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Cost-effectiveness of financial incentives for smoking cessation in pregnancy

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Authors reply:

We thank the authors Brailon and Bewley for taking the time to respond to some of the issues raised in our article. [1].

In terms of a response, we must emphasise that the CPIT trial on which the economic evaluation was based was a phase II trial, in which the primary objective was to explore therapeutic efficacy in patients. Also, the objective of the economic evaluation was to assess the cost-effectiveness of the addition of financial incentives to services as usual, not as an alternative to existing stop smoking services.

We will now address each of the comments by Brailon and Bewley in turn.

- *Boyd et al's conclusion that financial incentives (FI) for smoking cessation in deprived pregnant women "are highly cost-effective" is highly questionable when extrapolating short term cessation to life-time analysis.*

As detailed in the results table of our manuscript [1] the probabilistic sensitivity analysis – which formally assesses the uncertainty in the lifetime model [2] – found a 72% probability that the addition of financial incentives will be cost-effective (only a 28% probability that they are not cost-effective). The paper also explicitly addresses issues with the lifetime extrapolation, particularly uncertainty in relapse rates post birth, and formally explored this using probabilistic analysis on a range of scenarios to explore alternative assumptions in the lifetime extrapolation [1]. These scenario analyses again found the incentives arm to be the cost-effective option over a range of alternative model assumptions.

- *The original phase II randomised controlled trial has several limitations:*
 - a. The control group had a higher Fagerstrom score for all items*

As detailed in the CPIT trial paper [3] correction and control for the Fagerstrom score made no difference to the final results.

- b. FIs improve retention rates and patients might be more circumspect with the truth. False reporting of smoking status may be low when both saliva and urine cotinine are systematically monitored but is more likely in this study which used self report or exhaled carbon monoxide before giving participants £400.*

The trial primary outcome is the important issue (cotinine validated self-report of smoking near the end of pregnancy). The primary outcome used self-report on the telephone, followed by carbon monoxide and salivary cotinine validation, both of which had to be negative for quit to be confirmed. However it should be made clear that to receive payments a home visit had to succeed in collecting a carbon monoxide breath test which had to be negative and at the same time a saliva was collected for cotinine. So no payments were given at the primary outcome point near the end of pregnancy unless all samples were available for analysis.

In the FI group: 30 intervention were never contactable for validation vs 23 controls;

These patients were never designated for confirmation by carbon monoxide breath test and cotinine. Only 2 residual samples from the last 10 weeks of pregnancy were available from these participant both from the intervention group. Both samples indicated current smoking.

among 18 tested during routine care and considered as quitters (selfreport), four had blood cotinine levels indicating they were smoking.

This statement is not correct (3).

c. The authors considered patients who were lost to follow-up had continued to smoke. This will overestimate positive results

First, for 46 participants in the incentives group, contact could not be made at 34-38 weeks' gestation after multiple attempts, initially by the helpline and then by research nurses after contact checks. Ten had residual blood samples available, taken for other purposes in the last 10 weeks of pregnancy, and all 10 samples indicated current smoking when tested for cotinine. Similarly, three residual samples were available from 43 control participants, and all indicated current smoking.[3] Participants lost to follow-up were therefore examined using residual routine blood samples from late pregnancy assayed for cotinine, and all tested in both intervention and control groups were smokers.

- *Additionally the treatment was inadequate*
 - a. Both groups only received a single form of nicotine replacement therapy (NRT), at an inadequate dose (16 mg/24h). Smoking cessation rates in pregnant women are reported as 16% without medication and 36% with a combination of various forms of NRT. A single form of NRT at 16 mg/24h alone has shown no benefit. Combining patches with faster acting forms of NRT (a 'belt and braces' strategy) works substantially better than patches alone in all populations. As pregnancy increases nicotine metabolism, remembering the basic pharmacological principle of dose response effect is crucial.*

The two substantive trials of nicotine replacement therapy in pregnancy have shown no significant improvement in quit rate compared with placebo [4, 5]. The latter used current first line treatment available in the UK NHS.

