Author's response to reviews

Title: The effectiveness of financial incentives for smoking cessation during pregnancy: Is it from being paid or from the extra aid?

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Author's response to reviews: see over
Dear Dr van Teijlingen,

In reference to your email sent on behalf of the BMC Pregnancy & Childbirth Editorial Board, dated the 20th December 2011, we are grateful to you and the Board for reviewing our submitted manuscript entitled “The effectiveness of financial incentives for smoking cessation during pregnancy: Is it from being paid or from the extra aid?” and giving us the opportunity to respond on four points from Referee 1 and eight points from Referee 2, as detailed below:

Referee 1:

1. It would be helpful to further clarify the ‘opportunistic sampling frame’ used for this study and to clarify the recruitment procedures. Why were the groups different in size? How were the 78 participants selected whom the interviewer approached by telephone? What were the considerations for data saturation in both groups? In particular for the different experiences of the smoking cessation services it would be good to be reassured that the data was sufficient to support the interpretations made in this manuscript.

We acknowledge that description of the processes involved in selecting the participants was insufficient. We hope that the following information, in addition to the revisions we have made to the manuscript (see details below), clarify any uncertainties.

The difference in the number of participants recruited in each group (i.e. 20 in the incentivised group and 16 in the control group) reflects the difference in the number of women who had enrolled in the pilot financial incentives scheme vs. the comparison cohort, at the time the interviews took place. Although the aim of the pilot financial incentives scheme was to recruit 200 pregnant smokers and to compare their progress to that of 200 in the comparison cohort, at the time the current study was conducted, 91 women had enrolled in the pilot scheme and only 24 were eligible to be part of the comparison cohort (i.e. lived in areas within Birmingham selected as the “comparison” areas and had enrolled in the NHS Stop Smoking Services). These 115 pregnant smokers were the population from which the sample for the qualitative study was selected. Of the 91 women in the pilot scheme, 81 agreed at enrolment to be contacted about an interview. From these 81 the interviewer (EM) telephoned women in the order in which they had been recruited until 20 individuals had consented to be interviewed. Fifty-eight (n=58) women were contacted for this target to be met. All 24 women in the comparison cohort were contacted by a research midwife, who informed them about the possibility of being interviewed, and 20 agreed to be contacted by the interviewer. All these women were approached by the interviewer and 16 consented to be interviewed. In total, 78 pregnant smokers were approached by the interviewer to obtain the final sample of 36 women.

We have revised the manuscript to provide more detail on recruitment by adding the following information:

Participants were recruited through an opportunistic sampling frame involving a population of 115 pregnant smokers living in the greater Birmingham area, who were referred by their midwives to the NHS Stop-Smoking Services during the period September 2009 to May 2010 and:

i) were enrolled in a pilot scheme of incentivising smoking cessation run by the Birmingham East & North Primary Care Trust (BEN PCT), (in partnership with the Young Foundation as part of the Healthy Incentives (HI) Partnership (www.healthyincentives.org.uk), or
The financial incentive scheme pilot aimed to enrol 200 pregnant smokers by the end of 2010 and to compare their smoking cessation rates against those of a comparison cohort of 200 women, recruited for evaluation purposes from parts of the PCT where financial incentives were not offered. (page 5: lines 25-29)

At the time the current study was conducted, 91 women were enrolled in the pilot financial incentives scheme, of whom 81 consented to be contacted for an interview. We aimed to recruit 20 of these women for the interview and achieved this with telephone calls to the first 58. Furthermore, 24 pregnant smokers had been recruited into the comparison cohort, of whom 20 consented to be contacted for an interview. All these women were contacted and 16 agreed to be interviewed. (page 5: lines 31-36)

With regards to data saturation the following considerations informed our sample size:

i) Guest et al (2006)* recommend that for a group of relatively homogeneous individuals twelve interviews suffice for data saturation to be achieved. Others have recommended smaller sample sizes, for example Kuzel (1992)* suggests between six and eight interviews and Morse (1995)* at least six. Recruiting more than 12 in each group (and more than double this overall) is therefore highly likely to be sufficient to capture much of the range of women’s smoking cessation experiences and allow for exploration of some between-group differences.

ii) Analysis revealed that saturation was achieved by the 15th interview with regards to women’s reasons for wanting to quit smoking during pregnancy and to the factors they perceived as influencing their quit attempts was achieved in both groups. So although only 16 women were recruited from the comparison cohort (control group), the size of both groups seems sufficiently large to capture the range of women’s smoking cessation experiences.

