

# National Institute for Health and Care Excellence

## Public Health and Social Care Centre

*Surveillance decision: September 2015*

### Consideration of an update of the public health guideline on 'Quitting smoking in pregnancy and following childbirth' (PH26)

## 1 Background information

Guideline issue date: June 2010

First review date: September 2013

Second review date: September 2015

The current guideline can be found at: <http://www.nice.org.uk/ph26>

## 2 Surveillance decision

NICE guideline on [Quitting smoking in pregnancy and following childbirth](#) will be partially updated as part of the planned guideline on [Smoking cessation interventions and services](#) (which updates PH1 and PH10).

## 3 Surveillance process

Public health guidelines were previously reviewed at 3 year intervals after publication to determine whether all or part of it should be updated. In line with [Developing NICE guidelines: the manual](#), the process for deciding whether guidelines need updating is now usually undertaken every 2 years.

At the [last review](#) of PH26 (2013), several key studies were identified that were ongoing but likely to impact on recommendations in the guideline.

This review only examines the impact of that identified evidence on the recommendations.

## **4 Views of topic experts**

At the last review in 2013, PH26 was reviewed by an expert panel with representation from the Department of Health, academia and practitioners, including representation from the Royal College of Midwifery. The panel highlighted key ongoing research of relevance to the evidence base for the guideline which was due to report over the next 2 years.

The views of topic experts were not sought at this review.

## **5 Consideration of the evidence**

A formal search process was not deemed necessary as key studies had been identified at the previous review in 2013. Of the 5 effectiveness studies identified, all 5 studies have now been published. See Appendix 1 for a summary of these studies.

### ***Impact of the new evidence on the guideline***

An assessment of these studies indicated that they have the potential to influence 3 recommendations:

- Recommendation 1: Identifying pregnant women who smoke and referring them to NHS stop smoking services – action for midwives
- Recommendation 4: NHS stop smoking services – Initial and ongoing support
- Recommendation 5: Use of nicotine replacement therapy (NRT) and other pharmacological support

A summary of how each individual study may influence recommendations is available in Appendix 1, and a summary by intervention is provided below in Table 1.

**Table 1 Summary of evidence impact on guideline**

Evidence grouped by intervention	Likely to impact guideline	Recommendation	Type of impact
Opt-out referral pathway for smoking cessation services (1 study)	?	1	Currently recommendation 1 does implicitly refer to an opt-out approach. This new evidence may potentially make this more explicit; however, the impact may be minimal. The CO cut-off value may also be modified.
Incentives for smoking cessation (1 study)	✓	4	Possible new recommendation on incentives within recommendation 4.
NRT for smoking cessation (3 studies)	✓	5	Possible removal of recommendation on NRT or modification of wording within recommendation 5.

Impact on guideline: ✓ = evidence is likely to impact guideline; ? = evidence potentially may impact guideline. (NB the guideline committee will ultimately decide whether or not new evidence warrants a change to a recommendation, by considering the evidence in the whole alongside the policy and practice landscape and their expertise).

## 6 Related NICE guidance

NICE has a suite of guidelines on smoking cessation and antenatal care. Of particular relevance to PH26 are:

- [Brief interventions and referral for smoking cessation](#) (2006) NICE Public Health guidance 1 (PH1)
- [Smoking cessation services](#) (2008) NICE Public Health guidance 10 (PH10)
- [Smoking cessation in secondary care: acute, maternity and mental health services](#) (2013) NICE Public Health guidance 48 (PH48)
- [Antenatal Care](#) (2008) NICE Clinical Guideline 62 (CG62)

Two of these guidelines (PH1 and PH10) are already scheduled for an update as part of a joint update on [Smoking cessation interventions and services](#). The update of PH1 and PH10 is likely to involve looking for evidence of effective interventions on:

- Very brief advice from a healthcare professional
- Telephone quit lines
- Pharmacotherapies (including NRT)
- Behavioural support for young people
- Interventions for disadvantaged groups
- New media

- Incentives for smoking cessation
- Exercise interventions for smoking cessation

Given the scheduled update of PH1 and PH10, it is likely to be both more efficient and timely to also incorporate the update of NICE guideline on Quitting smoking in pregnancy and following childbirth within this.

Following this update CG62 may need refreshing.

## **7 Related NICE quality standards**

The following quality standards are related to this guideline and may need refreshing following an update of NICE guideline on Quitting smoking in pregnancy and following childbirth:

- [Antenatal Care](#) (2012) NICE Quality Standard 22
- [Smoking cessation: supporting people to stop smoking](#) (2013) NICE Quality Standard 43

## **8 Equality and diversity considerations**

There has been no evidence to indicate that the guideline does not comply with anti-discrimination and equalities legislation.

## **9 Views of stakeholders**

In line with [Developing NICE guidelines: the manual](#) stakeholder views were not sought as the decision is to partially update this guideline. Stakeholders will be able to comment on the draft scope of the [Smoking cessation interventions and services](#) guideline which will partially update PH26. The consultation on this scope is due 29 September to 27 October 2015.

## **10 Discussion**

NICE believe that the [Quitting smoking in pregnancy and following childbirth](#) guideline would benefit from a partial update, taking into account new evidence on opt-out referral pathways for smoking services, incentives for smoking cessation and

NRT for smoking cessation. Terminology and the healthcare and system structures referred to in the guideline also require updating, as will alignment to relevant NICE guidelines.

Given that there is already a scheduled guideline on [Smoking cessation interventions and services](#) (including updates of both PH1 and PH10), it is NICE’s opinion that it would be more efficient and timely to also incorporate the update of PH26 within this.

