



## Original Investigation

# Incentives for Smoking Cessation During Pregnancy: An Ethical Framework

Leonieke J. Breunis MD<sup>1</sup>, Jasper V. Been PhD<sup>1-3</sup>, Lieke de Jong-Potjer PhD<sup>1</sup>, Eric A.P. Steegers PhD<sup>1</sup>, Inez D. de Beaufort PhD<sup>4</sup>, Marlou L.A. de Kroon PhD<sup>1,5</sup>, Hafez Ismaili M'hamdi PhD<sup>4</sup>

<sup>1</sup>Erasmus MC – Sophia Children's Hospital, University Medical Centre Rotterdam, Department of Obstetrics and Gynaecology, Rotterdam, The Netherlands; <sup>2</sup>Erasmus MC – Sophia Children's Hospital, University Medical Centre Rotterdam, Department of Paediatrics, Division of Neonatology, Rotterdam, The Netherlands; <sup>3</sup>Erasmus MC – University Medical Centre Rotterdam, Department of Public Health, Rotterdam, The Netherlands; <sup>4</sup>Erasmus MC – University Medical Centre Rotterdam, Department of Medical Ethics and Philosophy of Medicine, Rotterdam, The Netherlands; <sup>5</sup>University Medical Centre Groningen, University of Groningen, Department of Health Sciences, Groningen, The Netherlands

Corresponding Author: Leonieke J. Breunis, MD, Room EE-2130, Erasmus MC, Wytemaweg 80, 3015 CN Rotterdam, The Netherlands. Telephone: 31-107-030-229; E-mail: [l.breunis@erasmusmc.nl](mailto:l.breunis@erasmusmc.nl)

## Abstract

**Introduction:** Smoking during pregnancy increases the risk of morbidity and mortality of the mother and child. The inability of the unborn child to protect itself, raises the social and academic responsibility to protect the child from the harmful effects of smoking. Interventions including rewards (incentives) for lifestyle changes are an upcoming trend and can encourage women to quit smoking. However, these incentives can, as we will argue, also have negative consequences, for example the restriction of personal autonomy and encouragement of smoking to become eligible for participation. To prevent these negative consequences, we developed an ethical framework that enables to assess and address unwanted consequences of incentive-based interventions whereby moral permissibility can be evaluated.

**Aims and Methods:** The possible adverse consequences of incentives were identified through an extensive literature search. Subsequently, we developed ethical criteria to identify these consequences based on the biomedical ethical principles of Beauchamp and Childress.

**Results:** Our framework consists of 12 criteria. These criteria concern (1) effectiveness, (2) support of a healthy lifestyle, (3) motivational for the target population, (4) stimulating unhealthy behavior, (5) negative attitudes, (6) personal autonomy, (7) intrinsic motivation, (8) privacy, (9) fairness, (10) allocation of incentives, (11) cost-effectiveness, and (12) health inequity. Based on these criteria, the moral permissibility of potential interventions can be evaluated.

**Conclusions:** Incentives for smoking cessation are a response to the responsibility to protect the unborn child. But these interventions might have possible adverse effects. This ethical framework aims to identify and address ethical pitfalls in order to avoid these adverse effects.

**Implications:** Although various interventions to promote smoking cessation during pregnancy exist, many women still smoke during pregnancy. Interventions using incentives for smoking cessation during pregnancy are a promising and upcoming trend but can have unwanted consequences. This ethical framework helps to identify and address ethical pitfalls in order to avoid these adverse effects. It can be a practical tool in the development and evaluation of these interventions and in evaluating the moral permissibility of interventions using incentives for smoking cessation during pregnancy.

## Introduction

Smoking is a major global public health problem that often continues during pregnancy.<sup>1</sup> The prevalence of smoking during pregnancy ranges from 0.8% in the African region to 8.1% in the European region, making it a worldwide problem.<sup>2</sup> Smoking during pregnancy is not only associated with maternal health risks, but also with mortality and morbidity of the (unborn) child, including preterm delivery and a low birth weight.<sup>3–5</sup> In addition, maternal smoking is associated with health problems of the child in later life, including asthma,<sup>6</sup> respiratory infections,<sup>7</sup> and cancer.<sup>8</sup> Although smoking cessation during pregnancy improves perinatal outcomes,<sup>9</sup> only half of all regular smokers successfully quit smoking during pregnancy.<sup>2</sup> Encouraging the mother to stop smoking therefore has the potential to significantly decrease the risk of adverse health outcomes for the mother and child. Because smoking during pregnancy carries a major public health burden with consequences for the mother and her (unborn) child the social and academic responsibility to protect the (unborn) child is clear and action must be taken.<sup>10</sup>

Currently, various interventions exist to promote smoking cessation during pregnancy. Although psychosocial interventions and additional nicotine replacement therapy increase the chance of successful cessation,<sup>11,12</sup> many women are unable to quit smoking despite these interventions. Therefore, there is a need to develop new smoking cessation interventions tailored to pregnant women.

