies published in the English language. No date limits were applied. Website searches were conducted in line with the protocol. The evidence reviews for PH26 were rechecked for cost effectiveness studies. 3368 results were downloaded and after removing 837 duplicates there were 2531 unique results for screening. A further 2 records were identified by the York Health Economics Consortium. Full details of all the search strategies are available in a separate document from the NICE Information Services team

2,533 records were assessed against the eligibility criteria for RQs H, I and J.

2,473 records were excluded based on information in the title and abstract for RQs H, I and J One reviewer assessed all of the records and a second reviewer blind-screened 10% of the records. The level of agreement between the two reviewers was 100%.

The full-text papers of 60 documents were retrieved and assessed and 1 study was assessed as meeting the eligibility criteria for RQ H.i. One reviewer assessed all of the full texts and a second reviewer blind-screened 10% of the records. The level of agreement between the two reviewers was 100%. For RQ H.i., 1 study was included.

Excluded studies

59 full text documents were excluded for this question. The documents and the reasons for their exclusion are listed in Appendix J– Excluded studies. Documents were excluded for the following reasons: ineligible study design (n=27), ineligible intervention (n=22), ineligible

patient population (n=6) and ineligible outcomes (n=4). The selection process is shown in Appendix F.

Summary of studies included in the economic evidence review

Table 5: Summary of the study included in the economic evidence review for opt-out smoking support

Study	Limitations	Applicability	Other comments	Costs	Effects	Incremental cost	Incremental effects	Economic analyses outcomes	Uncertainty
Bell 2018 (UK) Population: Pregnant smokers with single babies in North-East England Sample size: 10,594 smokers [a] Study aim: to evaluate the effectiveness of a complex intervention (BabyClear) to improve existing provision. BabyClear included referral and treatment of pregnant smokers in routine	Major limitations [d]	Partially applicable [e]	A before and after study design	Total costs of BabyClear 5 years: £572,009 Per baby delivered: £30.69	Quit rate during pregnancy, per delivery (smokers and non-smokers) Before BabyClear: 0.0398 After BabyClear: 0.072	BabyClear vs comparator : £30.69 per delivery	BabyClear vs comparator: 0.032 additional quitters per delivery The number needed to treat for each additional quitter was 31 pregnant women (smokers and non-smokers)	BabyClear vs comparator, cost per additional quitter: £952	No analysis of uncertainty was undertaken

Study	Limitations	Applicability	Other comments	Costs	Effects	Incremental cost	Incremental effects	Economic analyses outcomes	Uncertainty
practice. The study also aimed to assess the incremental costs to the NHS per additional woman quitting smoking. Intervention: The study was a before and after design, anchored at the introduction of BabyClear. Prior to the introduction of BabyClear,, universal carbon monoxide (CO) monitoring and opt-out referral had not been implemented . [b] BabyClear [c] was a system-wide package of measures to									

Study	Limitations	Applicability	Other comments	Costs	Effects	Incremental cost	Incremental effects	Economic analyses outcomes	Uncertainty
achieve better uptake of available smoking cessation services: • CO monitors and support materials to midwives who monitored CO at first antenatal appointment with routine-opt-out referral to smoking cessation advice where CO was above four parts per million • Skills training for maternity staff, smoking cessation advisors and administrators within smoking									

Study	Limitations	Applicability	Other comments	Costs	Effects	Incremental cost	Incremental effects	Economic analyses outcomes	Uncertainty
cessation services • An explicit referral pathway to cessation support was developed									

CO: carbon monoxide; NHS: National Health Service; UK: United Kingdom

(a) 27,050 non-smokers were also involved

(b) In its description of the intervention, the study implies what the 'prior' smoking cessation services were likely to have been. It describes how in England, the responsibility for commissioning smoking cessation services lies with local authorities, while responsibility for commissioning maternity services lies with NHS England and that antenatal care is delivered by NHS trusts but smoking cessation services may be delivered by a range of community-based providers. It then describes how the intervention was designed to strengthen links between these two services.

(c) Developed by the Tobacco Control Collaborating Centre

(d) The study was a before and after study with no consideration of long-terms costs and no analysis of uncertainty

(e) Costs were reported over five years but not discounted

Economic model

The evidence review identified one UK based cost-effectiveness study for opt out provision of stop smoking support. The committee noted the study had major limitations. In addition they could not be confident the results were attributable to opt-out referral given the multi-component nature of the intervention. To address their concerns economic modelling was considered to be informative for this research question.

The effectiveness of CO monitoring + opt-out provision was calculated using results from Campbell et al. (2017) identified in the current review (Evidence Review H). This study was selected because it was considered the most relevant and least subject to uncertainty.

The opt-out provision intervention in Campbell et al. (2017) (18) included (i) self-reported smoking status at the first antenatal "booking" appointment, and (ii) carbon monoxide (CO) monitoring to establish maternal smoking status at the "dating appointment", where expectant mothers receive their first ultrasound scan. CO monitoring was delivered to mothers at the dating appointment. Mothers who were identified as smokers (either through self-report or through CO testing) were referred to LSSS via a digital opt-out referral pathway. The only reason not to implement the opt-out referral was if the identified mother spontaneously refused the referral.

The intervention was compared to usual care before implementation. The comparator did not include CO monitoring. Instead, women confirmed their smoking status via self-report and were then referred to LSSS via digital opt-in pathways (18). In contrast to the opt-out referral, mothers who were identified as smokers were directly asked whether they wanted to be referred to LSSS or not. Consequently, the intervention and comparator under investigation in the primary economic modelling analysis was CO monitoring + opt-out referral versus no CO monitoring + opt-in referral.

Campbell et al. reported 93 of 2293 women (4.06%) in the CO monitoring + opt-out provision pathway reported smoking abstinence 4-weeks after setting a quit date, whilst 46 of the 2287 (2.01%) participants in the no CO monitoring + opt-in provision pathway achieved smoking abstinence 4-weeks after setting a quit date.

The base case analysis for CO monitoring + opt-out provision applied a 0% relapse rate between abstinence at 20-weeks and delivery at 40-weeks. In addition, a scenario analysis was conducted applying a 20% relapse rate in line with general population estimates reported by Coleman et al. (2010).

A "scenario" analysis was also undertaken which used the relative risk of cessation reported in the effectiveness review. The denominator for that analysis uses the number of referrals received by the stop smoking services. As a large proportion of the population in the opt-out referral pathway were identified as smokers via CO monitoring, whereas all of the population on the opt-in referral pathway were identified via self-report, the base for calculating the RR captures part of the impact of the intervention – specifically CO monitoring.

The analyses used a published economic model called the "economics of smoking in pregnancy" or ESIP model developed by the Division of Primary Care at the University of Nottingham (ref). The ESIP model estimates the lifetime costs and benefits of maternal smoking cessation during pregnancy for both mother and child. Parameter values, including unit costs and effectiveness rates were updated for each intervention and comparator.

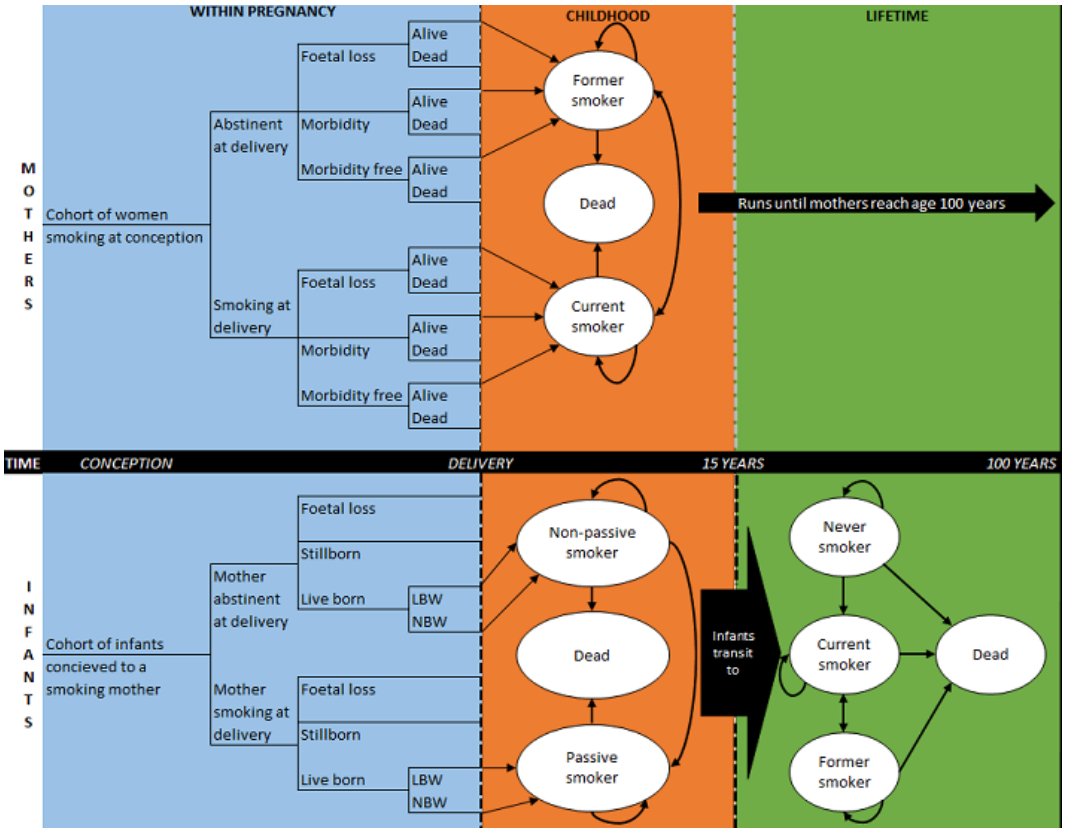
The model adopts an NHS and personal social services (PSS) perspective for costs and incorporates health outcomes as QALYs. It calculates the cost-effectiveness of smoking cessation interventions separately for maternal outcomes only, infant outcomes only, and maternal & infant outcomes combined, each over several time horizons including pregnancy, childhood (<15 years), and lifetime (<100 years). Discount rates of 3.5% for both costs and

benefits are applied (Developing NICE guidelines: The manual, 2018). A full description of the ESIP model, including model structure, input parameters, and methods to apply user defined inputs is provided in Jones et al. (2019).

A summary of the model structure and key results is provided below. A detailed report with full results and sensitivity analyses is provided in a separate economic modelling report (evidence review P)

In brief, the ESIP model progresses a cohort of 1000 pregnant women who smoke through an initial decision tree which maps maternal pregnancy outcomes. The cohort then enters a Markov model for the remaining time horizon. For mothers, the Markov component of the ESIP model contains health states related to smoking status, these being "current smoker", "former smoker", "dead". Between birth and 15 years infants enter an initial 'childhood' Markov model which estimates their burden of asthma, factoring in the impact of second-hand exposure to maternal smoking, according to their mothers smoking status. At age 16 years children transition to an 'adulthood' Markov model which estimates their life-time burden of smoking related morbidities and mortality. Different transition probabilities are applied according to the effectiveness of each intervention.

Figure X ESIP model structure



Model results

The CO monitoring + opt-out provision intervention was cost-effective for both the maternal only, and the maternal and child analyses. For both analyses the intervention was dominant, being cost saving and resulting in additional QALYs versus no CO monitoring + opt in provision (Table 6).

Table 6: Incremental cost-effectiveness results opt-out vs. opt-in provision

	Incremental population outcomes (n=1,000)				Incremental cost-effectiveness results (per person)		
	Intervention Costs	No. of quitters	Costs all quitters	QALYs all quitters	Total Costs	Total QALYs	ICER
Base case: 0% relapse							
Mother + child	£8,280.00	20.5	-£27,034	23.842	-£18.75	0.0238	Dominant
Mother	£8,280.00	20.5	-£10,101	4.756	-£1.82	0.0048	Dominant
Scenario: 20% relapse between weeks 20 and 40 of pregnancy							
Mother + child	£8,280.00	16.4	-£21,627	19.073	-£13.34	0.0191	Dominant
Mother	£8,280.00	16.4	-£8,080	3.805	£0.20	0.0038	£52.45

Cost-effectiveness results obtained for opt-out vs. opt-in provision of stop smoking support in a hypothetical population of 1,000 pregnant women, including smokers and non-smokers.

The inclusion of a 20% relapse rate between weeks 20 and 40 of pregnancy decreased the number of additional quitters attributable to CO monitoring+ opt-out provision from 20.5 to 16.4 per 1,000. The ICER for CO monitoring + opt-out provision remained dominant when including maternal and child outcomes. For the mother only analysis intervention costs exceeded cost savings per quitter with the result that the ICER was not dominant but remained cost-effective, being equal to £52.45, substantially less than the £20,000 threshold.

The cost-effectiveness results for the CO monitoring + opt-out provision analysis were robust in all deterministic scenario analyses which included changing the input values for the following parameters: RR of smoking cessation, intervention costs, time horizon, age of cohort, healthcare costs and QALYs.

Summary of the evidence

Table 7: Evidence summary

Outcome	Summary	Confidence	GRADE profile
Abstinence from smoking	Opt-out provision was significantly associated with a reduction in abstinence from smoking (Bauld, 2012) RR 0.73 (0.56 to 0.96) Opt-out provision was significantly associated with an increase in abstinence from smoking in two studies, - RR 1.75 (1.52 to 2.03), Bell 2018 - RR 1.39 (1.01 to 1.92), Campbell 2017	Low Low	1
Abstinence from smoking (grouped by maternal age category)	In one study (Bell 2018), - Opt-out provision was significantly associated with a reduction in abstinence from smoking in 15-20 year olds compared with 21-30 year olds, RR 0.76 (0.67 to 0.87) - Opt-out provision was significantly associated with an increase in abstinence from smoking in 31-40 year olds compared with 21-30 years RR 1.41 (1.28 to 1.56)	Low Low	2

Outcome	Summary	Confidence	GRADE profile
	- The intervention could not differentiate in abstinence from smoking between those who were 41-55 years compared with 21-30 years, RR 1.13 (0.77 to 1.66)	Very low	
Abstinence from smoking (grouped by maternal socioeconomic position)	In one study (Bell 2018), - Opt-out provision was significantly associated with an increase in abstinence from smoking in those in the least deprived fifth compared with middle three-fifths of distribution, RR 2.57 (2.26 to 2.93) - Opt-out provision was significantly associated with a reduction in abstinence from smoking in those in the most deprived fifth compared with middle three-fifths of distribution, RR 0.53 (0.43 to 0.66)	Low Low	3
Take up of provision following opt-out	Opt-out provision was significantly associated with an increase in the take up of provision following the opt-out referral (Campbell 2017) RR 1.46 (1.11 to 1.93)	Low	4
Acceptability of carbon monoxide (CO) testing	Two studies (Bauld 2017, Sloan 2016) Mixed feelings towards the use of CO testing	Moderate	GRADE CERQual table
Acceptability of automatic opt-out referral	Two studies (Bauld 2017, Sloan 2016) Divided opinion on positive or negative impacts	Moderate	GRADE CERQual table
Provision of information	One study (Sloan 2016) Explanation of referral pathway important	Low	GRADE CERQual table
Contact by stop smoking service	Two studies (Bauld 2017, Sloan 2016) Mixed descriptions on the level of contact provided and the impact	Low	GRADE CERQual table
Impact of CO screening on family/peer smoking behaviour	One study (Bauld 2017) Encouraged some women to consider the possible impact of peer/family smoking on their baby	Very low	GRADE CERQual table

Cost-effectiveness evidence statements

One cost-effectiveness analysis (Bell, 2018) found that the introduction of a complex intervention, which included routine opt-out referral for smoking cessation support following carbon monoxide monitoring, across the North-East of England increased smoking quit rates during pregnancy. The economic evaluation suggested that the introduction of the BabyClear intervention, which also included midwife and counsellor training, carbon monoxide monitors and support material, cost an additional £30.69 per baby delivered compared to smoking cessation services before the intervention. The cost per additional quitter was £952. The lifetime impact of smoking cessation was not considered and no analysis of uncertainty was performed. The evidence was drawn from a before and after study rather than a randomised trial. The analysis was assessed as partly applicable to the review question, with major limitations.

One directly applicable cost-utility analysis with minor limitations found that CO monitoring + opt-out provision was cost-effective for both the maternal only, and the maternal and child analyses. For both analyses the intervention was dominant, being cost saving and resulting in additional QALYs versus no CO monitoring + opt in provision. The cost effectiveness results were robust across the wide range of parameter values used in the deterministic scenario analyses.

The committee's discussion of the evidence

Interpreting the evidence

The outcomes that matter most

The committee discussed whether a greater emphasis should be placed on the intermediate outcome take up of provision following opt-out referral rather than the outcome abstinence from smoking. They noted that the intervention may seem less effective if the increased take up of support resulting from the intervention did not necessarily translate to increased abstinence amongst pregnant women. The committee agreed that abstinence from smoking was a key health outcome and that it was important to consider any resource implications of increased take up of support via an opt-out pathway. Based on this, the committee agreed that both outcomes should be considered of equal importance for decision-making in this review.

Confidence in the evidence

The committee acknowledged the limited evidence base identified in this review. There were 2 uncontrolled before and after studies, 1 interrupted time series analysis and 2 qualitative studies.

Quantitative evidence

Abstinence from smoking:

The committee noted that the included studies used routinely collected data rather than data collected specifically for the purposes of research.

Abstinence outcomes were reported in various ways: 4-weekly quit rate (Bauld 2012), quitting during pregnancy (Bell 2018) and stopping smoking 4-weeks after setting a quit date (Campbell 2017). It was assumed where not clearly stated in studies that outcomes were self-reported. The committee discussed the appropriateness of self-reported abstinence in relation to the level of truthful reporting. They concluded that whilst this may be a slight concern, it was a reasonable measure as any bias arising from this would likely be evenly distributed before and after implementation of the intervention. The committee agreed that the confidence in this outcome was moderate.

The committee discussed the uncertainty and the significant statistical heterogeneity among the results combined in a meta-analysis. They discussed possible sources of the heterogeneity. The committee considered the impact on a meta-analysis of the Bauld (2012) study, which showed that an opt-out intervention reduced abstinence from smoking in pregnant women. They noted that it was unclear in the paper if there had been any errors in

data collection and whether CO testing and the method of referring pregnant women had been implemented consistently. They discussed that the two other larger studies (Bell 2018, Campbell 2017) were published several years later and may have been able to implement referrals more comprehensively, possibly leading to increased abstinence. Based on these uncertainties, the committee had greater confidence in the two studies (Bell 2018, Campbell 2017) which showed effectiveness of the opt-out intervention in increasing abstinence. The committee did recognise that one study (Bell 2018) was a complex intervention and that the results of this study could not be clearly considered to be due to the opt-out part of the complex intervention.