- b. Phone calls can hardly replace face-to-face visits for psychological therapy, particularly in the deprived.*

This issue relating to motivational interviewing has already been discussed by ourselves and the responders in rapid responses to the main paper describing the CPIT trial[3] (Tappin D, Bauld L, Purves D et al. Financial incentives for smoking cessation in pregnancy: randomised controlled trial. BMJ 2015 27;350:h134)

- The Markov design to extrapolate short term cessation to life-time is inadequate.*

The Markov model design used to extrapolate short term cessation rates was appropriate for lifetime modelling of smoking cessation interventions, and additionally the approach used adhered to good practice modelling guidelines and the NICE reference case [6-8]. In economic evaluation modelling is required to extrapolate short term results over a patient lifetime to help make an informed decision based on currently available evidence [8; 9]. There are always issues regarding uncertainty in extrapolation and therefore, in line with best practice, probabilistic sensitivity analysis was undertaken on both the base case model and scenario analyses [2; 10] to explore and capture this uncertainty in both 95% confidence intervals, and then present the likelihood of being the cost-effective option in a cost-effectiveness acceptability assessment [11].

- While FIs appear to increase attempts to quit and short term treatment use, smoking cessation rates show only small absolute increases at best. Long term quit rates are not improved.*

There is growing evidence to question these statements [12]. Additionally, in the base case model we drew evidence from a wide range of existing literature to inform parameters on relapse post birth and long term cessation [13-17]. A recent English study provided biochemically verified quit and relapses at 6 months postpartum [18].

- This is unsurprising as FIs do not promote autonomy*

Practical autonomy is questionable when you 'have to' receive a psychological intervention because you provided the perceived expected response at your maternity booking appointment that you wanted to quit smoking, when in fact you had not even thought about smoking cessation. The offer of a financial incentive to think about smoking and cessation and to engage with services gives much greater self governance and autonomy to people who are used to being told what to do by health professionals. Then if you quit and realise the fruits of self governance by spending the 'love-to-shop' vouchers on yourself or your loved ones you start to achieve true autonomy. Continued cessation provides direct improvement in living standards by not having to spend at least £10 per day on cigarettes.

Lastly, the approach is far from fair. The most socially deprived citizens deserve better living conditions, an intervention which does work.

This statement is the authors opinion and is irrelevant to the question at hand which is regarding efficient spending of public money to improve smoking cessation amongst pregnant women for the health of themselves and their babies. Financial incentives have been proposed as a valuable addition to the behaviour change toolkit [19; 20], with a wide body of experimental evidence supporting their success in abstinence from a range of addictive substances (19-25) and also in the areas of education and obesity [20;24;26].

Braillon and Bewley conclude that “Maybe spending £400 more to train practitioners to do their jobs properly in the first place would be more ethical and cost effective than FIs”. This is the authors conjecture and not based on any evidence or an economic evaluation. It is important to understand that the objective of the economic evaluation was to explore the cost-effectiveness of the addition of financial incentives to services as usual, not as an alternative to existing stop smoking services. Current stop smoking services supported by the UK NHS are both effective and cost-effective[27;28]and include practitioner and GP advice, pharmacists and smoking cessation specialists face to face support, group therapy and telephone support [27]. A range of effective cessation services exist to support pregnant smokers, however, getting pregnant women to engage with cessation services and undertake a successful quit attempt has proved difficult nationally and internationally. Our study shows that financial incentives could also be a potentially cost-effective tool in addition to the stop smoking services [1].

We do however agree that the case for implementing financial incentives across the NHS is far from proved, and that a phase III definitive trial and economic evaluation of financial incentives to support smoking cessation during pregnancy should be carried out in the UK. It is important that such a trial also collects evidence on biochemically validated quit post birth. Financial incentives are potentially a highly cost effective intervention to help pregnant smokers stop and to improve the health and wealth of the poorest in our society. It is important that this potentially highly effective health promoting intervention is not lost in a haze of political rhetoric and poor science.

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