### Appendix 1 Summary of evidence and potential impact on the guideline

Evidence identified	Potential impact on guideline recommendations
<p>Study: Bauld et al. Implementation of routine biochemical validation and an 'opt out' referral pathway for smoking cessation in pregnancy.            Design &amp; setting: Pilot study in Birmingham, England            Population: 3712 women who entered the referral pathway            Intervention: Opt out self-referral pathway            Comparator: NA            Results: The number of women quitting did not increase during the study when compared with the previous year, despite higher referral rates in both areas.            Conclusion: The introduction of an opt out referral pathway between maternity and stop smoking services resulted in more women being referred for support to quit but not higher numbers of quitters, suggesting that automatic referral may include women who are not motivated to stop and who may not engage with services. Routine carbon monoxide (CO) monitoring introduced as part of a referral pathway should involve a cut-off of 4 p.p.m. to identify smoking in pregnancy.</p>	<p>This evidence provides information on an opt-out referral and also a lower CO cut-off value. As such it may be something a committee would use to modify the cut-off value and make a more explicit mention of opt-out self-referral within recommendation 1 (Identifying pregnant women who smoke and referring them to NHS stop smoking services – action for midwives). However, this evidence alone may only result in minimal changes.</p>
<p>Study: Berlin et al. Nicotine patches in pregnant smokers: randomised placebo controlled, multicentre trial of efficacy.            Design &amp; setting: Double-blind placebo-controlled RCT in France            Population: 476 women aged &gt;18 who smoke at least 5 cigarettes per day, and are 12-20 weeks pregnant            Intervention: 10-30mg daily dose of 16hr nicotine patches, with doses based on participants smoking level, plus behavioural support (N=203)            Comparator: placebo patches plus behavioural support (N=199)            Results: There was no difference in complete abstinence (OR = 1.08, 95% CI 0.45 to 2.60). No difference in birth weight.            Conclusion: Nicotine patches did not increase smoking cessation rates, despite higher than normal doses of nicotine.</p>	<p>This evidence provides a further indication that NRT does not consistently increase smoking cessation rates in pregnant women. As such the addition of this new evidence may be something a committee would use to reconsider the use of NRT in pregnant women and remove or modify the mention of NRT in recommendation 5 (Use of NRT and other pharmacological support).</p>
<p>Study: Cooper et al. The SNAP trial: a randomised placebo-controlled trial of nicotine replacement therapy in pregnancy – clinical effectiveness and safety until 2 years after delivery, with economic evaluation.            Population: 1050 women who smoke currently more than 5 cigarettes per day (at least 10 cigarettes before pregnancy) and 12-24 weeks pregnant            Intervention: 4-8 week supply of 15mg 16hr nicotine patches (N=521)</p>	

<p>Comparator: placebo patches (N=519)</p> <p>Results: There was a significantly increased validated smoking cessation rate at 1 month (OR = 2.05, 95% CI 1.46 to 2.88), but there was a non-significant difference in cessation rates at delivery (OR = 1.26, 95% CI 0.82 to 1.96). Infant outcomes at 2 years: 72.6% survived with no impairment on NRT; 65.5% for placebo (OR=1.40, 95% CI 1.05 to 1.86). Cost per quitter = £4926.</p> <p>Conclusion: This trial provides evidence that NRT is no more effective than placebo. Recommends future trials study higher dose patches, or patches combined with sprays/gum.</p>	
<p>Study: El-Mohandes et al. A randomised controlled trial of trans-dermal nicotine replacement in pregnant African American women.</p> <p>Design &amp; setting: Double-blind placebo-controlled RCT in DC, USA</p> <p>Population: 52 African American smokers aged at least 18 years and &lt;30 weeks pregnant</p> <p>Intervention: CBT plus 10 week dose adjusted NRT (N=26)</p> <p>Comparator: CBT (N=26)</p> <p>Results: There were no significant difference at visits 4 &amp; 5 but there was a significant difference at visit 3 (23% versus 0% quit rate; p=0.02) and visit 6 (19% versus 0% quit rate; p=0.05).</p> <p>Conclusion: The sample size was too small to reach conclusive results.</p>	
<p>Study: Tappin et al, Financial Incentives for smoking cessation in pregnancy: RCT.</p> <p>Design &amp; setting: Phase II superiority RCT in NHS Greater Glasgow &amp; Clyde</p> <p>Population: 612 self-reported pregnant smokers, aged over 16, &lt;24 weeks pregnant, and with CO of <math>\geq</math> 7ppm</p> <p>Intervention: Usual care plus financial incentive (N=306)</p> <p>Comparator: usual care (N=306)</p> <p>Results: There was a significantly increased smoking cessation rate at the end of pregnancy (RR = 2.63, 95% CI 1.73 to 4.01).</p> <p>Conclusion: This trial provides evidence of incentives increasing smoking cessation in pregnancy. However, further evidence is needed in different parts of the UK and different settings.</p>	<p>This evidence suggests that incentives may be an effective intervention for smoking cessation in pregnant women. It may be something a committee would use to make a new recommendation on the use of incentives within recommendation 4 (Initial and ongoing support).</p>

## References

Bauld L, Hackshaw L, Ferguson J, Coleman T, Taylor G, Salway R. Implementation of routine biochemical validation and an 'opt out' referral pathway for smoking cessation in pregnancy. *Addiction*. 2012 Dec;107 Suppl 2:53-60.

Berlin I, Grangé G, Jacob N, Tanguy ML. Nicotine patches in pregnant smokers: randomised, placebo controlled, multicentre trial of efficacy. *BMJ*. 2014 Mar 11;348:g1622.

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