They agreed that it would not be appropriate to combine the study results in a meta-analysis, but to present study results separately.

Take up of provision following opt-out:

Evidence showed an increased effect of the intervention on the take up of stop smoking support following opt-out referral (Campbell 2017). Take up of provision was defined as setting a quit date with stop smoking service support and the committee agreed that this was a good measure.

Qualitative evidence

The committee agreed that the evidence was informative, generally well conducted and had no particular concerns about risk of bias. The committee noted that the evidence demonstrated the variable delivery of the opt-out intervention, particularly levels of information provision and contact by the stop smoking service, and suggested that this may potentially explain the heterogeneity observed in the quantitative studies. The committee discussed the evidence showing that inadequate information provision across various stages of the opt-out pathway was a barrier for some women in taking up support. They discussed whether there was a need for a specific recommendation aimed at maternity care staff to provide adequate information, since all clinical treatment pathways should ensure that individuals are fully informed at each stage of the pathway. They agreed that, as opt-out is not a frequent method of providing treatment, a recommendation around information provision would enable women to actively participate in their care and self-management.

Benefits and harms

The committee agreed that the harms from implementing the opt-out pathway would be minimal. They pointed out that opt-out provision of stop smoking support is being implemented widely across NHS trusts and the intervention has been recommended in previous NICE guidance. The committee discussed the social value judgement in the removal of individual choice via the automatic opt-out referral. They considered the findings from the qualitative evidence that indicated that some participants in the studies found the automatic opt-out referral without consultation difficult, and reported feeling pushed into quitting.

The committee considered that there are clear benefits to stopping smoking in pregnancy, these benefits are substantial and therefore outweigh the possible concerns about using an opt out system.

Cost effectiveness and resource use

The committee discussed evidence from 1 published within-study economic evaluation based on an interrupted time series analysis of routine data before and after introducing an intervention aimed at improving referral and treatment of pregnant smokers in routine practice (Bell et al, 2018). The intervention comprised a package of measures including opt-out referral and CO testing. The study reported an increase in referrals and probability of quitting after introduction of the intervention. The additional cost per delivery was £31 and the incremental cost per additional quit was £952.The committee noted the study had major limitations. In addition, they were not confident the results were attributable to opt-out referral given the multi-component nature of the intervention.

Prior to conducting the economic analysis, the committee agreed that the primary analysis should be those that report the costs and outcomes for both mother and child combined. Whilst analyses focusing on the mother only were of interest, the committee did not consider them sufficient to capture “all” important consequences of the intervention. The finding that both sets of analyses showed opt-out referral with CO monitoring was dominant – that is less costly and more effective than opt-in provision – added to the committee’s confidence in considering the intervention highly cost-effective. The committee also noted the results were robust across all deterministic sensitivity analyses which varied estimates of effectiveness, intervention costs, time horizon, mother’s age, utility, disease costs and disease disutility.

The committee recognised the challenge in interpreting the evidence specifically regarding the benefits of opt-out referral pathways given that the intervention in the source studies combined CO monitoring and opt-out referral. However, they were satisfied the costs of the different elements had been appropriately captured in the analyses and that the findings are consistent with the evidence supporting a previous recommendation for CO monitoring plus opt-out referral.

Taken together with the findings from the effectiveness evidence, the cost per quitter falling within the range of values shown to be cost effective for other smoking cessation interventions and based on committee experience the committee considered opt-out referrals in routine practice can be cost effective.

The committee did not expect that the new recommendations would incur significant additional resource given that the intervention reflects current practice and carbon monoxide testing is used at various stages in pregnancy. The committee considered it unlikely that there would be a significant cost difference in setting up an opt-out referral pathway compared with other existing systems. They also noted that previous NICE guidance recommended opt-out referral pathways combined with CO monitoring which provides further assurance that new recommendations should not have significant additional resource.

Other factors the committee took into account

One study (Bell 2018) reported on change in abstinence following implementation of the opt-out intervention by maternal age categories (15-21 years, 31-40 years and 41-55 years, compared with 21-30 years) and socioeconomic position (least deprived fifth and most deprived fifth, compared with middle three-fifths of distribution). The committee had low confidence in these outcomes, given that the effectiveness of the intervention in these groups was only relative to that in the comparison groups used. They noted that abstinence figures were most likely to be irrespective of the intervention as they patterned current

knowledge about social inequalities in quitting smoking. They noted that these outcomes were not particularly useful in terms of decision-making and were difficult to interpret given that the study did not report absolute numbers.

The committee also considered what an appropriate carbon monoxide (CO) reading should be to initiate an automatic referral for stop smoking support. The committee discussed the CO levels used within the identified studies to initiate an opt-out referral, as being 4 parts per million (ppm) or above. Based on this and their expertise, the committee agreed that a lower value than previously recommended should be used at 4ppm to avoid missing someone who may need help to quit.

Recommendations supported by this evidence review

This evidence review supports recommendations 1.81.1 to 1.81.3.

References to included studies

Public health studies

1. Bauld Linda, Hackshaw Lucy, Ferguson Janet, Coleman Tim, Taylor Gordon, and Salway Ruth (2012) Implementation of routine biochemical validation and an 'opt out' referral pathway for smoking cessation in pregnancy. Addiction (Abingdon, and England) 107 Suppl 2, 53-60

2. Bauld Linda, Graham Hilary, Sinclair Lesley, Flemming Kate, Naughton Felix, Ford Allison, McKell Jennifer, McCaughan Dorothy, Hopewell Sarah, Angus Kathryn, Eadie Douglas, and Tappin David (2017) Barriers to and facilitators of smoking cessation in pregnancy and following childbirth: literature review and qualitative study. Health technology assessment (Winchester, and England) 21(36), 1-158

3. Bell Ruth, Glinianaia Svetlana V, Waal Zelda van der, Close Andrew, Moloney Eoin, Jones Susan, Araujo-Soares Vera, Hamilton Sharon, Milne Eugene Mg, Shucksmith Janet, Vale Luke, Willmore Martyn, White Martin, and Rushton Steven (2018) Evaluation of a complex healthcare intervention to increase smoking cessation in pregnant women: interrupted time series analysis with economic evaluation. Tobacco control 27(1), 90-98

4. Campbell Katarzyna A, Cooper Sue, Fahy Samantha J, Bowker Katharine, Leonardi-Bee Jo, McEwen Andy, Whitemore Rachel, and Coleman Tim (2017) 'Opt-out' referrals after identifying pregnant smokers using exhaled air carbon monoxide: impact on engagement with smoking cessation support. Tobacco control 26(3), 300-306

5. Sloan Melanie, Campbell Katarzyna A, Bowker Katharine, Coleman Tim, Cooper Sue, Brafman-Price Barbara, and Naughton Felix (2016) Pregnant Women's Experiences and Views on an "Opt-Out" Referral Pathway to Specialist Smoking Cessation Support: A Qualitative Evaluation. Nicotine & tobacco research : official journal of the Society for Research on Nicotine and Tobacco 18(5), 900

Economic studies

1. Bell Ruth, Glinianaia Svetlana V, Waal Zelda van der, Close Andrew, Moloney Eoin, Jones Susan, Araujo-Soares Vera, Hamilton Sharon, Milne Eugene Mg, Shucksmith Janet, Vale Luke, Willmore Martyn, White Martin, and Rushton Steven (2018) Evaluation of a complex healthcare intervention to increase smoking cessation in pregnant women: interrupted time series analysis with economic evaluation. Tobacco control 27(1), 90-98

Appendices

Appendix A – GRADE tables

Profile 1: Abstinence from smoking

Quality assessment							No of patients		Effect		Confidence
No of studies	Design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	Post implementation of opt-out pathway	Pre implementation of opt-out pathway	Relative (95% CI)	Absolute	
Abstinence from smoking (follow-up 12 months; assessed with: self-reported)											
1 a	before and after study	very serious[1]	NA	no serious indirectness	no serious imprecision	None	86/833 (10.3%)	97/687 (14.1%)	RR 0.73 (0.56 to 0.96)	38 fewer per 1000 (from 6 fewer to 62 fewer)	⊕OOO VERY LOW
Abstinence from smoking (follow-up 4 months[2]; assessed with: self-reported[3])											
1 b	interrupted time series	very serious[4]	NA	no serious indirectness	no serious imprecision	None	-	-	RR 1.75 (1.52 to 2.03)	-[5]	⊕OOO VERY LOW
Abstinence from smoking (follow-up 12 months; assessed with self-reported)											
1 c	before and after study	very serious[1]	NA	no serious indirectness	no serious imprecision	None	93/421 (22.1%)	46/290 (15.9%)	RR 1.39 (1.01 to 1.92)	62 more per 1000 (from 2 more to 146 more)	⊕OOO VERY LOW

[1] Concerns about selection bias, generalisability of results and bias in measurement of outcomes. No adjustment for any important confounders.
[2] Study notes post-intervention data was collected for a minimum of 4-months
[3] Study reports data on smoking status was obtained from maternity records (assumed that this data was self-reported)
[4] Concerns about selection bias, generalisability of results and bias in measurement of outcomes..
[5] One study did not provide absolute figures.

a) Bauld 2012
b) Bell 2018
c) Campbell 2017

Profile 2: Abstinence from smoking (grouped by maternal age category)

Quality assessment							No of patients		Effect		Confidence
No of studies	Design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	Post implementation of opt-out pathway	Pre implementation of opt-out pathway	Relative (95% CI)	Absolute	
Abstinence from smoking by age - 15-20 years (follow-up 4 months[1]; assessed with: self-reported[2], compared with 21-30 years)											
1 b	interrupted time series	very serious[3]	NA	no serious indirectness	no serious imprecision	None	-	-	RR 0.76 (0.67 to 0.87)	-[4]	⊕OOO VERY LOW
Abstinence from smoking by age - 31-40 years (follow-up 4 months[1]; assessed with: self-reported[2], compared with 21-30 years)											
1 b	interrupted time series	very serious[3]	NA	no serious indirectness	no serious imprecision	None	-	-	RR 1.41 (1.28 to 1.56)	-[4]	⊕OOO VERY LOW
Abstinence from smoking by age - 41-55 years (follow-up 4 months[1]; assessed with: self-reported[2], compared with 21-30 years)											
1 b	interrupted time series	very serious[3]	NA	no serious indirectness	serious[5]	None	-	-	RR 1.13 (0.77 to 1.66)	-[4]	⊕OOO VERY LOW

[1] Post-intervention data was collected for a minimum of 4-months
[2] Study reports data on smoking status was obtained from maternity records (assumed that this data was self-reported)
[3] Concerns about selection bias, generalisability of results and bias in measurement of outcomes.
[4] Study did not provide absolute figures.
[5] Confidence interval overlaps the line of no effect (MID).

a) Bauld 2012
b) Bell 2018
c) Campbell 2017

Profile 3: Abstinence from smoking (grouped by maternal socioeconomic position)

Quality assessment							No of patients		Effect		Confidence
No of studies	Design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	Post implementation of opt-out pathway	Pre implementation of opt-out pathway	Relative (95% CI)	Absolute	
Abstinence from smoking by socioeconomic position - Least deprived fifth (follow-up 4 months[1]; assessed with: self-reported[2], compared with middle three-fifths of distribution)											

1 b	interrupted time series	very serious[3]	NA	no serious indirectness	no serious imprecision	None	-	-	RR 2.57 (2.26 to 2.93)	-[4]	⊕OOO VERY LOW
Abstinence from smoking by socioeconomic position - Most deprived fifth (follow-up 4 months[1]; assessed with: self-reported[2], compared with middle three-fifths of distribution											
1 b	interrupted time series	very serious[3]	NA	no serious indirectness	no serious imprecision	None	-	-	RR 0.53 (0.43 to 0.66)	-[4]	⊕OOO VERY LOW

[1] Post-intervention data was collected for a minimum of 4-months
[2] Study reports data on smoking status was obtained from maternity records (assumed that this data was self-reported)
[3] Concerns about selection bias, generalisability of results and bias in measurement of outcomes
[4] Study did not provide absolute figures.

a) Bauld 2012
b) Bell 2018
c) Campbell 2017

Profile 4: Take-up of provision following opt-out

Quality assessment							No of patients		Effect		Confidence
No of studies	**Design**	**Risk of bias**	**Inconsistency**	**Indirectness**	**Imprecision**	**Other considerations**	**Post implementation of opt-out pathway**	**Pre implementation of opt-out pathway**	**Relative (95% CI)**	**Absolute**	
Take-up of provision following opt-out[1] (follow-up 12 months; assessed with: data from the stop smoking service for those referred)											
1 c	before and after study	very serious[2]	NA	no serious indirectness	no serious imprecision	None	121/421 (28.7%)	57/290 (19.7%)	RR 1.46 (1.11 to 1.93)	90 more per 1000 (from 22 more to 183 more)	⊕OOO VERY LOW

[1] Engagement defined as setting a quit date with stop smoking service support
[2] Concerns about selection bias, generalisability of results and bias in measurement of outcomes. No adjustment for important confounders.

a) Bauld 2012
b) Bell 2018
c) Campbell 2017

GRADE CERQual tables

Summary of review finding	Studies contributing to the review finding	Methodological limitations	Coherence	Adequacy	Relevance	CERQual assessment of confidence in the evidence
1. Acceptability of carbon monoxide (CO) testing Women expressed mixed feelings towards the use of the test in obtaining the truth about their self-reported smoking status. There was divided opinion on the impact of the test on changing smoking behaviour; either increasing motivation compared with advice alone or reducing motivation to quit in those with a lower reading than anticipated. Repeated use provided greater motivation by visually demonstrating the benefits of smoking cessation.	Bauld 2017, Sloan 2016	Minor concerns (unclear reflexivity in both studies, 1 study with selective recruitment and 1 study precluded purposive sampling)	No or very minor concerns (there is a good fit between the studies and the review finding)	Moderate concerns (data is moderately rich for descriptive data but only includes two studies)	Minor concerns (data is of direct relevance and generally covers the population of interest, although does include several post-partum women)	Moderate confidence 2 studies with minor methodological limitations. Moderately rich data, but only from 2 studies. Data is of direct relevance. No or very minor concerns about coherence.
Supporting quotations: Truth "I probably wouldn't have told them the truth because I smoke that much…would say that I smoked less than what I normally do." "Big level of trust isn't it, like, you know, trusting people and trusting what they say…it's not a nice feeling to be, like, told, well you might not be telling the truth we want you to prove it." Increased motivation "It makes it a lot better actually seeing the numbers than just being told…I just knew as soon as I saw that reading that it would have to be something that I had to do…that I knew I would have to do it a lot quicker." " It's just physical proof it can harm the baby…you can read on the side of the packet what it's got in it but until you see it you don't know…and it's like every time I go for a ciggie now it's like you're over the limit."						

Summary of review finding	Studies contributing to the review finding	Methodological limitations	Coherence	Adequacy	Relevance	CERQual assessment of confidence in the evidence
"I didn't quite realise exactly how much CO's going in…once I'd seen that…that's when I tried as much as possible to stop." <u>Reduced motivation</u> "If it's non-smoker level then there's no reason for me to quit!...if the reading was high then yeah I would be ashamed but because it was quite low it didn't bother me as much." <u>Repeated use</u> "It was a confidence boost, thinking well that's 2 weeks and it's like, the nicotine, the [CO]'s out of my body, what's it going to be like at 4? So I go again tomorrow and I'm quite looking forward to going."						
2. <u>Acceptability of automatic opt-out referral</u> Women were divided in opinion on whether the automatic referral was a positive 'push" to start quitting or whether they felt negative towards the lack of personal choice and feeling "pushed" into quitting.	Bauld 2017, Sloan 2016	Minor concerns (unclear reflexivity in both studies, 1 study with selective recruitment and 1 study precluded purposive sampling)	No or very minor concerns (there is a good fit between the studies and the review finding)	Moderate concerns (data is moderately rich for descriptive data but only includes two studies)	No or very minor concerns (data is of direct relevance and generally covers the population of interest, although does include several post-partum women)	Moderate confidence 2 studies with minor methodological limitations. Moderately rich data, but only from 2 studies. Data is of direct relevance. No or very minor concerns about coherence.
Supporting quotations: <u>Positive "push"</u> "Well I didn't really get a choice about it or anything really, I wasn't that bothered seeing as though I wanted it anyway. I think it's quite good really because it doesn't give people the choice…because then it's sort of pushing them towards it isn't it?" <u>Negative "push"</u> "I kind of felt like I was being forced into it a wee bit just because I wasn't quite ready…I suppose if I hadn't had went for it I'd have been still in the same position I was back then, so it did give me a bit of a boot." "There's people out there who don't like being pushed into something and if they are being pushed into something will react in a bad, like violent way."						

Summary of review finding	Studies contributing to the review finding	Methodological limitations	Coherence	Adequacy	Relevance	CERQual assessment of confidence in the evidence
"I know it's [CO testing] just routine. I know it's all in the best interests of the baby so I just kind of expected it really but she never asked me if I wanted to [be referred], she just told me that she was referring me to [local SSS]…she made me feel like I had no choice…like I didn't have a voice…but then, you know I should have a choice whether or not I want to go. There was no discussion…it was basically I'm referring you and it made me feel a little bit hopeless like she'd already made her mind up that I wouldn't be able to do it by myself."						
3. Provision of information Explanation of the opt-out referral pathway was an important factor in women's perceptions of the referral. Some women expressed receiving limited information on the rationale for the CO test prior to it being conducted, whilst others received a lack of information on how to interpret the readings of the test.	Sloan 2016	Minor concerns (unclear reflexivity and study precluded purposive sampling)	No or very minor concerns (there is a good fit between the study and the review finding)	Serious concerns (data is moderately rich for descriptive data but only includes one study)	No or very minor concerns (data is of direct relevance and generally covers the population of interest, although does include several post-partum women)	Low confidence 1 study with minor methodological limitations. Moderately rich data, but only from 1 study. Data is of direct relevance. No or very minor concerns about coherence.
Supporting quotations: Explanation of the opt-out referral pathway "They just basically told me what it is and asked if I would like to do it or not, gave me the option and I said yeah that's fine." "I think it's the whole informed choice thing again isn't it. It's about having the information there and being told right this is why, this is what we're doing, why we're doing it and this is why it's been brought in place and then you can make an informed decision…because at the moment nobody can object because they don't understand it." Lack of information "I couldn't understand why I needed to, because I mean after all my other dating scans I've never had to sit and wait for a [CO] appointment straight after…if everyone knew everyone was getting tested, it wouldn't make smokers feel discriminated against…felt of cornered if you like and singled out." "The feeling is that your being, it's another thing you're being checked up on…I don't think anybody has any objections to it from what I've read [on pregnancy forums], it was more the fact that nobody was told why and what…Is the whole point to find out if people are lying? What is the whole purpose of it cos I don't think it's ever been explained?"						