In recent years, a number of studies investigated whether women can be encouraged to quit smoking during pregnancy by offering them incentives (ie rewards for a specific goal with the purpose to motivate).<sup>13,14</sup> Examples of such incentives are cash payments, vouchers exchangeable for (luxury) goods, and salary bonuses.<sup>13</sup> Some randomized controlled studies in this area have found promising results in terms of sustained smoking cessation by the end of pregnancy and postpartum.<sup>14–16</sup> A recent Cochrane review concluded that the relative risk of smoking abstinence is 2.79 [95% confidence interval 2.10–3.72] at the end of pregnancy and 2.38 [95% confidence interval 1.51–3.69] at longest follow-up (up to 24 weeks postpartum) in favor of incentives.<sup>13</sup> Despite these promising results, critics express several issues concerning the use of incentives, such as a potential coercive character,<sup>17</sup> the risk of cheating,<sup>17</sup> and that they might be considered unfair to people who do not smoke in the first place.<sup>18</sup> Because of these potential unintended adverse consequences, we believe an ethical framework may be helpful to identify and address these adverse consequences when designing interventions in this area.

An ethical framework is a systematic categorization of criteria that can be used to determine whether the intervention under scrutiny—in this case incentives for smoking cessation during pregnancy—is morally permissible. We aimed to develop such a framework that can be used as a tool to identify and address ethical pitfalls in order to avoid unintended adverse consequences of incentives aimed at encouraging women to stop smoking during pregnancy.

## Materials and Methods

### Study Design

We performed three semi-structured searches in Pubmed to identify literature broadly relevant to the topic of our framework. Semi-structured searches are more pragmatic than systematic searches used for systematic reviews, less firmly bound by rules and offer the

possibility to gain broader knowledge on different subtopics of a main subject.

### Search Strategy

First, we identified articles concerning the predictors and consequences of smoking and smoking cessation during pregnancy using the following search equation: “(smoke [tiab] OR smoking [tiab]) AND (cessation [tiab] OR quit\* [tiab]) AND (pregnan\* [tiab] OR fetus [tiab] OR child [tiab] OR perinatal [tiab]) AND (health [tiab] OR risk [tiab] OR birth outcomes [tiab])”.

Secondly, we searched for current research on incentives for smoking cessation during pregnancy using the following search equation: “(smoking [tiab] OR smoke [tiab]) AND pregnan\* [tiab] AND (incentive OR reward)”. In addition, we searched systematic reviews on the topic in the Cochrane Library with the terms “smoking” and “pregnancy”. Thirdly, we searched for articles about moral concerns and moral strengths of interventions using incentives for smoking cessation during pregnancy with the following search equation: “(barrier\* [tiab] OR pitfall\* [tiab] OR problem\* [tiab] OR consequence\* [tiab] OR concern\* [tiab] OR moral [tiab] OR ethic\* [tiab] OR facilitator\* [tiab]) AND (smoking [tiab] OR smoke [tiab]) AND pregnan\* [tiab]”. We did not search for ongoing trials in different databases because these registrations often lack a detailed description of the intervention relevant to allow proper assessment of ethical aspects. The articles that were identified via these searches and used to inform the framework are described in [eTable 1](#), available at *Nicotine and Tobacco Research* online. Sometimes clarification was needed on certain topics (eg biochemical validation) and additional non-structured searches were performed. We refer to the literature retrieved from these searches in the text.

### Framework Synthesis

We explored differences between the interventions, and moral strengths and weaknesses of the interventions. These differences entailed a wide range of details of the study approach and intervention, such as recruitment method, incentive scheme used, and the target population. LB listed these aspects and categorized the moral strengths and weaknesses regarding differences in these aspects between the studies. We used the frameworks of ten Have M et al.<sup>19</sup> and Kass<sup>20</sup> as guidelines for exploring moral strengths and weaknesses. The framework of ten Have et al. provides a tool for exploring ethical pitfalls in programs for the prevention of overweight and obesity. The ethical principles are similar to some ethical principles within interventions for smoking cessation during pregnancy. The framework of Kass provides a tool for ethics analysis of public health programs in general. We categorized the moral strengths and weaknesses by applying the ethical principles of Beauchamp and Childress,<sup>21</sup> which are generally accepted as the overarching ethical principles of biomedical research.<sup>20,22</sup> The four principles are beneficence, nonmaleficence, respect for autonomy and justice. A detailed explanation of each principle is stated below. Although there is an abundance of ethical principles available within the domain of bioethics these principles can always be subsumed under one of the four principles of Beauchamp of Childress.