These considerations are reflected in the following additions we have made to the manuscript:

Following recommendations by Guest et al (2006) [23], as well as those by Kuzel (1992) [24] and Morse (1995) [25], this sample size is considered sufficient for achieving data saturation. Saturation of data for the themes of interest was achieved in both groups by the 15th interview, suggesting that the group sizes were sufficiently large to capture the range of women’s smoking cessation experiences. (page 5: lines 38-42)

2. For the geographic area this study was conducted in it seems surprising/unusual that 34 out of 36 pregnant woman were classified as white British. Would the authors comment on possible reasons for non-white british people potentially being underrepresented in their sample?

Given that one third of the population in Birmingham (where this study was conducted) belongs to an ethnic minority group (www.birmingham.gov.uk/census)*, the referee is justified in being

* The full reference can be found in the manuscript
concerned that perhaps non-white women were underrepresented our sample. Women of ethnic minority groups are however:

i) less likely than the general population to smoke (National Statistics, 2006)*
ii) less likely than white women to smoke while pregnant (Hawkins et al, 2008)*
iii) less likely than white women to set a quit date with the NHS Stop Smoking Services (The NHS Information Centre for Health and Social Care, 2011)* (implying perhaps that are less likely than white women to use the services)

The study’s sample therefore seems representative both of pregnant smokers in general and of pregnant smokers who access the NHS Stop Smoking Services, which we have now explained in the manuscript:

Although, minority ethnic groups constitutes approximately one third of the Birmingham city’s population (with the Pakistani being the largest minority group followed by the Indian) [24], women from minority ethnic groups are less likely to smoke compared to the general population. [25] Compared to white women, they are also less likely to smoke during pregnancy [26] and are less likely to set quit dates with the stop smoking services. [27]

3. How comparable were the two groups? My understanding of the recruitment and consent procedures is that women in the FI scheme agreed to be interviewed when they were initially allocated to the FI scheme whereas women allocated to the standard Smoking cessation services appear to be invited to take part in the interview at a later stage. Where both groups at point of consent offered £20 for taking part in the interviews? Is it possible that the groups differed as a function of slightly different recruitment procedures?

Given the slightly different recruitment processes adopted for each group, we understand the referee’s concern about their comparability. We believe however, that the groups did not differ as a function of the different recruitment processes, given that differences in the latter were very slight: Upon their enrolment to the financial incentives scheme, women in the pilot scheme agreed to be contacted by a researcher about the interview, without being informed of the £20 participation compensation. Those agreeing to be contacted were then approached by the interview via telephone, who elaborated on the purpose of the study and informed women about the availability of £20 for participating. Women in the comparison cohort were contacted by a research midwife who briefly informed them about the possibility of being interviewed and enquired about their willingness to be contacted by the interviewer. She gave minimal information about the study and did not inform women of the £20 participation compensation.

Similar to the procedure adopted for women in the pilot group, the interviewer informed women in the control group both about the study and about the compensation. The only difference in the recruitment processes adopted for each group was that women in the pilot group were given written information about the possibility of being interviewed and consented to be contacted by a researcher by ticking the appropriate box, whereas women in the control group were verbally informed about the possibility of being interviewed and verbally consented to be contacted by the interviewer.

We have made the following revisions to the manuscript to clarify this:

* The full reference can be found in the manuscript
Women taking part in the financial incentives scheme for smoking cessation were asked by the call-centre’s representative about their willingness to be contacted about the possibility of being interviewed about their experiences of quitting smoking. Women not taking part in the scheme were informed by a research midwife working for BEN PCT of the possibility of being interviewed. Women in both groups willing to be contacted about the study were approached by the interviewer (EM) via telephone. She informed them about the purpose of the research and enquired about their willingness to participate. At this point all women were advised that they would receive £20 in cash to compensate for their time spent completing the study. A time and place [for a face-to-face interview] was arranged with those agreeing to be interviewed. (page 7: lines 12-21)

4. Would it be helpful to add a little flow chart to describe the recruitment and interview process?

A flow chart has been added to the manuscript on page 6.

Referee 2

Major Compulsory revisions:

Incentives were provided to women based on their residence, and these women were compared to women who were not offered incentives. It was not clear to me how the pilot areas were determined (p5), and whether there might be any bias. Were they randomly chosen?

Invitations to join the pilot financial incentives scheme were not randomized but rather were offered in different parts of a geographical area in England. As stated in the manuscript (page 15: lines 37-38), this may have resulted in different delivery of the services, regardless of the intention to keep the services identical across groups, which could explain women’s differential experiences of the Stop Smoking Services.