Summary of review finding	Studies contributing to the review finding	Methodological limitations	Coherence	Adequacy	Relevance	CERQual assessment of confidence in the evidence
"I asked because nobody actually explained what the numbers meant…we didn't get a sheet or anything like that, I think that would have been helpful…yeah it's telling them I'm a smoker but what's the point if like all it's going to say is yes she's a smoker. Well I've told you that! I came back and googled it."						
4. Contact by the stop smoking service There were mixed descriptions on level of contact by the stop smoking service (SSS). Some women described receiving an initial phone call and appointment shortly after referral. Other women stated a lack of contact from the SSS ultimately hindered their motivation and chances of quitting. Several women felt that individual motivation was key to quitting irrespective of support from a formal stop smoking service.	Bauld 2017, Sloan 2016	Minor concerns (unclear reflexivity in both studies, 1 study with selective recruitment and 1 study precluded purposive sampling)	No or very minor concerns (there is a good fit between the studies and the review finding)	Serious concerns (data is relatively thin from both studies)	Minor concerns (data generally covers the population of interest, although does include several post-partum women. Data is of relevance, however does not specifically focus on the acceptability of opt-out provision)	Low confidence 2 studies with minor methodological limitations. Relatively thin data from 2 studies. Data is relevant but does not specifically focus on acceptability. No or very minor concerns about coherence.
Supporting quotations: "I thought the phone call was going to come really quickly, just to help me like start everything off you know…quite gutted now. You know I've been trying to do it on my own, I've cut down quite considerably from what I used to do…I just need that little extra push, that encouragement." "I think at the end of the day if people want to stop smoking, like it or not they do it on their own anyway…I think it is good but at the same time if people don't want to stop they won't so I think it's a bit of a waste of time referring people that don't want to and aren't going to."						
5. Impact of CO screening on family/peer smoking behaviour	Bauld 2017	Minor concerns	No or very minor concerns	Serious concerns	Moderate concerns	Very low confidence

Summary of review finding	Studies contributing to the review finding	Methodological limitations	Coherence	Adequacy	Relevance	CERQual assessment of confidence in the evidence
The screening tool encouraged some women who had already cut down to also consider the impact of family/peer smoking on their baby, which resulted in a change in smoking behaviour in these individuals.		(unclear reflexivity and study exhibited selective recruitment)	(there is a good fit between the study and the review finding)	(data is very thin from one study)	(data is of partial relevance and does not focus specifically on the population of interest or the acceptability of opt-out provision)	1 study with thin data and minor methodological limitations. Data is of partial relevance and does not specifically focus on acceptability. No or very minor concerns about coherence.
Supporting quotations: "When it goes up it's horrible, but even if it only goes up a couple, my mum still smokes, so like if she is having a fag I don't go near her anymore, but she used to smoke in the house and now she doesn't she smokes outside".						

Matrix for integration of qualitative and effectiveness evidence

Quantitative outcomes	Related GRADE profile	Narrative exploration of qualitative review findings in relation to outcome
Abstinence from smoking	1	The lack of clear effectiveness of the intervention at increasing abstinence from smoking could be due to several of the qualitative review findings which included **some** women reporting: • Mixed perceptions of carbon monoxide (CO) test including mixed motivation towards changing smoking behaviour following screening • Mixed perceptions of automatic opt-out referral in relation to personal choice • Varying levels of information provision to permit informed decision-making • Varying levels of contact by the stop smoking service to implement support. The studies do not include sufficient information to determine whether these findings are linked to the evidence identified for this outcome.

Quantitative outcomes	Related GRADE profile	Narrative exploration of qualitative review findings in relation to outcome
Take up of provision following opt-out referral	4	The increased take up of opt-out provision could be due to several of the qualitative review findings which included **some** women reporting: • Positive perceptions of carbon monoxide (CO) test including increased motivation towards changing smoking behaviour following screening • Positive perceptions of automatic opt-out referral in being an introduction to consider quitting • Information provision to permit informed decision-making • Acceptable levels of contact from the stop smoking service to implement support. The study does not include sufficient information to determine whether these findings are linked to the evidence identified for this outcome.

Appendix B – Public health evidence tables

Bauld 2012

Bibliographic reference/s	**Bauld Linda, Hackshaw Lucy, Ferguson Janet, Coleman Tim, Taylor Gordon, and Salway Ruth (2012) Implementation of routine biochemical validation and an 'opt out' referral pathway for smoking cessation in pregnancy. Addiction (Abingdon, and England) 107 Suppl 2, 53-60**	
Study name	Bauld 2012	
Registration	Not reported	
Study type	Pilot uncontrolled before and after study	
Study dates	Opt-out referral pathway implemented between August 2010 to March 2011	
Objective	To introduce opt-out referral pathway for smoking cessation in pregnancy and to compare different methods for identifying pregnant smokers in maternity care.	
Country/ Setting	2 NHS areas: Dudley and South Birmingham in the West Midlands Region, England	
Number of participants / clusters	3,712 women entered the referral pathway: 1,498 in Dudley and 2,214 in South Birmingham. No information on power reported, numbers in both study sites were not sufficient to detect significant differences in quit rates.	
Attrition	Not applicable as not panel data.	
Participant /community characteristics.	780 maternal smokers: Dudley study site was largely community based. Out of the 1,498 pregnant women entering the referral pathway, 404 (27%) were identified as smokers. South Birmingham study site was hospital based. Out of the 2,214 pregnant women entering the referral pathway, 376 (17%) were identified as smokers. Other participant characteristics not reported.	
Method of allocation	Pilot study implemented the intervention in both NHS areas at either the booking appointment in Dudley or at the 12-week scan in South Birmingham. Both sites had a higher prevalence of smoking than the national average and had different models of maternity care.	
Inclusion criteria	No specific inclusion criteria reported	
Exclusion criteria	No specific exclusion criteria reported.	
Intervention	**TIDieR Checklist criteria**	**Details**
	Brief Name	Opt-out referral pathway
	Rationale/theory/Goal	Not reported.
	Intervention elements	Dudley: First stage of opt-out referral took place at the 6-8-week appointment at the booking appointment. Second stage of opt-out referral took place between 21-24 weeks of pregnancy. South Birmingham: First stage of opt-out referral took place at the appointment for the

Bibliographic reference/s	**Bauld Linda, Hackshaw Lucy, Ferguson Janet, Coleman Tim, Taylor Gordon, and Salway Ruth (2012) Implementation of routine biochemical validation and an 'opt out' referral pathway for smoking cessation in pregnancy. Addiction (Abingdon, and England) 107 Suppl 2, 53-60**	
Study name	Bauld 2012	
		12-week scan. Second stage of opt-out referral took place at 28 weeks of pregnancy. For both sites: women were asked at both stages to self-report their smoking status which was then validated using carbon-monoxide (CO) breath test. Women who had a reading of more than 4 parts per million (ppm) or had recently quit smoking since conception were referred to the stop smoking service (SSS) unless they opted out.
	Provider	Provider of referral: Dudley; midwives South Birmingham; maternity assistants.
	Method of delivery	Delivery of stop smoking support was by stop smoking specialist.
	Location	Dudley and South Birmingham
	Duration	The pathway was implemented between August 2010 - March 2011 in Dudley and October 2010 - March 2011 in South Birmingham.
	Intensity	NA
	Tailoring/adaptation	NA
	Planned treatment fidelity	NA
	Actual treatment fidelity	NA
	Other details	Urine testing for the presence of cotinine (as another measurement for exposure to tobacco) were also completed over a 3-month period but not over the total data collection period due to resource limitations.
Comparison	**TIDieR Checklist criteria**	**Details**
	Brief Name	Time comparison (before intervention implementation)
	Rationale/theory/Goal	Not reported.
	Intervention elements	Previous system asked pregnant women who smoke(d) if they wish to be referred to SSS and relied mainly on self-reported smoking status.
	Provider	Provider of referral: Maternity care staff
	Method of delivery	Delivery of stop smoking support was by stop smoking specialist. Method of delivery not reported.
	Location	Dudley and South Birmingham

<table>
<tr><td>Bibliographic reference/s</td><td colspan="2">Bauld Linda, Hackshaw Lucy, Ferguson Janet, Coleman Tim, Taylor Gordon, and Salway Ruth (2012) Implementation of routine biochemical validation and an 'opt out' referral pathway for smoking cessation in pregnancy. Addiction (Abingdon, and England) 107 Suppl 2, 53-60</td></tr>
<tr><td>Study name</td><td colspan="2">Bauld 2012</td></tr>
<tr><td rowspan="6"></td><td>Duration</td><td>Not reported</td></tr>
<tr><td>Intensity</td><td>NA</td></tr>
<tr><td>Tailoring/adaptation</td><td>NA</td></tr>
<tr><td>Planned treatment fidelity</td><td>NA</td></tr>
<tr><td>Actual treatment fidelity</td><td>NA</td></tr>
<tr><td>Other details</td><td>None</td></tr>
<tr><td>Follow up</td><td colspan="2">12 months (comparison to equivalent months in the year before the study; Quarter 3: October- December 2009/2010 and Quarter 4: January- March 2010)</td></tr>
<tr><td>Data collection</td><td colspan="2">Data was collected from the maternity booking, stop smoking service and biochemical samples (CO and cotinine) at the initial appointment to determine smoking status.

Data collection included:
-Self reported smoking status as either ‘smoker’, ‘ex-smoker’ and ‘never smoker’
-Proportion of women who:
either accepted referral, declined or had already been referred
accepted the CO test
attended an antenatal clinic appointment and were referred to SSS
attended an appointment with the stop smoking advisor
set a quit date
defined as abstinent (abstinence was measured at 4 weeks after a quit date and required women to report not smoking at all for the past 2 weeks and with an exhaled CO lower than 5 ppm).</td></tr>
<tr><td>Critical outcomes measures and effect size. (time points)</td><td colspan="2">Abstinence from smoking during pregnancy
<u>Women who reported smoking cessation 4-weeks following opt-out referral in 2010/2011 compared with previous year 2009/2010 (no-opt out) at both sites</u>

<table>
<tr><td colspan="2" rowspan="2">South Birmingham and Dudley site</td><td colspan="2">Outcome – 4-week quitters</td><td rowspan="2">Total</td><td rowspan="2">RR (95% CI)*</td></tr>
<tr><td>Yes</td><td>No</td></tr>
<tr><td rowspan="3">Intervention-opt-out referral</td><td>Yes</td><td>86</td><td>747</td><td>833</td><td rowspan="3">0.73 (0.56 to 0.96)</td></tr>
<tr><td>No</td><td>97</td><td>590</td><td>687</td></tr>
<tr><td>Total</td><td>183</td><td>1,337</td><td>1,520</td></tr>
</table>
*Results presented combine Quarter 3 (October- December) and Quarter 4 (January – March) and were calculated by the review team using referral data from NHS stop smoking services from both sites. Quit rates were self-reported.</td></tr>
</table>

Bibliographic reference/s	**Bauld Linda, Hackshaw Lucy, Ferguson Janet, Coleman Tim, Taylor Gordon, and Salway Ruth (2012) Implementation of routine biochemical validation and an 'opt out' referral pathway for smoking cessation in pregnancy. Addiction (Abingdon, and England) 107 Suppl 2, 53-60**		
Study name	Bauld 2012		
Important outcomes measures and effect size. (time points)	None reported.		
Statistical Analysis	Statistical analysis was conducted relating to methods used for identifying smokers, which is not of specific relevance to this review question.		
Risk of bias (ROB) EPOC RoB	**Abstinence from smoking during pregnancy.**		
	Outcome	**Judgement**	**Comments**
	Random sequence generation	High	Before and after study A proportion of midwifes at the Dudley site were unwilling/unable to change practice to incorporate routine CO monitoring and automatic referral - Dudley site participants were only a subset of the eligible women. Both sites had a higher prevalence of smoking during pregnancy compared with the national average.
	Allocation concealment	High	Before and after study
	Baseline outcome measurements similar	Low	
	Incomplete outcome data	Low	No apparent selective reporting of results.
	Knowledge of the allocated interventions adequately prevented during the study	Unclear	
	Protection against contamination	Unclear	No important confounders are identified or controlled for in the study. Both areas had differing models of service delivery (community and hospital based).
	Selective outcome reporting	Unclear	No attempt made to account for this missing data. There is a discrepancy between data reported for referrals from antenatal hospitals to NHS SSS and outcomes following referral to SSS.

Bibliographic reference/s	**Bauld Linda, Hackshaw Lucy, Ferguson Janet, Coleman Tim, Taylor Gordon, and Salway Ruth (2012) Implementation of routine biochemical validation and an 'opt out' referral pathway for smoking cessation in pregnancy. Addiction (Abingdon, and England) 107 Suppl 2, 53-60**		
Study name	Bauld 2012		
			Outcome assessment was comparable for both study sites. Four week quit rates, a subjective outcome, were self-reported and not confirmed with biochemical testing. Outcome assessors were not reported as being blinded.
	Other risks of bias	None	
	Overall Risk of Bias	High	
	Other outcome details: None		
Source of funding	Department of Health		
Comments	Comparisons between outcomes achieved before and after the study were limited, due to limited information being collected routinely by local services including quit rates.		
Additional references	None		

Bauld 2017

Bibliographic reference	**Bauld Linda, Graham Hilary, Sinclair Lesley, Flemming Kate, Naughton Felix, Ford Allison, McKell Jennifer, McCaughan Dorothy, Hopewell Sarah, Angus Kathryn, Eadie Douglas, and Tappin David (2017) Barriers to and facilitators of smoking cessation in pregnancy and following childbirth: literature review and qualitative study. Health technology assessment (Winchester, and England) 21(36), 1-158**
Trial registration	Not reported.
Study type	Mixed-methods study- Qualitative component of relevance to this review question.
Study dates	Recruitment period was between November 2013 and September 2014 for pregnant women.
Aim	To explore the barriers to and facilitators of smoking cessation experienced by women during pregnancy and post-partum; and elicit views on interventions to support cessation.

Bibliographic reference	**Bauld Linda, Graham Hilary, Sinclair Lesley, Flemming Kate, Naughton Felix, Ford Allison, McKell Jennifer, McCaughan Dorothy, Hopewell Sarah, Angus Kathryn, Eadie Douglas, and Tappin David (2017) Barriers to and facilitators of smoking cessation in pregnancy and following childbirth: literature review and qualitative study. Health technology assessment (Winchester, and England) 21(36), 1-158**	
Country/geographical location	Scotland, UK	
Setting/School type	2 NHS sites: Area A serving an area in Scotland (exclusively opt-out referral pathway of relevance to this review question) Area B serving England (included both opt-in and opt-out referral pathways- not captured in this evidence table as data on views about opt-out pathways could not be separated from views on opt-in pathways)	
Inclusion criteria	<u>For pregnant women</u> - Age ≥ 16 years - English speaking - Referred to NHS obstetrics services at study area A or B - 6-15 weeks gestation at maternity booking - Self-reported smoker at maternity booking	
Exclusion criteria	No specific exclusion criteria reported.	
Intervention	**TIDieR Checklist criteria**	**Details**
	Brief Name	Opt-out referral pathway
	Rationale/theory/Goal	Not reported
	Materials used	Not reported
	Procedures used	Smoking status was self-reported at maternity booking appointment and a compulsory carbon monoxide (CO) screening test. This was followed by an opt-out referral to NHS stop smoking service for women with a CO reading of ≥ 4 parts per million.
	Provider	Maternity services and stop smoking services (smoking cessation advisor)
	Method of delivery	Telephone and face to face contact
	Location	Study Area A in Scotland
	Duration	Usually support was provided in 6-8 week blocks
	Intensity	NA
	Tailoring/adaptation	NA
	Modifications	NA
	Planned treatment fidelity	NA
	Actual treatment fidelity	NA
	Other details	None
Comparison	**TIDieR Checklist criteria**	**Details**

Bibliographic reference	**Bauld Linda, Graham Hilary, Sinclair Lesley, Flemming Kate, Naughton Felix, Ford Allison, McKell Jennifer, McCaughan Dorothy, Hopewell Sarah, Angus Kathryn, Eadie Douglas, and Tappin David (2017) Barriers to and facilitators of smoking cessation in pregnancy and following childbirth: literature review and qualitative study. Health technology assessment (Winchester, and England) 21(36), 1-158**	
	Brief Name	No comparison- not applicable
Follow up	Not applicable	
Qualitative methods	Research question(s)	To explore the perspectives and experiences of the barriers to and facilitators of smoking cessation in pregnancy, and to elicit their views on existing services and interventions to support cessation.
	Theoretical approach	Social-ecological framework (SEF) consisting of 5 key factors; individual characteristics, interpersonal factors, community factors, organisational factors and societal factors. SEF was also used to examine and explore the finding from interviews.
	Data collection	Two female, non-smoking researchers conducted interviews. Interviews were audio recorded and ranged from 25 minutes to 1 hour 20 minutes. Topic guides were prepared to guide semi-structured discussions. All interviews were transcribed.
	Method and process of analysis	Data analysis was undertaken by 3 individuals. This included: - Study of transcripts - Coding and categorising all transcripts and insertion into 1 of the 3 SEF levels being examined: interpersonal, individual or organisational - Summarisation of key findings emerging from each code into higher-level categories - Researchers discussed how the categories related to each other, resulting in preliminary themes - Themes were then further refined. The adequacy and consistency of coding between researchers was assessed as follows: - NVivo software was used to resolve dual coding and was used overall to assist coding and analysis. - Inconsistencies in coding between researchers were resolved by

<table>
<tr><td>Bibliographic reference</td><td colspan="2">Bauld Linda, Graham Hilary, Sinclair Lesley, Flemming Kate, Naughton Felix, Ford Allison, McKell Jennifer, McCaughan Dorothy, Hopewell Sarah, Angus Kathryn, Eadie Douglas, and Tappin David (2017) Barriers to and facilitators of smoking cessation in pregnancy and following childbirth: literature review and qualitative study. Health technology assessment (Winchester, and England) 21(36), 1-158</td></tr>
<tr><td></td><td></td><td>discussion and minor changes to the coding framework.</td></tr>
<tr><td></td><td>Population and sample collection</td><td>Area A included 21 pregnant women who were or had been smokers. In the study area, 17.3% of pregnant women smoke during pregnancy, which is lower than the Scottish average of 20.0%, and may represent a more affluent population than Scotland as a whole.

<table>
<tr><td>Characteristic</td><td>Area A</td></tr>
<tr><td>Age (years) mean (range)</td><td>27 (18-42)</td></tr>
<tr><td>Aged <25 years n (%)</td><td>7 (33)</td></tr>
<tr><td>Living in most deprived areas* n (%)</td><td>15 (71)</td></tr>
<tr><td>Gestation at interview (weeks) mean (range)</td><td>19 (14-27)</td></tr>
<tr><td>Smoking at interview n (%)</td><td>11 (52)</td></tr>
<tr><td>Engaged with the SSS by time of interview n (%)</td><td>21 (100)</td></tr>
</table>
*Assessed using the Index of Multiple Deprivation (IMD) of Scottish Index of Multiple Deprivation at postcode level.
Purposive sampling using a sampling frame which accounted for maternal age (25% of sample were aged under 25) and deprivation (75% of sample were from postcodes with lowest IMD) and included current smokers and those who had quit at roughly 20 weeks gestation.</td></tr>
<tr><td>Results</td><td colspan="2">Outcome: Acceptability of intervention</td></tr>
<tr><td></td><td>Key themes</td><td></td></tr>
<tr><td></td><td>Acceptability of the opt out referral to a stop-smoking service
(Organisational SEF level)</td><td>Women described receiving an initial phone call from a smoking cessation advisor several days after referral, shortly followed by an appointment within 1 week. There was a perception that even with the opt-out pathway, some women still saw the referral as optional whilst other women recalled being told that they had to be referred. Some women felt the automatic referral was a</td></tr>
</table>

Bibliographic reference	**Bauld Linda, Graham Hilary, Sinclair Lesley, Flemming Kate, Naughton Felix, Ford Allison, McKell Jennifer, McCaughan Dorothy, Hopewell Sarah, Angus Kathryn, Eadie Douglas, and Tappin David (2017) Barriers to and facilitators of smoking cessation in pregnancy and following childbirth: literature review and qualitative study. Health technology assessment (Winchester, and England) 21(36), 1-158**		
		positive motivation to start quitting, whereas others felt they had no choice but to start quitting without being ready. *"I kind of felt like I was being forced into it a wee bit just because I wasn't quite ready…I suppose if I hadn't had went for it I'd have been still in the same position I was back then, so it did give me a bit of a boot" (smoker).*	
	Acceptability of the carbon monoxide (CO) monitoring (Organisational SEF level)	Women screened described feeling "bad" or "embarrassed" at seeing their CO reading. Generally, women felt CO monitoring was a motivational tool to consider the health effects of smoking on their baby and to think about smoking cessation. When the tool was used repeatedly this provided greater motivation by visually demonstrating the benefits of smoking cessation. The tool encouraged some women consider the potential risks of family/peer smoking on their baby, which led to a change in smoking behaviour of these individuals. *"I didn't quite realise exactly how much CO's going in…once I'd seen that…that's when I tried as much as possible to stop" (smoker)* *"It was a confidence boost, thinking well that's 2 weeks and it's like, the nicotine, the [CO]'s out of my body, what's it going to be like at 4? So I go again tomorrow and I'm quite looking forward to going" (non-smoker)* *"When it goes up it's horrible, but even if it only goes up a couple, my mum still smokes, so like if she is having a fag I don't go near her anymore, but she used to smoke in the house and now she doesn't she smokes outside" (non-smoker)*	
Risk of bias	Item	Yes/No/Can't tell	Comments
	1. Was there a clear statement of the aim of the research?	Yes	Aim of research and population clearly stated.
	2. Is a qualitative methodology appropriate?	Yes	Subjective experiences and barriers / facilitators sought.
	3. Was the research design appropriate to	Yes	Interviews were sufficient to obtain views and experiences.

Bibliographic reference	Bauld Linda, Graham Hilary, Sinclair Lesley, Flemming Kate, Naughton Felix, Ford Allison, McKell Jennifer, McCaughan Dorothy, Hopewell Sarah, Angus Kathryn, Eadie Douglas, and Tappin David (2017) Barriers to and facilitators of smoking cessation in pregnancy and following childbirth: literature review and qualitative study. Health technology assessment (Winchester, and England) 21(36), 1-158		
	address the aims of the research?		
	4. Was the recruitment strategy appropriate to the aims of the research?	No	Purposive sampling was completed to achieve maximum diversity within the sample of recruited women. The research also had clear inclusion criteria appropriate for the study aim. However, only women who were in contact with the stop smoking service were recruited, meaning that women who smoke(d) but were not in contact with the service were not recruited.
	5. Was the data collected in a way that addressed the research issue?	Yes	Topic guides were prepared prior to the interviews to support semi-structured discussion and aid data collection. Telephone interviews were conducted, recorded and transcribed.
	6. Has the relationship between researcher and participants been adequately considered?	Can't tell	One researcher was pregnant during fieldwork, however reflexivity unclear.
	7. Have ethical issues been taken into consideration?	Yes	Interested women were given a study sheet and gave permission for their contact information to be passed on the research team. Researchers explained the study and answered any questions and obtained verbal consent. Prior to the interview written consent was obtained. NHS ethics approval was obtained.
	8. Was the data analysis sufficiently rigorous?	Yes	Methods used in analysis (including coding, dealing with dual coding/coding inconsistencies and data analysis) and how themes were categorised and refined are reported. Analysis was undertaken by 3 researchers.

Bibliographic reference	**Bauld Linda, Graham Hilary, Sinclair Lesley, Flemming Kate, Naughton Felix, Ford Allison, McKell Jennifer, McCaughan Dorothy, Hopewell Sarah, Angus Kathryn, Eadie Douglas, and Tappin David (2017) Barriers to and facilitators of smoking cessation in pregnancy and following childbirth: literature review and qualitative study. Health technology assessment (Winchester, and England) 21(36), 1-158**		
	9. Is there a clear statement of findings?	Yes	Findings are explicit, and report both positive and negative views of the opt-out referral pathway. Findings link back to the original research question.
	10. Is the research valuable?	Can't tell	As the views of pregnant women on opt-out referral is only a small proportion of the overall findings reported, there is limited discussion on the implications of implementing the pathway.
Overall risk of bias	Low risk of bias		
Source of funding	The National Institute for Health Research (NIHR)		
Comments	Participants were offered £15 voucher as an incentive to take part in the study.		

Bell 2018

Bibliographic reference/s	**Bell Ruth, Glinianaia Svetlana V, Waal Zelda van der, Close Andrew, Moloney Eoin, Jones Susan, Araujo-Soares Vera, Hamilton Sharon, Milne Eugene Mg, Shucksmith Janet, Vale Luke, Willmore Martyn, White Martin, and Rushton Steven (2018) Evaluation of a complex healthcare intervention to increase smoking cessation in pregnant women: interrupted time series analysis with economic evaluation. Tobacco control 27(1), 90-98**
Study name	Bell 2018
Registration	Not reported
Study type	Interrupted time series analysis
Study dates	Intervention introduced between November 2012 and July 2013
Objective	To evaluate the effectiveness of a complex intervention (with opt-out referral) to improve referral and treatment of pregnant smokers in routine practice
Country/ Setting	8 acute NHS hospital trusts and 12 local authority areas in North East England.
Number of participants / clusters	Total records of 37,726 participants who had given singleton delivery across 8 trusts. 10,594 mothers classified as smokers during pregnancy. Participants were not involved in the design or conduct of the study.
Attrition	Attrition not applicable as panel data.
Participant /community characteristics.	<u>Maternal characteristics of smokers in study cohort in North East England</u>

Variable	Maternal smokers in cohort: total and (%)

<table>
<tr><td>Bibliographic reference/s</td><td colspan="2">Bell Ruth, Glinianaia Svetlana V, Waal Zelda van der, Close Andrew, Moloney Eoin, Jones Susan, Araujo-Soares Vera, Hamilton Sharon, Milne Eugene Mg, Shucksmith Janet, Vale Luke, Willmore Martyn, White Martin, and Rushton Steven (2018) Evaluation of a complex healthcare intervention to increase smoking cessation in pregnant women: interrupted time series analysis with economic evaluation. Tobacco control 27(1), 90-98</td></tr>
<tr><td>Study name</td><td colspan="2">Bell 2018</td></tr>
<tr><td></td><td colspan="2">
<table>
<tr><td>Age (years):
15-20
21-30
31-40
41+
Missing</td><td>
1,626 (15.3)
6,226 (58.8)
2,600 (24.5)
141 (1.3)
1 (0.0)</td></tr>
<tr><td>Parity:
First child
Second child
Third + child
Missing</td><td>
3,000 (28.3)
2,942 (27.8)
2,796 (26.4)
1,856 (17.5)</td></tr>
<tr><td>BMI* (kg/m^2):
Underweight (<20)
Healthy (20-24.9)
Overweight (25-29.9)
Obese (30+)
Missing</td><td>
304 (2.9)
3,389 (32.0)
1,990 (18.8)
1,752 (16.5)
3,159 (29.8)</td></tr>
<tr><td>Ethnic group:
White
Caucasian
Missing</td><td>
10,041 (94.8)
224 (2.1)
329 (3.1)</td></tr>
<tr><td>SEP**:
Least deprived (0-16)
Middle three-fifths (17-64)
Most deprived (65-80)
Missing</td><td>
1,231 (11.6)
8,536 (80.6)
698 (6.6)
129 (1.2)</td></tr>
<tr><td>Total</td><td>10,594</td></tr>
</table>
*BMI: Body mass index
**Socioeconomic position (SEP) categories defined by fifths of Index of Multiple Deprivation (IMD) score.

Reported characteristics for non-smokers, not extracted.
</td></tr>
<tr><td>Method of allocation</td><td colspan="2">Intervention was already implemented across trusts.</td></tr>
<tr><td>Inclusion criteria</td><td colspan="2">Singleton delivery.</td></tr>
<tr><td>Exclusion criteria</td><td colspan="2">Multiple pregnancies were excluded.</td></tr>
<tr><td>Intervention</td><td>TIDieR Checklist criteria</td><td>Details</td></tr>
<tr><td></td><td>Brief Name</td><td>BabyClear complex intervention</td></tr>
<tr><td></td><td>Rationale/theory/Goal</td><td>Developed by the Tobacco Control Collaborating Centre, aimed at</td></tr>
</table>

Bibliographic reference/s	**Bell Ruth, Glinianaia Svetlana V, Waal Zelda van der, Close Andrew, Moloney Eoin, Jones Susan, Araujo-Soares Vera, Hamilton Sharon, Milne Eugene Mg, Shucksmith Janet, Vale Luke, Willmore Martyn, White Martin, and Rushton Steven (2018) Evaluation of a complex healthcare intervention to increase smoking cessation in pregnant women: interrupted time series analysis with economic evaluation. Tobacco control 27(1), 90-98**	
Study name	Bell 2018	
		improving skills, resources and referral pathways across local healthcare systems. Intervention not explicitly developed with behavioural theory, its components indicate that it included behaviour change techniques; action planning, monitoring and provision of information.
	Intervention elements	- Core intervention consisted of skills training for healthcare and smoking cessation staff, carbon monoxide (CO) monitoring with routine opt-out referral for smoking cessation support and an explicit referral pathway and follow-up protocol. - Full intervention included an additional risk perception element at first antenatal appointment (implementation was delayed and not evaluated). -CO monitoring of all pregnant women integrated into routine care occurred at pre-booking/booking appointment. -Women with a CO reading above 4 parts per million were referred via an opt-out referral to Stop Smoking in Pregnancy Service (SSPS) -CO monitoring and opt-out referral of pregnant smokers for those who had not already engaged with SSPS occurred at all future appointments.
	Provider	Referrals made by midwifery team
	Method of delivery	Delivery of stop smoking support was face to face by a stop smoking specialist.
	Location	North East England
	Duration	Intervention was introduced between November 2012 and July 2013
	Intensity	NA
	Tailoring/adaptation	NA
	Planned treatment fidelity	NA
	Actual treatment fidelity	NA
	Other details	Smoking status was smoking at any time during pregnancy. Quitting during pregnancy defined as “any mother classified as a smoker

Bibliographic reference/s	**Bell Ruth, Glinianaia Svetlana V, Waal Zelda van der, Close Andrew, Moloney Eoin, Jones Susan, Araujo-Soares Vera, Hamilton Sharon, Milne Eugene Mg, Shucksmith Janet, Vale Luke, Willmore Martyn, White Martin, and Rushton Steven (2018) Evaluation of a complex healthcare intervention to increase smoking cessation in pregnant women: interrupted time series analysis with economic evaluation. Tobacco control 27(1), 90-98**	
Study name	Bell 2018	
		during pregnancy but recorded as a non-smoker at delivery". Referral for smoking cessation advice defined as a delivery with: "date of referral; being sent information or contacted by a smoking cessation service; an appointment booked or attended with the smoking cessation service; a record of a quit date being set; or any record of smoking status recorded for 'quit at 4 weeks'". Deliveries were classified as before intervention or after intervention based on when the pregnancy reached 11 weeks gestation.
Comparison	**TIDieR Checklist criteria**	**Details**
	Brief Name	Time comparison (before intervention implementation)
	Rationale/theory/Goal	Not reported
	Intervention elements	Not reported
	Provider	Referrals made by midwifery team.
	Method of delivery	Delivery of stop smoking support was by stop smoking specialist.
	Location	North East England
	Duration	Not reported
	Intensity	NA
	Tailoring/adaptation	NA
	Planned treatment fidelity	NA
	Actual treatment fidelity	NA
	Other details	None
Follow up	4 months or more post-intervention	
Data collection	Electronic records of deliveries obtained from trusts including a pre-intervention and post-intervention period with at least 4 months of data post-intervention Data on referrals and quit attempts obtained from smoking cessation services (including referral dates, appointments, quit dates and quit status at 4 weeks). Clinical and demographic variables obtained from maternity records including smoking status of mother at booking and delivery. Both data from referrals/quit attempts and delivery data were matched using maternal NHS number or by mother's date of birth and postcode. No information on blinding of assessors.	

<table>
<tr><td>Bibliographic reference/s</td><td>Bell Ruth, Glinianaia Svetlana V, Waal Zelda van der, Close Andrew, Moloney Eoin, Jones Susan, Araujo-Soares Vera, Hamilton Sharon, Milne Eugene Mg, Shucksmith Janet, Vale Luke, Willmore Martyn, White Martin, and Rushton Steven (2018) Evaluation of a complex healthcare intervention to increase smoking cessation in pregnant women: interrupted time series analysis with economic evaluation. Tobacco control 27(1), 90-98</td></tr>
<tr><td>Study name</td><td>Bell 2018</td></tr>
<tr><td>Critical outcomes measures and effect size. (time points)</td><td>
Abstinence from smoking during pregnancy
<u>Effect of BabyClear intervention on quitting by delivery*</u>
<table>
<tr><td></td><td>aOR** (95% CI)</td><td>aRR*** calculated by analyst</td></tr>
<tr><td>After implementation of intervention, compared with before</td><td>1.81 (1.55 to 2.12)</td><td>1.75 (1.52 to 2.03)</td></tr>
</table>
*Based on 9,967 cases included in model (6.6% cases with missing data excluded).
**Reported by study. Adjusted for maternal ethnicity, age, parity and deprivation.
***Calculated by review team. The quit rate during pregnancy before the intervention at 0.0398 per delivery was used to calculate the aRR.

<u>Effect of BabyClear intervention (after vs before) on quitting by delivery depending on SEP category compared with middle three-fifths of distribution*</u>
<table>
<tr><td></td><td>aOR** (95% CI)</td><td>aRR*** calculated by analyst</td></tr>
<tr><td>Least deprived fifth</td><td>2.75 (2.39 to 3.18)</td><td>2.57 (2.26 to 2.93)</td></tr>
<tr><td>Most deprived fifth</td><td>0.52 (0.42 to 0.65)</td><td>0.53 (0.43 to 0.66)</td></tr>
</table>
*Based on 9,967 cases included in model (6.6% cases with missing data excluded).
**Reported by study. Adjusted for maternal ethnicity, age, parity.
***Calculated by review team. The quit rate during pregnancy before the intervention at 0.0398 per delivery was used to calculate the aRR (no figure was reported specifically for the middle three- fifths of distribution).

<u>Effect of BabyClear intervention (after vs before) on quitting by delivery depending on maternal age category compared with 21-30 years*</u>
<table>
<tr><td></td><td>aOR** (95% CI)</td><td>aRR*** calculated by analyst</td></tr>
<tr><td>15-20 years</td><td>0.75 (0.66 to 0.87)</td><td>0.76 (0.67 to 0.87)</td></tr>
<tr><td>31-40 years</td><td>1.43 (1.29 to 1.60)</td><td>1.41 (1.28 to 1.56)</td></tr>
<tr><td>41-55 years</td><td>1.14 (0.76 to 1.71)</td><td>1.13 (0.77 to 1.66)</td></tr>
</table>
</td></tr>
</table>

<table>
<tr><td>Bibliographic reference/s</td><td>Bell Ruth, Glinianaia Svetlana V, Waal Zelda van der, Close Andrew, Moloney Eoin, Jones Susan, Araujo-Soares Vera, Hamilton Sharon, Milne Eugene Mg, Shucksmith Janet, Vale Luke, Willmore Martyn, White Martin, and Rushton Steven (2018) Evaluation of a complex healthcare intervention to increase smoking cessation in pregnant women: interrupted time series analysis with economic evaluation. Tobacco control 27(1), 90-98</td></tr>
<tr><td>Study name</td><td>Bell 2018</td></tr>
<tr><td></td><td>*Based on 9,967 cases included in model (6.6% cases with missing data excluded).
**Reported by study. Adjusted for maternal ethnicity, parity and deprivation.
***Calculated by review team. The quit rate during pregnancy before the intervention at 0.0398 per delivery was used to calculate the aRR (no figure was reported specifically for the 21-30 years age category).