To clarify how the pilot and comparison areas were chosen, we have added the following information to the manuscript:

Pilot areas were selected from the districts of Birmingham with the highest prevalence of smoking during pregnancy. (page 5: lines 24-25)

Comparison areas were chosen by matching the pilot areas with two geographically similar districts with equivalent rates of smoking during pregnancy and comparable socio-economic composition. (page 5: lines 29-31)

P5, 2 para, please briefly describe the NHS Stop Smoking Services and provide references. It was not clear what these services women received. For example, in the results (p11) that it was mentioned that all women had access to NRT. Also was there biochemical feedback with women who were not incentivized?

The referee is justified in being unclear about the services offered by the NHS Stop Smoking Services, as these were not described in the document. Guidelines exist with regards to the delivery of the NHS Stop Smoking Services, which include the following specifications: all smokers motivated to quit should (a) be offered nicotine replacement therapy (NRT) and other stop smoking medicines on prescription, (b) have their CO levels monitored and (c) be provided
with feedback on their progress based on their CO levels (Chambers, 2009). Given that the provision of services was meant to be identical across the two groups in this study, non-incentivised as well as incentivised women should have received smoking-related biochemical feedback. As mentioned in the manuscript, however, references to CO level monitoring and provision of progress-related feedback were absent from the accounts of non-incentivised women. One possible explanation for this finding is that whereas monitoring in the incentivised group was conducted routinely due to attainment of the vouchers being contingent upon the results of such monitoring, monitoring in the non-incentivised group was inconsistent or occurred less often (page 10: lines 41-53) This is consistent with the finding that provision of CO monitoring varies within the NHS Stop Smoking Services (May S & McEwen, 2008).

Details about NHS Stop Smoking Services (with references) have now been added to the manuscript as a footnote on page 5:

The NHS Stop Smoking Services were set up in England in 1999 to provide assistance to smokers motivated to quit. Services are provided in group or individual sessions, depending on local circumstances and patient preferences. Services vary in the types of interventions they provide and in their approaches to delivery. [20] Guidelines however specify that Nicotine replacement therapy (NRT), Champix (varenicline) and Zyban (bupropion), in combination with intensive behavioural support should be offered to all smokers using the services. Other elements services should include are: monitoring of carbon monoxide (CO) levels and feedback of results. [21]. The guidelines also specify that pregnant smokers should be offered the full range of services, including biochemical verification of smoking status and nicotine replacement therapy. [21]

Reference 21 is not a study of pregnant women and incentives (p 12). This is not an appropriate reference or it should be specified that this was among non-pregnant smokers.

The manuscript has been amended to specify that this reference refers to non-pregnant smokers:

This is consistent with the findings of a recent investigation showing that the majority of quitters, among non-pregnant smokers, did not consider incentive-attainment as a main reason for quitting smoking. **(page 13: lines 20-22)**

A limitation of the study is the lack of details of how the program was implemented. For example, it was noted in the discussion that there may have been differential delivery of services. Can this be elaborated or evidence as such provided?

Differential delivery of the services in this study refers to CO level monitoring, provision of progress-related feedback and provision of the appropriate nicotine replacement therapy. Specifically, the former two were mentioned by incentivised women, but not by non-incentivised women, as having positively influenced their quitting efforts. Furthermore, problems with the latter were mentioned by non-incentivised women, but not by incentivised women. One possible explanation for these differences is that the services the two groups of women received differed in these two respects.

With regards to how the services were implemented, more information is available for the incentivised than non-incentivised women, implying that delivery was more controlled in the incentivised group. Women in this group were offered one voucher per week for the first four weeks of their quit attempts, as well as at three months, five months and 2 months post-partum (a

*The full reference can be found in the manuscript*
maximum of seven vouchers was offered to each woman). Because attainment of the vouchers was contingent on biochemically confirmed smoking cessation, women were required to attend their local NHS Stop Smoking Services (offered at a pharmacy or their GP practice) at these times, to confirm their abstinence by having their CO levels checked. Furthermore, they were all offered an option of nicotine replacement smoking cessation aids, including patches, inhalators and lozenges. Although CO-level monitoring and provision of progress-related feedback and nicotine replacement therapy should also have been offered to the non-incentivised women, as part of the NHS Stop Smoking Services protocol (Chambers 2009)*, provision of the vouchers required adherence to a strict protocol for CO monitoring and NRT provision, thereby ensuring their presence in services delivered to incentivised women (as mentioned in the manuscript on page 14: lines 33-51). Without the addition of the vouchers, delivery of services would not have necessarily been so standardised. Indeed services differ within the NHS Stop Smoking Services (May S & McEwen, 2008)*. Although guidelines exist on how the services should be delivered (Chambers, 2009)*, records are not routinely kept on CO monitoring or offers of nicotine replacement therapy.