<u>Effect of BabyClear intervention (after vs before) on quitting by delivery compared with not referred*</u>

<table>
<tr><td></td><td>aOR** (95% CI)</td><td>aRR*** calculated by analyst</td></tr>
<tr><td>Referred, quit date</td><td>4.18 (3.53 to 4.94)</td><td>3.71 (3.21 to 4.27)</td></tr>
<tr><td>Referred, no quit date</td><td>3.33 (2.99 to 3.71)</td><td>3.05 (2.77 to 3.35)</td></tr>
</table>
* Involves engagement with smoking cessation services. Based on 9,967 cases included in model (6.6% cases with missing data excluded).
**Reported by study. Adjusted for maternal ethnicity, age, parity and deprivation.
***Calculated by review team. The quit rate during pregnancy before the intervention at 0.0398 per delivery was used to calculate the aRR (no figure was reported specifically for those not referred).</td></tr>
<tr><td>Important outcomes measures and effect size. (time points)</td><td>None reported</td></tr>
<tr><td>Statistical Analysis</td><td>A complete case dataset was created for use in the analysis.
Logistic regression mixed-effects modelling with random intercept for trust was used to assess the effects of the intervention on quitting smoking before delivery.
Quitting as a binary response variable (yes/no) for individual pregnancies. The model adjusted for ethnicity, age, parity and deprivation.</td></tr>
<tr><td>Risk of bias (ROB)
ROBINS-I tool</td><td>Abstinence from smoking during pregnancy: Effect of BabyClear intervention on quitting by delivery
<table>
<tr><th>Outcome</th><th>Judgement</th><th>Comments</th></tr>
<tr><td>Random sequence generation</td><td>High</td><td>Before and after study</td></tr>
<tr><td>Allocation concealment</td><td>High</td><td>Before and after study</td></tr>
</table></td></tr>
</table>

Bibliographic reference/s	**Bell Ruth, Glinianaia Svetlana V, Waal Zelda van der, Close Andrew, Moloney Eoin, Jones Susan, Araujo-Soares Vera, Hamilton Sharon, Milne Eugene Mg, Shucksmith Janet, Vale Luke, Willmore Martyn, White Martin, and Rushton Steven (2018) Evaluation of a complex healthcare intervention to increase smoking cessation in pregnant women: interrupted time series analysis with economic evaluation. Tobacco control 27(1), 90-98**		
Study name	Bell 2018		
	Baseline outcome measurements similar	Low	
	Incomplete outcome data	High	Study used routine data rather than data collected specifically for research and absolute results are not reported. No attempts were made to account for missing data.
	Knowledge of the allocated interventions adequately prevented during the study		Intervention referral pathway is reasonably defined. However, information relating to referral was determined retrospectively
	Protection against contamination	High	An additional risk perception element of the intervention encountered delayed implementation and impact was not evaluated. Outcome assessors were not reported as being blinded.
	Selective outcome reporting	High	No apparent selective reporting of results. Smoking status was not confirmed with biochemical testing. Organisations collected different variables or defined variables differently, which were then combined. Routinely collected data also varied in definition and completeness in

Bibliographic reference/s	**Bell Ruth, Glinianaia Svetlana V, Waal Zelda van der, Close Andrew, Moloney Eoin, Jones Susan, Araujo-Soares Vera, Hamilton Sharon, Milne Eugene Mg, Shucksmith Janet, Vale Luke, Willmore Martyn, White Martin, and Rushton Steven (2018) Evaluation of a complex healthcare intervention to increase smoking cessation in pregnant women: interrupted time series analysis with economic evaluation. Tobacco control 27(1), 90-98**		
Study name	Bell 2018		
			different organisations.
	Other risks of bias	Unclear	Results may not be generalisable to other settings, where there may be lower baseline prevalence of smoking during pregnancy.
			.
	Overall Risk of Bias	High	
	Other outcome details: All other outcomes as above.		
Source of funding	NIHR School for Public Health Research		
Comments	It is not clear to identify which specific aspects of the complex intervention resulted in the observed changes. Intervention was “introduced under conditions likely to be replicable in similar health systems with access to smoking cessation services with trained advisors”.		
Additional references	None		

Campbell 2017

Bibliographic reference/s	**Campbell Katarzyna A, Cooper Sue, Fahy Samantha J, Bowker Katharine, Leonardi-Bee Jo, McEwen Andy, Whitemore Rachel, and Coleman Tim (2017) 'Opt-out' referrals after identifying pregnant smokers using exhaled air carbon monoxide: impact on engagement with smoking cessation support. Tobacco control 26(3), 300-306**
Study name	Campbell 2017
Registration	Not reported
Study type	Uncontrolled before and after study
Study dates	Before implementation of opt-out referral (opt-in): May – October 2012 After implementation of opt-out referral: May – October 2013

<table>
<tr><td>Bibliographic reference/s</td><td>Campbell Katarzyna A, Cooper Sue, Fahy Samantha J, Bowker Katharine, Leonardi-Bee Jo, McEwen Andy, Whitemore Rachel, and Coleman Tim (2017) 'Opt-out' referrals after identifying pregnant smokers using exhaled air carbon monoxide: impact on engagement with smoking cessation support. Tobacco control 26(3), 300-306</td></tr>
<tr><td>Study name</td><td>Campbell 2017</td></tr>
<tr><td>Objective</td><td>To compare rates of referral to stop smoking services (SSS), engagement with SSS and cessation before and after implementation of opt-out referrals.</td></tr>
<tr><td>Country/ Setting</td><td>Sherwood Forest Hospitals NHS Foundation Trust, Nottinghamshire, UK.
Involved 2 antenatal clinics at the trust: Kings Mill Hospital (KMH) and Sherwood Women’s Centre (SWC)</td></tr>
<tr><td>Number of participants / clusters</td><td>1,060 maternal smokers:
In the before period (opt-in referrals): 2,287 women received antenatal care, including 536 (23.4%) smokers (self-reported)
In the after period (opt-out referrals): 2,293 women received antenatal care, including 524 (22.9%) smokers (self-reported)
Sample size estimate:
Based on available data from 12 months prior to April 2012 from KMH with 3.0% of 3,286 women setting a quit date.
Estimated 1,684 women would be available for referral with 3.0% setting a quit date (95% CI of 2.2 to 3.8%, ±0.8% margin) for 6 months before and after intervention implementation.
Actual number of women eligible for referral at both hospitals was approximately 800 participants higher compared with the sample size estimate, based on 800 women attending SWC for antenatal care annually.</td></tr>
<tr><td>Attrition</td><td>Not applicable as not panel data</td></tr>
<tr><td>Participant /community characteristics.</td><td><u>Participant characteristics for pregnant smokers who set a quit date before and after implementation of opt-out referral.</u>
<table>
<tr><th>Participant characteristics</th><th>Before (n= 57)</th><th>After (n =121)</th></tr>
<tr><td>Age (mean)</td><td>26.0</td><td>25.8</td></tr>
<tr><td>Age - median (IQR)</td><td>22.7 – 30.3</td><td>21.9 – 30.2</td></tr>
<tr><td>IMD* quintile, n (%)
1 (least deprived)
2
3
4
5 (most deprived)</td><td>
2 (3.5)
4 (7.0)
10 (17.5)
17 (29.8)
24 (42.1)</td><td>
1 (0.8)
7 (5.8)
15 (12.5)
39 (32.5)
58 (48.3)**</td></tr>
</table>
*IMD = Index of Multiple Deprivation (derived from postcodes)
**Missing data for IMD quintiles for one woman.

Sample may not be generalisable to other settings.</td></tr>
<tr><td>Method of allocation</td><td>Intervention was recently implemented across trust.</td></tr>
<tr><td>Inclusion criteria</td><td>No specific inclusion criteria reported.</td></tr>
</table>

Bibliographic reference/s	**Campbell Katarzyna A, Cooper Sue, Fahy Samantha J, Bowker Katharine, Leonardi-Bee Jo, McEwen Andy, Whitemore Rachel, and Coleman Tim (2017) 'Opt-out' referrals after identifying pregnant smokers using exhaled air carbon monoxide: impact on engagement with smoking cessation support. Tobacco control 26(3), 300-306**	
Study name	Campbell 2017	
Exclusion criteria	No specific exclusion criteria reported.	
Intervention	**TIDieR Checklist criteria**	**Details**
	Brief Name	Opt-out referral pathway
	Rationale/theory/Goal	Not reported.
	Intervention elements	At the 8-12 weeks booking appointment, all women were asked to self-report their smoking status. At the 12 week-dating scan, all women were offered the carbon monoxide (CO) test to identify smokers irrespective of their earlier self-reported smoking status. Women with CO levels of 4 parts per million (ppm) or greater were referred to the stop smoking service unless they refused (opted out). In addition, support was provided by stop smoking service (SSS) consisting of: <u>Encouragement to set a quit date</u> As part of the service, women were encouraged to set a smoking quit date <u>Behavioural support</u> Women were offered behavioural support over a period of 12 weeks. <u>Nicotine replacement therapy</u> Women were offered up to 12 weeks of NRT at no cost, every fortnight dependent on being abstinent. <u>Pregnancy lead</u> After implementation of the intervention, a pregnancy lead offered half a day service per week offering support to pregnant smokers. This was later withdrawn due to lack of demand.
	Provider	Referral provided by: 5 healthcare assistants at KMH Midwife at SWC
	Method of delivery	Delivery of stop smoking support was by stop smoking specialist. Opt-out referral to SSS was electronic and occurred at dating scan.
	Location	Nottinghamshire New Leaf stop smoking service (community based)
	Duration	Implemented between May – October 2013

Bibliographic reference/s	**Campbell Katarzyna A, Cooper Sue, Fahy Samantha J, Bowker Katharine, Leonardi-Bee Jo, McEwen Andy, Whitemore Rachel, and Coleman Tim (2017) 'Opt-out' referrals after identifying pregnant smokers using exhaled air carbon monoxide: impact on engagement with smoking cessation support. Tobacco control 26(3), 300-306**	
Study name	Campbell 2017	
	Intensity	NA
	Tailoring/adaptation	NA
	Planned treatment fidelity	NA
	Actual treatment fidelity	NA
	Other details	None
Comparison	**TIDieR Checklist criteria**	**Details**
	Brief Name	Time comparison (before intervention implementation: 'opt-in' referrals)
	Rationale/theory/Goal	Not reported.
	Intervention elements	Opt-in system did not include CO monitoring to validate self-reported smoking status at first booking appointment (8-12 weeks). At the booking appointment self-reported smokers were asked if they wished to be referred to the SSS. Opt-in referrals were also offered at later stages including at 25 and 34 weeks gestation (also at delivery and twice postnatally). Smoking was not normally discussed at the 12-week and 20-week scan. In addition, support was provided by stop smoking service (SSS) as outlined for the intervention group.
	Provider	Referral provided by midwives
	Method of delivery	Delivery of stop smoking support was by stop smoking specialist. Opt-in referrals were sent electronically to SSS.
	Location	Nottinghamshire New Leaf stop smoking service (community based)
	Duration	Not reported
	Intensity	NA
	Tailoring/adaptation	NA
	Planned treatment fidelity	NA
	Actual treatment fidelity	NA
	Other details	None
Follow up	12 months. (Comparison to equivalent months in the year before opt-out implemented May – October 2012).	
Data collection	Individual participant data was collected from an electronic system (integrated with electronic medical records) to provide information on	

<table>
<tr><td>Bibliographic reference/s</td><td>Campbell Katarzyna A, Cooper Sue, Fahy Samantha J, Bowker Katharine, Leonardi-Bee Jo, McEwen Andy, Whitemore Rachel, and Coleman Tim (2017) 'Opt-out' referrals after identifying pregnant smokers using exhaled air carbon monoxide: impact on engagement with smoking cessation support. Tobacco control 26(3), 300-306</td></tr>
<tr><td>Study name</td><td>Campbell 2017</td></tr>
<tr><td></td><td>'booking' appointment data on the number of women receiving antenatal care, on their smoking status, and to obtain information on the ultrasound appointment.
The stop smoking service (SSS) database was used to obtain information on engagement and cessation outcomes.
Data collection included:
- At booking appointment (before and after): number of women booked for maternity care, smoking status at booking and number of women referred to SSS at booking.
- At 12 week dating scan (after only): number of women attending scan appointment, smoking status, number of women referred to SSS at the appointment.
- Data from the SSS 'QuitManager' database (before and after): age, Index of Multiple Deprivation (IMD) quintiles (derived from postcodes), number of women engaging with SSS (setting a quit date), number of women reporting abstinence at 4 weeks post quit date.</td></tr>
<tr><td>Critical outcomes measures and effect size. (time points)</td><td>Take up of provision following opt-out
<u>Engagement with stop smoking service during pregnancy (after versus before implementation of intervention)*</u>

<table>
<tr><td colspan="2" rowspan="2"></td><td colspan="2">Outcome – women who set a quit date</td><td rowspan="2">Total</td><td rowspan="2">RR (95% CI)**</td></tr>
<tr><td>Yes</td><td>No</td></tr>
<tr><td rowspan="3">Intervention-opt-out referral</td><td>Yes</td><td>121</td><td>300</td><td>421</td><td rowspan="3">1.46 (1.11 to 1.93)</td></tr>
<tr><td>No</td><td>57</td><td>233</td><td>290</td></tr>
<tr><td>Total</td><td>178</td><td>533</td><td>711</td></tr>
</table>
*Engagement defined as setting a quit date with SSS support. Includes pregnant women who were successfully contacted by the SSS within 24 weeks after referral.
** Calculated by the review team based on referrals received by stop smoking services.

Abstinence from smoking during pregnancy
<u>Smoking cessation 4-weeks after the quit date following opt-out referral (after versus before implementation of intervention)*</u>

<table>
<tr><td colspan="2" rowspan="2"></td><td colspan="2">Outcome – stopping smoking 4 weeks after setting quit date</td><td rowspan="2">Total</td><td rowspan="2">RR (95% CI)**</td></tr>
<tr><td>Yes</td><td>No</td></tr>
<tr><td></td><td>Yes</td><td>93</td><td>328</td><td>421</td><td>1.39 (1.01 to 1.92)</td></tr>
</table></td></tr>
</table>

<table>
<tr><td>Bibliographic reference/s</td><td colspan="6">Campbell Katarzyna A, Cooper Sue, Fahy Samantha J, Bowker Katharine, Leonardi-Bee Jo, McEwen Andy, Whitemore Rachel, and Coleman Tim (2017) 'Opt-out' referrals after identifying pregnant smokers using exhaled air carbon monoxide: impact on engagement with smoking cessation support. Tobacco control 26(3), 300-306</td></tr>
<tr><td>Study name</td><td colspan="6">Campbell 2017</td></tr>
<tr><td></td><td colspan="6">
<table>
<tr><td rowspan="2">Intervention-opt-out referral</td><td>No</td><td>46</td><td>244</td><td>290</td><td rowspan="2"></td></tr>
<tr><td>Total</td><td>139</td><td>572</td><td>711</td></tr>
</table>
*Quit rates were self-reported. Abstinence from smoking of an at least 2-week duration recorded at 4 weeks after starting a quit attempt.
** Calculated by the review team based on referrals received by stop smoking services.
</td></tr>
<tr><td>Important outcomes measures and effect size. (time points)</td><td colspan="6">None reported.</td></tr>
<tr><td>Statistical Analysis</td><td colspan="6">Statistical analysis was used to compare age and IMD quintiles between smokers who set a quit date before and after implementation of opt-out referral using x^2 and t-tests (based on the table presented previously showing participant characteristics). Women who set a quit date were of similar age (t = 0.1226, p = 0.9026) and from equally highly deprived areas (x^2 = 2.8263, p = 0.587).</td></tr>
<tr><td>Risk of bias (ROB)
ROBINS-I tool</td><td colspan="6">Take up of provision following opt-out
<table>
<tr><th>Outcome</th><th>Judgement</th><th>Comments</th></tr>
<tr><td>Random sequence generation</td><td>High</td><td>Before and after study</td></tr>
<tr><td>Allocation concealment</td><td>High</td><td>Before and after study</td></tr>
<tr><td>Baseline outcome measurements similar</td><td>Unclear</td><td>Matching before and after time periods controlled for the possible effects of annual stop smoking campaigns.</td></tr>
<tr><td>Baseline characteristics similar</td><td>Low</td><td>There were no significant differences between women from both before and after periods that set a quit date in relation to age and from deprivation.</td></tr>
<tr><td>Incomplete outcome data</td><td></td><td>Intervention is well defined.
There was no adjustment for important confounders.</td></tr>
<tr><td>Knowledge of the allocated interventions adequately prevented during the study</td><td>High</td><td></td></tr>
<tr><td>Protection against contamination</td><td>Unclear</td><td>The pregnancy lead to offer face-to-face support</td></tr>
</table>
</td></tr>
</table>

Bibliographic reference/s	**Campbell Katarzyna A, Cooper Sue, Fahy Samantha J, Bowker Katharine, Leonardi-Bee Jo, McEwen Andy, Whitemore Rachel, and Coleman Tim (2017) 'Opt-out' referrals after identifying pregnant smokers using exhaled air carbon monoxide: impact on engagement with smoking cessation support. Tobacco control 26(3), 300-306**		
Study name	Campbell 2017		
			to pregnant smokers following implementation, was discontinued due to lack of demand. It is not clear what impact this deviation may have had on the outcomes reported. Some women were referred without an entry of a CO reading. Outcome assessors were not reported as being blinded.
	Selective outcome reporting	High	Study used routine data rather than data collected specifically for research and limited results are reported. As such, it is not clear whether data was omitted or not.
	Other risks of bias	Unclear	Sample may not be generalisable to other settings, based on the trust providing services to an area with higher smoking rates than the national average.
	Overall Risk of Bias	High	
	Other outcome details: As above.		
Source of funding	National Institute for Health Research (NIHR)		
Comments	Some referred women had no entry of receiving CO testing, although referral without screening would not likely occur and so the pathway may have been implemented more comprehensively than the study reports. Opt-out pathway was introduced alongside existing opt-in referrals.		
Additional references	None		

Sloan 2016

Bibliographic reference	**Sloan Melanie, Campbell Katarzyna A, Bowker Katharine, Coleman Tim, Cooper Sue, Brafman-Price Barbara, and Naughton Felix (2016) Pregnant Women's Experiences and Views on an "Opt-Out" Referral Pathway to Specialist Smoking Cessation Support: A Qualitative Evaluation. Nicotine & tobacco research: official journal of the Society for Research on Nicotine and Tobacco 18(5), 900-5**	
Trial registration	Not reported	
Study type	Qualitative	
Study dates	Women attending the 12-week scan between August and November 2013 were asked for consent to be interviewed (dependent on carbon monoxide test reading).	
Aim	To explore the views and experiences of pregnant smokers participating in routine carbon monoxide testing and an opt-out referral pathway.	
Country/geographical location	United Kingdom	
Setting/School type	UK hospital trust	
Inclusion criteria	No specific inclusion criteria	
Exclusion criteria	No specific exclusion criteria.	
Intervention	**TIDieR Checklist criteria**	**Details**
	Brief Name	Opt-out referral pathway
	Rationale/theory/Goal	Not reported
	Materials used	Not reported
	Procedures used	At the 12 week dating scan women were introduced to a routine carbon monoxide (CO) breath test to determine smoking status. Women with a reading of at least 4 parts per million (ppm) were referred to the stop smoking service (SSS) unless they specifically declined (opted out).
	Provider	Health support worker (HSW) provided referral Stop smoking services provided specialist smoking cessation support.
	Method of delivery	SSS to initiate support by contacting women twice, or if unsuccessful sent a letter to invite them to call for support.
	Location	Pathway was introduced in antenatal clinic in a hospital trust.
	Duration	Not reported.
	Intensity	NA
	Tailoring/adaptation	NA
	Modifications	NA
	Planned treatment fidelity	NA

<table>
<tr><td>Bibliographic reference</td><td colspan="2">Sloan Melanie, Campbell Katarzyna A, Bowker Katharine, Coleman Tim, Cooper Sue, Brafman-Price Barbara, and Naughton Felix (2016) Pregnant Women's Experiences and Views on an "Opt-Out" Referral Pathway to Specialist Smoking Cessation Support: A Qualitative Evaluation. Nicotine & tobacco research: official journal of the Society for Research on Nicotine and Tobacco 18(5), 900-5</td></tr>
<tr><td></td><td>Actual treatment fidelity</td><td>NA</td></tr>
<tr><td></td><td>Other details</td><td>Not reported</td></tr>
<tr><td>Comparison</td><td>TIDieR Checklist criteria</td><td>Details</td></tr>
<tr><td></td><td>Brief Name</td><td>No comparison</td></tr>
<tr><td>Follow up</td><td>Not applicable</td><td></td></tr>
<tr><td>Qualitative methods</td><td>Research question(s)</td><td>To explore the views and experiences of pregnant smokers participating in routine carbon monoxide testing and an opt-out referral pathway</td></tr>
<tr><td></td><td>Theoretical approach</td><td>Not reported</td></tr>
<tr><td></td><td>Data collection</td><td>Two female university researchers conducted telephone interviews between December 2013 and June 2014. Interviews lasted between 18-46 minutes and were recorded and transcribed.</td></tr>
<tr><td></td><td>Method and process of analysis</td><td>5 key stages of analysis included:
Study of transcripts
Identifying and refining themes
Developing a coding scheme
Coding the data
Amalgamating the extracts from individual transcripts with others of the same theme.
The framework method was used for the analysis of data within and between groups. Three independent reviewers assessed 20% of transcripts to check consistency of coding/analysis.</td></tr>
<tr><td></td><td>Population and sample collection</td><td>18 women were interviewed with varying smoking levels (ranging 3-40 cigarettes/daily, at interview 4 had quit smoking, 11 reported cutting down and 3 women no change). Gestation at interview was at least 16 weeks, most between 17-24 weeks, whilst 3 women were interviewed post-partum.
<table>
<tr><th>Characteristic</th><th>Number (%)</th></tr>
<tr><td>Age:
18-21
22-25
26-29
≥30
Missing</td><td>
6 (33)
5 (28)
3 (17)
3 (17)
1 (6)</td></tr>
<tr><td>Ethnic group:
White British
White European</td><td>
17 (94)
1 (6)</td></tr>
</table>
</td></tr>
</table>

<table>
<tr><td>Bibliographic reference</td><td colspan="3">Sloan Melanie, Campbell Katarzyna A, Bowker Katharine, Coleman Tim, Cooper Sue, Brafman-Price Barbara, and Naughton Felix (2016) Pregnant Women's Experiences and Views on an "Opt-Out" Referral Pathway to Specialist Smoking Cessation Support: A Qualitative Evaluation. Nicotine & tobacco research: official journal of the Society for Research on Nicotine and Tobacco 18(5), 900-5</td></tr>
<tr><td></td><td></td><td colspan="2"><table>
<tr><td>Household socioeconomic classification:
5
7
8</td><td>
1 (6)
10 (56)
7 (39)</td></tr>
<tr><td>Referral to SSS category:
Accepted referral to SSS
Rejected referral to SSS (opted-out)</td><td>
12 (66)
6 (33)</td></tr>
</table></td></tr>
<tr><td rowspan="4">Results</td><td colspan="3">Outcome: Acceptability of intervention</td></tr>
<tr><td>Key themes</td><td colspan="2"></td></tr>
<tr><td>Expectations of the opt-out referral pathway</td><td colspan="2">Women thought that the CO test was just another addition to the routine tests carried out at the dating scan appointment. Despite this, several women felt uncomfortable with the new, unexpected test and felt it was “rather sprung on people”. A number of women stated that they would have preferred to have been given information prior to the test.
“I couldn’t understand why I needed to, because I mean after all my other dating scans I’ve never had to sit and wait for a [CO] appointment straight after…if everyone knew everyone was getting tested, it wouldn’t make smokers feel discriminated against…felt of cornered if you like and singled out”. (referred)</td></tr>
<tr><td>Acceptability of the opt-out referral pathway</td><td colspan="2"><u>CO test</u>
Nearly all women reported that they felt the routine CO test was simple, quick, non-invasive and convenient given that they were already present for their appointment when the test was conducted. A small proportion of women felt that that they were being “checked up on” in the context of the test being conducted to check whether they were being truthful about their smoking status. The issue of trust was again linked with lack of information.
“The feeling is that your being, it’s another thing you’re being checked up on…I don’t think anybody has any objections to it from what I’ve read [on pregnancy forums], it was more the fact that nobody was told why and what…Is the whole point to find out if people are lying? What is the whole purpose of it cos I don’t think it’s ever been explained?” (referred)</td></tr>
</table>

Bibliographic reference	Sloan Melanie, Campbell Katarzyna A, Bowker Katharine, Coleman Tim, Cooper Sue, Brafman-Price Barbara, and Naughton Felix (2016) Pregnant Women's Experiences and Views on an "Opt-Out" Referral Pathway to Specialist Smoking Cessation Support: A Qualitative Evaluation. Nicotine & tobacco research: official journal of the Society for Research on Nicotine and Tobacco 18(5), 900-5	
		Generally, women felt that their health support worker had been non-judgemental and thought the test was a positive tool in obtaining the "truth". A small number of women felt the test negatively impacted their relationship with the health support worker. *"I probably wouldn't have told them the truth because I smoke that much…would say that I smoked less than what I normally do" (referred)* *"Big level of trust isn't it, like, you know, trusting people and trusting what they say…it's not a nice feeling to be, like, told, well you might not be telling the truth we want you to prove it" (opted out*) <u>Referral to SSS</u> There was a divide in opinions on the automatic referral to SSS: 1) Some women were not troubled about the lack of choice due to either wanting support, not feeling forced to accept or seeing the lack of choice as a push to start quitting. *"well I didn't really get a choice about it or anything really, I wasn't that bothered seeing as though I wanted it anyway. I think it's quite good really because it doesn't give people the choice…because then it's sort of pushing them towards it isn't it?" (referred)* 2) Some women were unhappy or expressed negative feelings with the perceived lack of personal choice from the opt-out referral pathway. *"There's people out there who don't like being pushed into something and if they are being pushed into something will react in a bad, like violent way" (opted out).* *"I know it's [CO testing] just routine. I know it's all in the best interests of the baby so I just kind of expected it really but she never asked me if I wanted to [be referred], she just told me that she was referring me to [local SSS]…she made me feel like I had no choice…like I didn't have a voice…but then, you know I should have a choice whether or not I want to go. There was no discussion…it was basically I'm referring you and it made me feel a little bit hopeless like she'd already made her mind up that I wouldn't be able to do it by myself" (opted out).*

Bibliographic reference	Sloan Melanie, Campbell Katarzyna A, Bowker Katharine, Coleman Tim, Cooper Sue, Brafman-Price Barbara, and Naughton Felix (2016) Pregnant Women's Experiences and Views on an "Opt-Out" Referral Pathway to Specialist Smoking Cessation Support: A Qualitative Evaluation. Nicotine & tobacco research: official journal of the Society for Research on Nicotine and Tobacco 18(5), 900-5	
		Several women stated that they had not been able to make an informed decision on the opt-out pathway based on being given a lack of information by the health support worker. *"I think it's the whole informed choice thing again isn't it. It's about having the information there and being told right this is why, this is what we're doing, why we're doing it and this is why it's been brought in place and then you can make an informed decision…because at the moment nobody can object because they don't understand it" (referred).* Methods used to explain the pathway was an important factor in women's perceptions of the referral. Nearly half of the women interviewed felt that they had been given a distinct choice and the method explained to them was more of an opt-in rather than an opt-out referral pathway. *"They just basically told me what it is and asked if I would like to do it or not, gave me the option and I said yeah that's fine" (referred).*
	Impact of the opt-out referral pathway	<u>CO monitoring</u> Most women interviewed felt that seeing their CO reading enhanced their motivation compared with only receiving smoking cessation advice. *"It makes it a lot better actually seeing the numbers than just being told…I just knew as soon as I saw that reading that it would have to be something that I had to do…that I knew I would have to do it a lot quicker" (opted out)* *" It's just physical proof it can harm the baby…you can read on the side of the packet what it's got in it but until you see it you don't know…and it's like every time I go for a ciggie now it's like you're over the limit" (referred).* A few women felt that having a lower reading than they expected provided reassurance that they did not need to quit. *"If it's non-smoker level then there's no reason for me to quit!...if the reading was high then yeah I would be ashamed but because it was quite low it didn't bother me as much" (opted out)* Whilst some women felt well informed of the readings of the CO test, some women reported that they did not receive sufficient information following the test to be able to interpret the reading and health implications.

Bibliographic reference	**Sloan Melanie, Campbell Katarzyna A, Bowker Katharine, Coleman Tim, Cooper Sue, Brafman-Price Barbara, and Naughton Felix (2016) Pregnant Women's Experiences and Views on an "Opt-Out" Referral Pathway to Specialist Smoking Cessation Support: A Qualitative Evaluation. Nicotine & tobacco research: official journal of the Society for Research on Nicotine and Tobacco 18(5), 900-5**		
		"I asked because nobody actually explained what the numbers meant…we didn't get a sheet or anything like that, I think that would have been helpful…yeah it's telling them I'm a smoker but what's the point if like all it's going to say is yes she's a smoker. Well I've told you that! I came back and googled it" (referred). <u>Contact by SSS</u> Majority of women who accepted referral to SS mentioned that they were unaware of attempts of contact by the SSS. Several women suggested that the lack of contact negatively affected their chances of quitting and had received no immediate support from the HSW. *"I thought the phone call was going to come really quickly, just to help me like start everything off you know…quite gutted now. You know I've been trying to do it on my own, I've cut down quite considerably from what I used to do…I just need that little extra push, that encouragement" (referred).* There was mixed feeling towards the impact of the automatic referral on quitting. Several women stated intrinsic motivation to quit was the most important factor irrespective of support from a formal stop smoking service. *"I think at the end of the day if people want to stop smoking, like it or not they do it on their own anyway…I think it is good but at the same time if people don't want to stop they won't so I think it's a bit of a waste of time referring people that don't want to and aren't going to" (opted out).*	
Risk of bias	Item	Yes/No/Can't tell	Comments
	1. Was there a clear statement of the aim of the research?	Yes	Aim of research and population clearly stated
	2. Is a qualitative methodology appropriate?	Yes	Subjective experiences and barriers / facilitators sought.
	3. Was the research design appropriate to	Yes	Interviews were sufficient to obtain views and experiences.

Bibliographic reference	**Sloan Melanie, Campbell Katarzyna A, Bowker Katharine, Coleman Tim, Cooper Sue, Brafman-Price Barbara, and Naughton Felix (2016) Pregnant Women's Experiences and Views on an "Opt-Out" Referral Pathway to Specialist Smoking Cessation Support: A Qualitative Evaluation. Nicotine & tobacco research: official journal of the Society for Research on Nicotine and Tobacco 18(5), 900-5**		
	address the aims of the research?		
	4. Was the recruitment strategy appropriate to the aims of the research?	Can't tell	Whilst true purposive sampling could not take place, women were selected for interview to ensure representation from those individuals who accepted referral and those who made the decision to opt-out and who reported smoking at different levels.
	5. Was the data collected in a way that addressed the research issue?	Yes	Telephone interviews were conducted, recorded and transcribed. Interviews were conducted until no new themes emerged.
	6. Has the relationship between researcher and participants been adequately considered?	Can't tell	No information.
	7. Have ethical issues been taken into consideration?	Yes	Women were asked for consent to be contacted for an interview. Women were provided an information sheet and contacted, with those interested in being interviewed providing verbal consent. No information on ethics approval.
	8. Was the data analysis sufficiently rigorous?	Yes	Methods used in analysis (including organising and comparing data, coding and data management) and to determine themes which are named. Twenty percent of transcripts were independently analysed by 3 researchers to ensure consistency in coding and analysis. There was a focus on deviant cases to increase validity of findings.
	9. Is there a clear statement of findings?	Yes	Findings are explicit, and report both positive and negative views of the opt-out referral pathway. Findings link back to the original research question.

Bibliographic reference	**Sloan Melanie, Campbell Katarzyna A, Bowker Katharine, Coleman Tim, Cooper Sue, Brafman-Price Barbara, and Naughton Felix (2016) Pregnant Women's Experiences and Views on an "Opt-Out" Referral Pathway to Specialist Smoking Cessation Support: A Qualitative Evaluation. Nicotine & tobacco research: official journal of the Society for Research on Nicotine and Tobacco 18(5), 900-5**		
	10. Is the research valuable?	Yes	Several of the findings are in line with other qualitative studies in this area. No assessment to which the evidence can be transferred to other populations, although the researchers state to consider the study findings on how to best implement the pathway on a wider scale in the UK and possibly other developed countries.
Overall risk of bias	Low risk of bias		
Source of funding	National Institute for Health Research (NIHR)		
Comments	Women gave verbal consent before the start of the interview.		

Appendix C –Review protocols

Review protocol for opt-out stop smoking support

ID	Field (based on PRISMA-P	Content
I	Review question	5.1a. Is opt-out provision of stop smoking support for pregnant women who smoke[3] effective and cost effective in increasing uptake of the support and increasing smoking cessation? 5.1b. Is opt-out provision of stop smoking support acceptable to women who are pregnant? What are the barriers and facilitators to taking up the support?
II	Type of review question	Mixed methods
III	Objective of the review	Smoking during pregnancy is associated with a variety of health risks for mother and baby, and is one of the focuses of the new Saving Babies Lives Care Bundle. Whilst PH26 (Smoking: stopping in pregnancy and after childbirth) recommends pregnant women who smoke or have quit within the last two weeks are referred via an opt-out system for specialist stop smoking support, this is not universally implemented. This review aims to ascertain whether providing support on an opt-out basis can increase uptake of stop smoking support, or increase smoking cessation among pregnant women
IV	Eligibility criteria – population/disease/condition/issue/domain	**Included**: Women who are pregnant and who smoke or have quit within the last two weeks. Women who have recently quit are also likely to be eligible for opt out provision under current practice. **Excluded**: Women who are trying to conceive or have recently given birth.

[3] Throughout, smoking refers to the use of all smoked tobacco products.

		Women who quit smoking more than 2 weeks ago. Women who use other substances or use smokeless tobacco products. **Setting** Maternity services and other primary care settings which may refer to or provide stop smoking support.
V	Eligibility criteria – intervention(s)/exposure(s)/prognostic factor(s)	**Included**: Opt-out provision of stop smoking support at any point during pregnancy. Stop smoking support is defined as: • Pharmacological support only • Behavioural support only • Pharmacological and behavioural support. • E-cigarettes (alone or in combination with pharmacological and/or behavioural support) **Excluded**: Minimal interventions which are not classed as stop smoking support for the purposes of this review: self-help material, very brief advice, brief advice, general information on smoking harms or benefits of stopping smoking. Provision not clearly described as being opt-out. Women-and-partner interventions where results for pregnant women are not presented separately.
VI	Eligibility criteria – comparator(s)/control or reference (gold) standard	**Included**: No intervention

		Usual practice Opt-in referral systems Other appropriate comparators, including active interventions.
VII	Outcomes and prioritisation	**Quantitative outcomes (5.1a)** <u>Critical outcomes</u> Smoking status at longest available follow-up prior to birth, and longest total follow-up. Measured as: • Abstinence from smoking (relative risk) Where continued abstinence is presented, this is preferred over point-prevalence abstinence. Point prevalence measures will only be used where no continuous measure is reported. Where biochemically validated measures are available (i.e. saliva cotinine / carbon monoxide validation), these will be preferred to self-reported measures. Self-reported measures will only be used where no validated measure is reported. • Take up of provision following opt-out (relative risk) <u>Important outcomes</u> • Adverse or unintended (positive or negative) effects. • Health-related quality of life (using validated patient-report measures, for example EQ-5D). **Qualitative outcomes (5.1b)**

		Qualitative evidence on opt-out referral systems for pregnant women who smoke will be examined where available. Evidence should relate to views of pregnant women who smoke or who used to smoke on: • The acceptability of opt-out referral systems. **Cost/resource use associated with the intervention** The following outcomes will be extracted in reviews of the health economic evidence, where available: • cost per quality-adjusted life year • cost per unit of effect • net benefit • net present value • cost/resource impact or use associated with the intervention or its components
VIII	Eligibility criteria – study design	**Included study designs**: • Systematic reviews of included study designs • RCTs (including cluster RCTs) • Controlled and uncontrolled before-and-after studies • Interrupted time series <u>Economic studies</u>:

		• Cost-utility (cost per QALY) • Cost benefit (i.e. net benefit) • Cost-effectiveness (Cost per unit of effect) • Cost minimization • Cost-consequence <u>Qualitative studies:</u> • Focus groups, interview-based studies or surveys with open-ended responses. Must be related to opt-out provision of stop smoking support in pregnant women. **Excluded study designs**: • Cohort studies • Cross-sectional surveys (except for qualitative data) • Correlation studies • Case control studies
IX	Other inclusion exclusion criteria	**Studies** This review is the result of a gap identified in PH26 by the 2015 review surveillance report. This is a new review for the Tobacco update. **Exclusion criteria**

		Only studies carried out in OECD countries will be included (for effectiveness data) and in the UK (for qualitative data). Only studies published in 1998 onwards will be included. Only full published studies (not protocols or summaries even where they include some data) will be included. **Systematic Review** Relevant systematic reviews (SRs) identified from database searches will be citation searched. Highly relevant systematic reviews may be included as a primary source of data. These SRs will be assessed against the inclusion criteria for this protocol, and their quality will be assessed using the ROBIS tool. Where the SR is highly relevant and of high quality, details or data from the systematic review may be used. In addition to any SRs meeting the above criteria, other primary studies will be included if they were published after the publication date of the SR and meet the protocol inclusion criteria. Full economic analyses and costing studies identified from searches will be included. Costing data will not be used for the purpose of the effectiveness review. Health economics reviews and modelling will be conducted by the York Health Economics Consortium (YHEC). Only papers published in the English language will be included.