Our findings indicate a difference in the stop smoking experiences of pregnant smokers who were incentivised for cessation and of those who were not incentivised. One possible explanation for these differences is that they reflect a difference in the delivery of support from the services, in terms of CO monitoring, provision of progress-related feedback and of NRT. Although the effectiveness of financial incentives in promoting smoking cessation during pregnancy has been previously demonstrated (Lumley et al, 2004), the effectiveness of the particular incentives scheme used in the current pilot has not been established, and is pending formal evaluation. This is stated in the manuscript as one of the study’s limitations (page 15: lines 42-43). We propose that if the incentivise scheme is shown to be effective in promoting smoking cessation, one possible explanation would be that its impact is due wholly or partially to increased levels of support from the services, provided in the form of monitoring, progress-related feedback and delivery of appropriate NRT. Obviously no conclusions can be established from the findings of the present study, given that a) the study is exploratory in nature and does not allow for causal inferences to be established (mention on page 15: lines 41-42) and b) findings are based on women’s self report of the factors they perceived as influencing their quit attempts, which might not reflect actual influences (mentioned on page 15: lines 19-25).

In summary, we are not concluding that the effectiveness of incentives is mediated by increased levels of support from the services. Based on our findings, we are only suggesting this as a hypothesis, which requires testing, for the possible mechanisms by which financial incentive schemes operate to influence smoking cessation during pregnancy, if indeed they do.

We have attempted to clarify this in the manuscript:

If differences in the delivery of the Stop Smoking Services are actual rather than perceived and if the incentives scheme is shown to be effective in promoting smoking cessation, then one possible explanation would be that its impact is due wholly or in part to increased levels of support from

* The full reference can be found in the manuscript
the services, provided in the form of monitoring, progress-related feedback and/or delivery of appropriate NRT. Given the exploratory nature of the current study, in addition to the lack of a formal evaluation of the effectiveness of the incentive scheme, this hypothesis has not yet been tested. Further research is necessary to establish whether the potential effectiveness of financial incentives is indeed mediated by increased levels of support from the services. (page 15: lines 6-14)

Minor Essential Revisions

In the results section, a number of times it was noted that certain factors were similar across groups and then the authors referenced a table (p7, 2.a; p10, 1st para). It would have been more clear to briefly summarize these factors in the text.

Brief descriptions have been added to the manuscript:

These were grouped under three sub-themes: (i) Awareness of the consequences of smoking and quitting; (ii) Dispositional factors (positive mood, motivational strength and personality characteristics); and (iii) Low addiction (Table 2). (page 8: lines 38-40)

...which were grouped under five sub-themes: (i) Availability of support; (ii) Lack of exposure to smoke; (ii) Lack of opportunity to smoke; (iv) Stop Smoking Services; and (v) Financial incentives (Table 2). (page 8: lines 44-46)

These were grouped under four sub-themes: (i) Disregarding the consequences of smoking and quitting; (ii) Dispositional factors, (negative mood, lack of motivation strength and personality characteristics); (iii) Perceived benefits of smoking; and (iv) Addiction (Table 3). (page 11: lines 10-13)

which were grouped under five sub-themes: (i) Lack of support; (ii) Exposure to smoke; (ii) Availability of cigarettes and opportunity to smoke; (iv) Stop Smoking Services; and (v) Financial incentives (Table 3). (page 11: 16-18)

Discretionary Revisions

It might be more compelling to add the effect size of incentives versus counseling (p3, para 2).

The effect size and related confidence intervals of financial incentives vs. all other interventions for smoking cessation during pregnancy have been added to the manuscript:

financial incentives vs. other interventions: OR 0.73, 95% CI 0.66 to 0.82. (page 3: lines 15-16)

P5, last paragraph: Mispelled consent “Women in both groups consent…”

The referee seems to have misunderstood the sentence. In this particular instance the word ‘content’ was chosen not ‘consent’. We have now altered to word to willing, to avoid this error.

Women in both groups willing to be contacted about the study were approached by the interviewer (EM) via telephone (page 7: lines 16-17)
We hope that the information provided in this letter and the revisions made to the manuscript are sufficient to address the issues raised by the referees. However, please do not hesitate to contact us if you need further clarifications.

We look forward to hearing you in the near future.

Best wishes

Yours sincerely

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