X	Proposed sensitivity/sub-group analysis, or meta-regression	The following factors will be of interest in any meta-regression or subgroup analysis:
		
		• Person delivering the stop smoking support
		  ○ referred to as part of a formal stop smoking service vs. by the individual identifying smoking
		• Age of mother
		  ○ mothers <25 vs mothers 25+
		• Deprivation
		  ○ deprived vs not deprived, as defined by study
		• Quit status of mother

		○ recently quit (within last 2 weeks) vs not yet quit at point of referral ○ first quit attempt vs previous quit attempts
XI	Selection process – duplicate screening/selection/analysis	The review will use the priority screening function within the EPPI-reviewer systematic reviewing software. Double screening will be carried out for 10% of titles and abstracts by a second reviewer. Disagreements will be resolved by discussion. Inter-rater reliability will be assessed and reported. If below 90%, a second round of 10% double screening will be considered. The study inclusion and exclusion lists will be checked with members of the PHAC to ensure no studies are excluded inappropriately.
XII	Data management (software)	EPPI Reviewer will be used: • to store lists of citations • to sift studies based on title and abstract • to record decisions about full text papers • to order freely available papers via retrieval function • to request papers via NICE guideline Information Services • to store extracted data Cochrane Review Manager 5 will be used to perform meta-analyses. Any meta-regression analyses will be undertaken using the R software package. Qualitative data will be summarised using secondary thematic analysis. A matrix approach will be used to compare findings with quantitative evidence.
XIII	Information sources – databases and dates	The following methods will be used to identify the evidence: • the databases listed below will be searched with an appropriate strategy. • the websites listed below will be searched or browsed with an appropriate strategy. • studies included in the evidence reviews for PH26 which support the recommendations that are being updated and potentially meet the criteria for the current review will be added to the search results. • studies included in the surveillance reviews for PH26 will be added to the search results.

		• selected studies that are potentially relevant to the current review will be identified from the bibliography of any systematic reviews identified during the search process that are not being included in their own right. • forward citation searching and reference harvesting will be done using selected studies prioritised from the surveillance reviews, the studies included in PH26, scoping searches or any relevant systematic reviews identified in the search process. **Database strategies** The database strategy will be adapted as appropriate from the one used in PH26 in 2009, taking into account the resources available to this review, the subscriptions that NICE has, changes in indexing policies and the final scope for the current evidence review. The principal search strategy is listed in Appendix A. The search strategy will take this broad approach: (smoking OR tobacco OR cigarettes OR shisha) AND (pregnancy OR maternity services OR obstetrics OR midwifery) AND (referral OR opt in OR opt out) AND 1998-Current AND Limits Feedback on the principal database strategy will be sought from PHAC members. The principal search strategy will be developed in MEDLINE (Ovid interface) and then adapted, as appropriate, for use in the other sources listed, taking into account their size, search functionality and subject coverage. The databases will be: • British Nursing Index (BNI) via HDAS • Cochrane Central Register of Controlled Trials (CENTRAL) via Wiley • Cochrane Database of Systematic Reviews (CDSR) via Wiley • Cumulative Index to Nursing and Allied Literature (CINAHL) via HDAS • Embase via Ovid

		• Health Management Information Consortium (HMIC) via Ovid • MEDLINE via Ovid • MEDLINE-in-Process (including Epub Ahead-of-Print) via Ovid • PsycINFO via Ovid • Social Policy and Practice (SPP) via Ovid **Database search limits** Database functionality will be used, where available, to exclude: • non-English language papers • animal studies • editorials, letters and commentaries • conference abstracts and posters • registry entries for ongoing or unpublished clinical trials • duplicates. Sources will be searched from 1998 to current. The database search strategies will not use any search filters for specific study types. **Cost effectiveness evidence** A separate search will be done for cost effectiveness evidence. The search filter listed in Appendix A will be applied to the principal search strategy. The following databases will be searched again: • Embase via Ovid • MEDLINE via Ovid • MEDLINE-in-Process (including Epub Ahead-of-Print) via Ovid In addition, the following sources will be searched without study-type filters: • Campbell Collaboration via https://campbellcollaboration.org/library.html • EconLit via Ovid • HTA database via CRD https://www.crd.york.ac.uk/CRDWeb/ • NHS EED via CRD https://www.crd.york.ac.uk/CRDWeb

		The main website results will be rescanned to check if there are any results potentially relevant to cost effectiveness. **Web of Science** Forward citation searching and reference harvesting will be conducted using Web of Science (WOS) Core Collection. Only those references which NICE can access through its WOS subscription will be added to the search results. Only papers published in 1998-Current and in the English language will be included in the search results. Duplicates will be removed in WOS before downloading. **Websites** The following websites will be searched with an appropriate strategy: • Health Services/Technology Assessment Texts (HSTAT) https://www.ncbi.nlm.nih.gov/books/NBK16710 • NICE Evidence Search https://www.evidence.nhs.uk The websites of relevant organisations, including the ones below, will be browsed: • Action on Smoking and Health (ASH) http://ash.org.uk/home • Local Government Association https://www.local.gov.uk • National Centre for Smoking Cessation and Training http://www.ncsct.co.uk • Northern Ireland Assembly http://www.niassembly.gov.uk/ • Public Health England https://www.gov.uk/government/organisations/public-health-england • Royal College of Midwives https://www.rcm.org.uk • Royal College of Nursing https://www.rcn.org.uk • Royal College of Paediatrics and Child Health https://www.rcpch.ac.uk/ • Royal College of Physicians https://www.rcplondon.ac.uk • Scottish Government https://www.gov.scot • Smoking Toolkit Study http://www.smokinginengland.info • UK Centre for Tobacco and Alcohol Studies http://ukctas.net/index.html

		• University of Bath Tobacco Control Research Group https://researchportal.bath.ac.uk/en/organisations/uk-centre-for-tobacco-control-studies • University of Stirling Centre for Tobacco Control Research https://www.stir.ac.uk/about/faculties-and-services/health-sciences-sport/research/research-groups/centre-for-tobacco-control-research/publications • Welsh Government https://gov.wales/?lang=en • World Health Organization Europe http://www.euro.who.int/en/health-topics/disease-prevention/tobacco The website results will be reviewed on screen and documents in English and published from 1998-Current that are potentially relevant will be listed with their title and abstract (if available) in a Word document. The initial screening decision will be made using this Word file. Any items selected for review at full text will be added to EPPI-Reviewer. **Quality assurance** The guidance Information Services team at NICE will quality assure the principal search strategy and peer review the strategies for the other databases. Any revisions or additional steps will be agreed by the review team before being implemented. Any deviations and a rationale for them will be recorded in the search history document. **Search results** The database search results will be downloaded to EndNote before duplicates are removed using automated and manual processes. The de-duplicated file will be exported in RIS format for loading into EPPI-Reviewer for data screening.
XIV	Identify if an update	This question is a new question for the Tobacco update.
XV	Author contacts	Please see the guideline development page
XVI	Highlight if amendment to previous protocol	For details please see section 4.5 of Developing NICE guidelines: the manual

XVII	Search strategy – for one database	For details please see appendix B.
XVIII	Data collection process – forms/duplicate	A standardised evidence table format will be used and published as appendix D (effectiveness evidence tables) or H (economic evidence tables).
XIX	Data items – define all variables to be collected	For details please see evidence tables in appendix D (effectiveness evidence tables) or H (economic evidence tables).
XX	Methods for assessing bias at outcome/study level	Standard study checklists will be used to critically appraise individual studies. For details please see Appendix H of Developing NICE guidelines: the manual The risk of bias across all available evidence will be evaluated for each outcome using an adaptation of the 'Grading of Recommendations Assessment, Development and Evaluation (GRADE) toolbox' developed by the international GRADE working group http://www.gradeworkinggroup.org/ GRADE will be used to assess confidence in the findings from quantitative evidence synthesis. GRADE-CERQual will be used to assess confidence in the findings from qualitative evidence syntheses.
XXI	Criteria for quantitative synthesis (where suitable)	For details please see section 6.4 of Developing NICE guidelines: the manual Non-randomised studies are at risk of confounding. These studies should adjust for confounders which are decided by the committee to have important potential to affect the result, or the allocation into intervention or control groups. These factors are: - Peer or family smoking - Baseline smoking status (where sample includes people who smoke) - Socioeconomic status Where adjusted results are provided, these will be used in analysis. Where no adjustment has taken place, this will be considered when assessing risk of bias.

XXII	Methods for analysis – combining studies and exploring (in)consistency	**Heterogeneity** Data from different studies will be pooled in a meta-analysis where they are investigating the same outcome and where the resulting meta-analysis may be useful for decision-making. Cluster and individual randomised controlled trials will be pooled. Randomised and non-randomised controlled studies investigating the same outcomes will be pooled. Results will be stratified by design (cluster, individual, randomised and non-randomised for a maximum of four groups stratified) and the P value of the interaction between study design and effect evaluated. A P value of <0.2 will be considered significant. If interaction is significant, results will be presented separately for each group, but if not, will be presented with one averaged effect estimate. It is anticipated that studies included in the review will be heterogeneous with respect to participants, interventions, comparators, setting and study design. Where significant between study heterogeneity in methodology, population, intervention or comparator is identified by the reviewer in advance of data analysis, random effects models will be used. If methodological heterogeneity is not identified in advance but the I^2 value is ≥50%, random effects models will also be used. If the I^2 value is above 50%, heterogeneity will be judged to be serious and so will be downgraded by one level in GRADE. If the I^2 value is above 75%, heterogeneity will be judged to be very serious and will be downgraded by two levels in GRADE. If the studies are found to be too heterogeneous to be pooled statistically, a narrative synthesis will be conducted. **Imprecision** No minimally important difference (MID) thresholds relevant to this guideline were identified from the COMET database or other published source. MIDs were agreed by committee. Uncertainty is introduced where confidence intervals cross the MID threshold. If the confidence interval crosses one lower MID threshold, this indicates 'serious' risk of imprecision. Crossing both MID thresholds indicates 'very serious' risk of imprecision in the effect estimate. Where the MID is

		'any significant change' there is effectively only one threshold (the line of no effect), and so only one opportunity for downgrading. In this instance, outcomes will be downgraded again if they are based on small samples (<300 people). MIDs for outcomes will be included in the methods section of the individual reviews.
XXIII	Meta-bias assessment – publication bias, selective reporting bias	For details please see Appendix H of Developing NICE guidelines: the manual.
XXIV	Assessment of confidence in cumulative evidence	For details please see sections 6.4 and 9.1 of Developing NICE guidelines: the manual.
XXV	Rationale/context – Current management	For details please see the introduction to the evidence review.
XXVI	Describe contributions of authors and guarantor	A multidisciplinary committee will develop the guideline. The committee will be convened by Public Health Internal Guidelines Development (PH-IGD) team and chaired by Sharon Hopkins in line with section 3 of Developing NICE guidelines: the manual. Staff from Public Health Internal Guidelines Development team will undertake systematic literature searches, appraise the evidence, conduct meta-analysis where appropriate and draft the guideline in collaboration with the committee. Cost-effectiveness analysis will be conducted by YHEC where appropriate. For details please see Developing NICE guidelines: the manual.
XXVII	Sources of funding/support	PH-IGD is funded and hosted by NICE
XXVIII	Name of sponsor	PH-IGD is funded and hosted by NICE
XXIX	Roles of sponsor	NICE funds PH-IGD to develop guidelines for those working in the NHS, public health and social care in England.
XXX	PROSPERO registration number	CRD42019133445

Appendix D – Literature search strategies

Search approach

The MEDLINE searches below were run after QA, peer review and consultation with the committee. The strategies were adapted as appropriate to the other databases listed in the protocol (see the sources tables below). The searches were done between 9-10 April 2019.

Additional search results were obtained from the surveillance review for PH26, scoping searches and from forwards citation searching and reference checking using Web of Science.

A joint search for grey literature was done for review questions on opt-out stop smoking support and incentives during pregnancy using the websites listed in the protocol. This was due to both review questions being closely related and overlap in the search terms.

Full details of all the search strategies are available in a separate document from the NICE guidance Information Services team.

Sources searched to identify the evidence

Database name	Date searched	Database Platform	Database segment or version	No. of records
British Nursing Index (BNI)	09/04/2019	HDAS	1992 to present	50
Cochrane Central Register of Controlled Trials (CENTRAL)	09/04/2019	Wiley	Cochrane Central Register of Controlled Trials Issue 4 of 12, April 2019	180
Cochrane Database of Systematic Reviews (CDSR)	09/04/2019	Wiley	Cochrane Database of Systematic Reviews Issue 4 of 12, April 2019	13
Cumulative Index to Nursing and Allied Literature (CINAHL)	09/04/2019	HDAS	1981 to present	239
Embase	09/04/2019	Ovid	Embase 1974 to 2019 April 08	432
Health Management Information Consortium (HMIC)	09/04/2019	Ovid	HMIC Health Management Information Consortium 1979 to January 2019	11
MEDLINE	09/04/2019	Ovid	Ovid MEDLINE(R) 1946 to April 08, 2019	350
MEDLINE-in-Process (including Epub Ahead-of-Print)	09/04/2019	Ovid	Ovid MEDLINE(R) Epub Ahead of Print April 08, 2019, Ovid MEDLINE(R) In-Process & Other Non-Indexed Citations 1946 to April 08, 2019	12
PsycINFO	09/04/2019	Ovid	PsycINFO 1806 to April Week 1 2019	63
Social Policy and Practice (SPP)	09/04/2019	Ovid	Social Policy and Practice 201901	3
Forward citation searching	10/04/2019	Clarivate	Web of Science Core Collection (1990-present)	131
Surveillance	10/04/2019	-		1
Scoping searches	10/04/2019	-		5

Database strategy– main search as run in MEDLINE and adapted for other sources

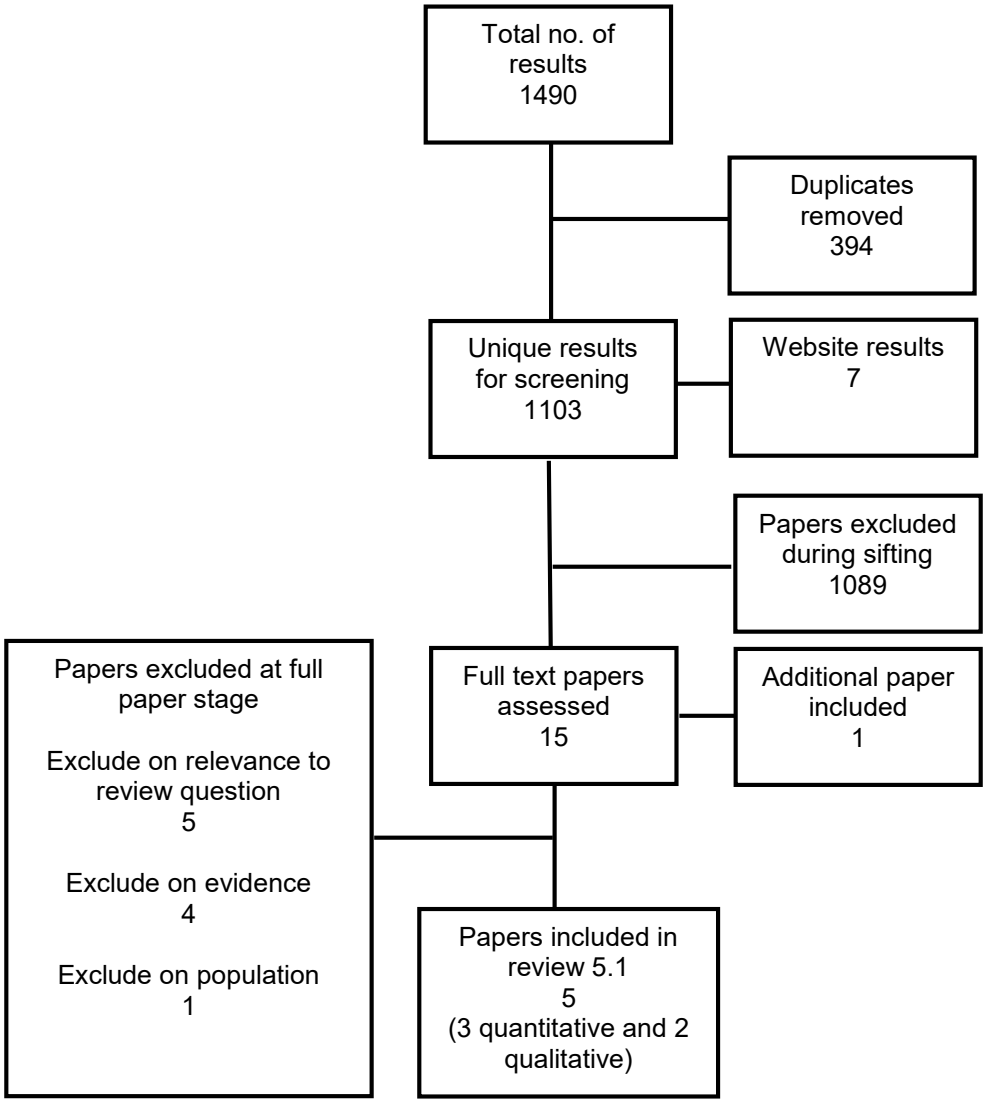
Database(s): **Ovid MEDLINE(R)** 1946 to April 08, 2019

Search Strategy:

#	Searches	Results
1	exp "tobacco use"/	2431
2	tobacco/	29431
3	"tobacco use disorder"/	10617
4	"tobacco use cessation"/	1064
5	"tobacco use cessation devices"/	1556
6	smoking/	135367
7	exp Pipe smoking/	87
8	smoking reduction/	23
9	"smoking cessation"/	26597
10	Smoking cessation agents/	32
11	nicotine/	24526
12	Smokers/	721
13	Ex-smokers/	12
14	exp Smoking Devices/	8349
15	(smoking* or smoker* or antismok* or anti smok* or anti-smok* or exsmoker* or ex-smoker* or "ex smoker*").ti,ab.	207173
16	(tobacco* or nicotin* or cigar* or cigs).ti,ab.	182766
17	(bidi or bidis or beedi or beedis or kretek* or hand roll* or handroll* or rollies).ti,ab.	483
18	(waterpipe* or water pipe* or dokha or dokhas or hookah or hookahs or hooka or hookas or shisha or shishas or sheesha or sheeshas).ti,ab.	1482
19	or/1-18	357576
20	exp Pregnancy/	858264
21	exp Pregnancy complications/	407621
22	Pregnant Women/	7367
23	exp Maternal Health Services/	45672
24	Midwifery/	18494
25	obstetrics/	21712
26	obstetric nursing/	2951
27	nurse midwives/	6950
28	pregnan*.ti,ab.	429285

29	(ante natal* or ante-natal* or antenatal* or pre natal* or pre-natal* or prenatal* or peri natal* or peri-natal* or perinatal*).ti,ab.	163236
30	(maternity* or maternal* or obstetric* or midwif* or midwiv*).ti,ab.	301161
31	or/20-30	1094341
32	19 and 31	24286
33	"Referral and Consultation"/	62688
34	Choice Behavior/	30637
35	Gatekeeping/	645
36	Patient Acceptance of Health Care/	41852
37	Patient compliance/	55402
38	Treatment refusal/	11543
39	("opt in" or "opt out" or "opting in" or "opting out" or "opted in" or "opted out" or "opts in" or "opts out" or default*).ti,ab.	13987
40	((referral* or pathway* or gatekeep*) adj3 (optional* or compulsor* or mandatory* or oblige* or obligation* or obliging* or automatic* or enforc* or impose* or imposing or coerc* or voluntary* or involuntary* or volunteer* or discretion* or compel* or uncompel* or routine*)).ti,ab.	955
41	((treatment* or service* or intervention* or pharmacotherap* or support* or "stop smoking" or SSS or counsel* or therapy* or therapies* or system* or scheme* or program* or initiative*) adj3 (optional* or compulsor* or mandatory* or oblige* or obligation* or obliging* or automatic* or enforc* or impose* or imposing or coerc* or voluntary* or involuntary* or volunteer* or discretion* or compel* or uncompel* or routine*)).ti,ab.	45412
42	((patient* or smoker* or woman* or women* or client*) adj3 (choice* or acceptance* or* unaccept* or refus* or comply* or compliance* or complie* or noncomply* or noncompliance* or noncomplie* or non-comply* or non-compliance* or non-complie* or non comply* or non compliance* or non complie* or cooperat* or uncooperat*)).ti,ab.	42396
43	or/33-42	286090
44	32 and 43	492
45	Animals/ not (Animals/ and Humans/)	4535477
46	44 not 45	479
47	limit 46 to (letter or historical article or comment or editorial or news or case reports)	14
48	46 not 47	465
49	limit 48 to english language	441
50	limit 49 to yr="1998 -Current"	350

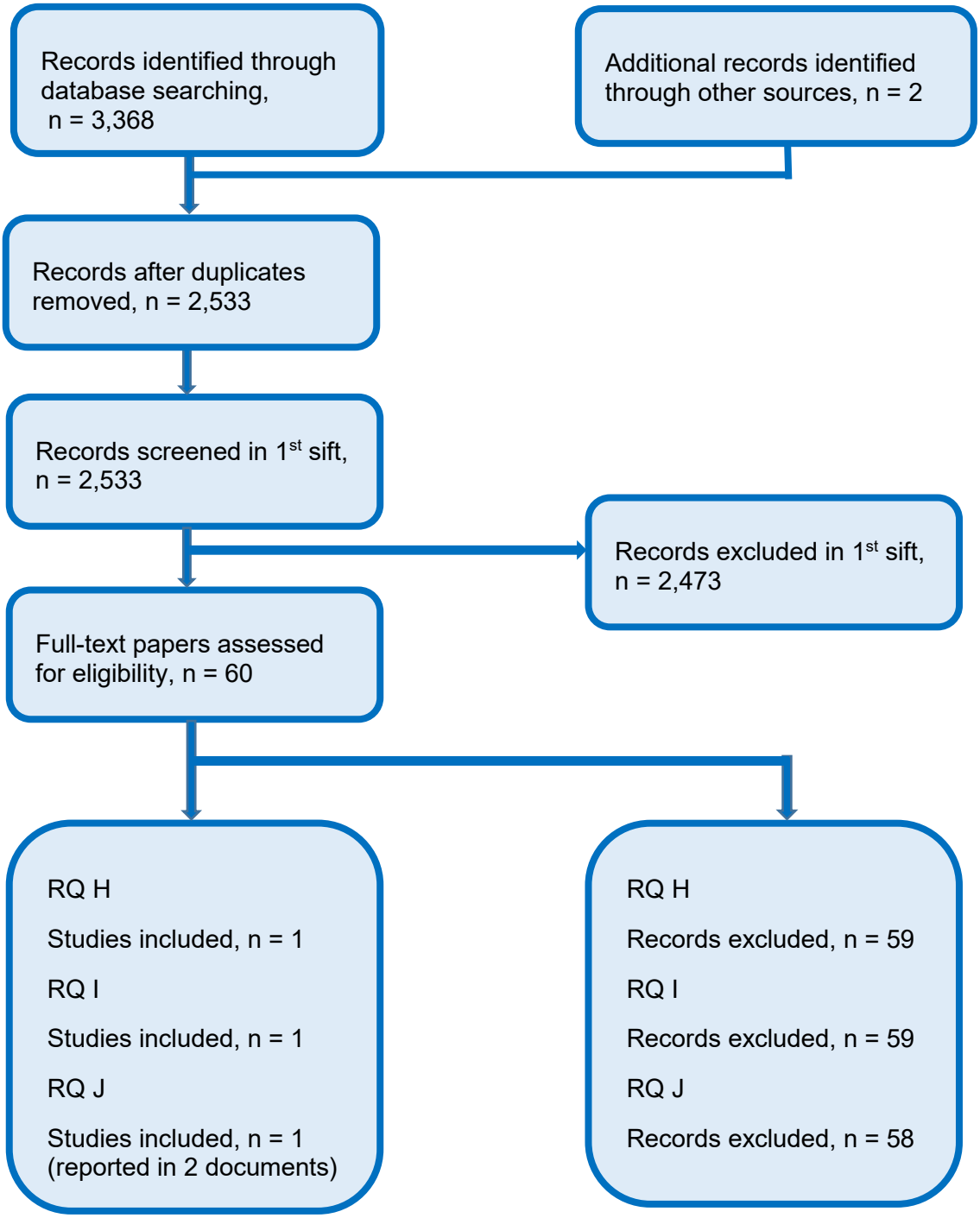
Appendix E – Public health evidence study selection



Appendix F – Economic evidence study selection

The following flowchart shows the record selection process for all three review questions.

Figure 1: Flow chart of economic evidence study selection for the guideline



Appendix G – Economic evidence tables

See health economic evidence profiles in appendix H

Appendix H – Health economic evidence profiles

Table 8: Health economic evidence profiles of studies included in the economic evidence review for opt-out smoking support

Study	Bell 2018			
Study details	**Population & interventions**	**Costs**	**Health outcomes**	**Cost-effectiveness**
Economic analysis: Cost effectiveness analysis (CEA) **Study aim:** To evaluate the effectiveness of a complex intervention (BabyClear) to improve existing provision. BabyClear included referral and treatment of pregnant smokers in routine practice. The study also aimed to assess the incremental costs to the NHS per additional woman quitting smoking. **Study design:** Economic evaluation using an interrupted time series analysis of quit rates. **Approach to analysis:** Quit rates taken from databases of smoking cessation services using	**Population:** Smoking women pregnant with single babies in 8 NHS trusts in North East England Sample size: 10,594 smokers [a] **Intervention:** The study was a before and after design, anchored at the introduction of BabyClear. Prior to the introduction of BabyClear, universal carbon monoxide (CO) monitoring and opt-out referral had not been implemented [b] BabyClear [c]. Package of measures to achieve better uptake	**Total costs:** BabyClear (5 years): £572,009 BabyClear (per baby delivered): £30.69 **Currency & cost year:** GBP £, 2013 **Cost components incorporated:** Direct costs: Training of staff, equipment and consumables Indirect costs: Changes in workload	**Quit rate during pregnancy (smokers and non-smokers):** Before BabyClear: 0.0398 per delivery After BabyClear: 0.072 per delivery	**Cost effectiveness ratios** BabyClear cost £30.69 per delivery with an additional 0.032 quitters per delivery giving a cost per additional quitter with the intervention of £952. The number needed to treat for each additional quitter was 31 pregnant women. (smokers and non-smokers). **Analysis of uncertainty** None undertaken

Study	Bell 2018			
Study details	**Population & interventions**	**Costs**	**Health outcomes**	**Cost-effectiveness**
a before and after analysis. Methods of analysing costs were poorly described ('routine sources' were used for cost sources). **Perspective:** NHS **Time horizon:** Five years **Treatment effect duration:** Limited to cessation at delivery **Discounting:** Not undertaken	of available smoking cessation services: • CO monitors and support materials to midwives who monitored CO at first antenatal appointment with routine-opt-out referral to smoking cessation advice where CO was above four parts per million • Skills training for maternity staff, smoking cessation advisors and administrators within smoking cessation services • An explicit referral pathway to cessation support was developed			
Data sources				
Health outcomes: This was a before and after study that captured the outcomes. **Quality-of-life weights:** Not applicable, the study used a cost-effectiveness analysis model measuring cost per quitter **Cost sources:** Costs were taken directly from the NHS budget for the intervention and unspecified published sources				
Comments				
Source of funding: National Institute for Health Research (NIHR) **Limitations:** Author-recognised limitations: non-randomised study using routinely collected data from organisations that collect data differently, findings may not be generalisable to all settings (e.g. where a lower baseline prevalence of smoking during				

Study	Bell 2018			
Study details	**Population & interventions**	**Costs**	**Health outcomes**	**Cost-effectiveness**
pregnancy is found), the effect of BabyClear beyond 4 months (or in the post-natal period) was not determined (relapse rates are reported to be around 40% postpartum), unintended positive consequences were not quantified (e.g. partners stopping smoking) **Other:** None				
Overall applicability: Partially applicable **Overall quality:** Potentially serious limitations				
Abbreviations: CO: carbon monoxide; PSA: probabilistic sensitivity analysis				

(a) 27,050 non-smokers were also involved

(b) In its description of the intervention, the study implies what the 'prior' smoking cessation services were likely to have been. It describes how in England, the responsibility for commissioning smoking cessation services lies with local authorities, while responsibility for commissioning maternity services lies with NHS England and that antenatal care is delivered by NHS trusts but smoking cessation services may be delivered by a range of community-based providers. It then describes how the intervention was designed to strengthen links between these two services.

(c) Developed by the Tobacco Control Collaborating Centre

Appendix I – Health economic analysis

For full details of the model and results including sensitivity analyses see separate modelling report (Evidence Review P).

Appendix J – Excluded studies

Public health studies

Study Citation	Reason for excluding
Ashwin Cathy, and Watts Kim (2010) Exploring the views of women on using nicotine replacement therapy in pregnancy. Midwifery 26(4), 401-6	**Exclude on relevance**; unclear that intervention is offered on an opt-out basis.
Bellman S, Johnson E J, and Lohse G L (2001) To opt-in or opt-out? It depends on the question. Communications of the Acm 44(2), 25-27	**Exclude on relevance**; not of relevance to review question.
Buchanan Cole, Nahhas Georges J, Guille Constance, Cummings K Michael, Wheeler Cameron, and McClure Erin A (2017) Tobacco Use Prevalence and Outcomes Among Perinatal Patients Assessed Through an "Opt-out" Cessation and Follow-Up Clinical Program. Maternal and child health journal 21(9), 1790-1797	**Exclude on target group** and evidence**;** target group not all pregnant and insufficient data reported for extraction.
Herberts Carolina CPsychol, and Sykes Catherine CPsychol (2012) Midwives' Perceptions of Providing Stop-Smoking Advice and Pregnant Smokers' Perceptions of Stop-Smoking Services Within the Same Deprived Area of London. Journal of Midwifery & Women's Health 57(1), 67	**Exclude on relevance;** unclear that intervention is offered on an opt-out basis.
Hotham Elizabeth D, Atkinson Elinor R, and Gilbert Andrew L (2002) Focus groups with pregnant smokers: Barriers to cessation, attitudes to nicotine patch use and perceptions of cessation counselling by care providers. Drug and Alcohol Review 21(2), 163-168	**Exclude on relevance;** unclear that intervention is offered on an opt-out basis.
Howard L M, Bekele D, Rowe M, Demilew J, Bewley S, and Marteau T M (2013) Smoking cessation in pregnant women with mental disorders: a cohort and nested qualitative study. BJOG : an international journal of obstetrics and gynaecology 120(3), 362-70	**Exclude on evidence** and relevance**;** insufficient data reported for extraction and unclear that intervention is offered on an opt-out basis.
Macaskill, S, Bauld, L, Eadie, D and Tappin, D. (2008) Smoking Cessation Support in Pregnancy in Scotland, Health Scotland, Glasgow.	**Exclude on evidence;** study design is descriptive
McGowan Agnes, Hamilton Shirley, Barnett Deborah, Nsofor Margaret, Proudfoot Judith, and Tappin David M (2010) 'Breathe': the stop smoking service for pregnant women in Glasgow. Midwifery 26(3), e1-e13	**Exclude on evidence;** study design is descriptive
Secker-Walker R H, Solomon L J, Flynn B S, Skelly J M, and Mead P B (1998) Reducing smoking during pregnancy and postpartum: Physician's advice supported by individual counseling. Preventive Medicine 27(3), 422-430	**Exclude on relevance;** unclear that intervention is offered on an opt-out basis.
Westcott Nancy, and Navidad Ana (2018) Incorporating routine carbon monoxide monitoring into antenatal care: developing an opt-out referral system to promote smokefree pregnancy. Women & Birth 31,	**Exclude on evidence;** conference abstract only and no full text available.

Economic studies

Reference	Reason for exclusion
Antonopoulos MS, Bercume CM. Varenicline (Chantix): A new treatment option for smoking cessation. P and T. 2007;32(1):20.	Ineligible patient population

Reference	Reason for exclusion
Askew DA, Guy J, Lyall V, Egert S, Rogers L, Pokino L-A, et al. A mixed methods exploratory study tackling smoking during pregnancy in an urban Aboriginal and Torres Strait Islander primary health care service. BMC Public Health. 2019;19(1):343.	Ineligible study design
Ayadi MF, Adams EK, Melvin CL, Rivera CC, Gaffney CA, Pike J, et al. Costs of a smoking cessation counseling intervention for pregnant women: comparison of three settings. Public Health Rep. 2006;121(2):120-6.	Ineligible intervention
Barker DC. III. Maternal smoking cessation: a cost effective strategy for managed care. Introduction. Tob Control. 2000; 9(Suppl 1): i60. Available from: https://tobaccocontrol.bmj.com/content/9/suppl_1/i60	Ineligible study design
Bauld L, Graham H, Sinclair L, Flemming K, Naughton F, Ford A, et al. Barriers to and facilitators of smoking cessation in pregnancy and following childbirth: literature review and qualitative study. Health Technol Assess. 2017;21(36):1-158.	Ineligible study design
Berlin N, Goldzahl L, Bauld L, Hoddinott P, Berlin I. Public Acceptability of Financial Incentives to Reward Pregnant Smokers Who Quit Smoking: A United Kingdom-France Comparison. Eur J Health Econ. 2018;19(5):697-708.	Ineligible patient population
Boucher J, Konkle ATM. Understanding inequalities of maternal smoking-bridging the gap with adapted intervention strategies. IJERGQ. 2016;13(3):282.	Ineligible study design
Boyd KA, Briggs AH, Bauld L, Sinclair L, Tappin D. Are financial incentives cost-effective to support smoking cessation during pregnancy? Addiction (Abingdon, England). 2016;111(2):360-70.	Ineligible intervention
Buchanan C, Nahhas GJ, Guille C, Cummings KM, Wheeler C, McClure EA. Tobacco Use Prevalence and Outcomes Among Perinatal Patients Assessed Through an "Opt-out" Cessation and Follow-Up Clinical Program. Matern Child Health J. 2017;21(9):1790-97.	Ineligible study design
Canadian Agency for Drugs and Technologies in Health. Smoking cessation interventions for pregnant women and mothers of infants: a review of the clinical effectiveness, safety, and guidelines. Ottawa: CADTH; 2012. Available from: https://www.cadth.ca/smoking-cessation-interventions-pregnant-women-and-mothers-infants-review-clinical-effectiveness.	Ineligible outcomes
Chamberlain C, O'Mara-Eves A, Oliver S, Caird JR, Perlen SM, Eades SJ, et al. Psychosocial interventions for supporting women to stop smoking in pregnancy. (CD001055). London: Cochrane Collaboration; 2013. Available from: https://www.cochranelibrary.com/cdsr/doi/10.1002/14651858.CD001055.pub5/full.	Ineligible study design
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Appendix K – Research recommendations

No research recommendations have been made for review H.