Moral strengths and weaknesses were translated to criteria that can be used to evaluate moral permissibility of an intervention that uses incentives to encourage women to quit smoking during pregnancy. The criteria were developed by LB, JB, and HM. We present our results as an ethical framework, which is presented in

supplementary box 1, available at *Nicotine and Tobacco Research* online. When in supplementary box 1, available at *Nicotine and Tobacco Research* online a statement is marked “+,” it may be considered a strong aspect of the intervention. This implies that the ethical pitfall does not apply to the (proposed) intervention. When a question is marked “▲”, an ethical pitfall may be present. This does not necessarily imply that the intervention is ethically wrong, but that changes or additions to the (intended) intervention may be advisable. For the purpose of this manuscript when referring to “incentives” we consider solely the rewards women receive for smoking cessation. We consider “the intervention” as the whole infrastructure surrounding the provision of the incentives.

## Results

### The Framework

Table 1 provides a summary of the supplementary box 1, available at *Nicotine and Tobacco Research* online, which we developed based on the various ethical pitfalls that we identified. The criteria are categorized according to the ethical principles of Beauchamp and Childress,<sup>21</sup> to evaluate the moral permissibility of a planned or existing intervention for smoking cessation in pregnant women using incentives. Below, we discuss these criteria in more detail.

### Beneficence

When creating any public health intervention, the main goal has to be the improvement of public health and decreasing morbidity and mortality.<sup>20</sup> The goals of an incentive-based approach for smoking cessation during pregnancy are a better health for mother and child, obtained by as less as possible exposure to tobacco smoke during pregnancy. This corresponds well with Beauchamp and Childress's

**Table 1.** Ethical Criteria for Interventions Using Incentives to Encourage Pregnant Women to Quit Smoking<sup>a</sup>

<i>Beneficence</i>
Criterion 1: Is the intervention effective?
Criterion 2: Does the incentive support a healthy lifestyle?
Criterion 3: Is the intervention considered a motivator by the target population?
<i>Nonmaleficence</i>
Criterion 4: Does the intervention avoid stimulating unhealthy behavior?
Criterion 5: Is the risk for negative attitudes toward participants and the intervention minimized?
<i>Respect for autonomy</i>
Criterion 6: Is personal autonomy respected?
Criterion 7: Does the intervention also address intrinsic motivation?
Criterion 8: Is privacy respected?
<i>Justice</i>
Criterion 9: Is the intervention fair to non-smokers?
Criterion 10: Does the intervention allocate the incentives to those who deserve them?
Criterion 11: Is the intervention cost-effective?
Criterion 12: Does the intervention improve the health of those whose health is most impaired?

<sup>a</sup>This table is a summary of supplementary box 1, available at *Nicotine and Tobacco Research* online, available at *Nicotine and Tobacco Research* online. Supplementary box 1, available at *Nicotine and Tobacco Research* online provides an overview of the ethical criteria and ethical pitfalls within each criterion.

principle of beneficence.<sup>21</sup> This principle entails that interventions should be aimed at improving the well-being of those who are being targeted by the intervention.<sup>21</sup> Specifying this principle entails that the intervention is (likely to be) effective in decreasing the number of women who smoke during pregnancy, that the incentive supports a healthy lifestyle, and that the intervention is considered a motivator by the target population.

### Criterion 1: Is the Intervention Effective?

There has to be a scientific base for the effectiveness of the smoking cessation intervention. Although recent literature shows that providing incentives to women to quit smoking during pregnancy results in more women who quit,<sup>13</sup> not all intended interventions will succeed. Research has been done on various incentive schemes. For example on contingent (incentives when a participant has quit smoking) and non-contingent incentives (incentives for attendance to a helpful session without the obligation for smoking cessation to receive this incentive),<sup>13</sup> the interval between incentives,<sup>16</sup> and the added value of a reset when a smoker relapses.<sup>23</sup> Also, studies investigating the effect of delayed rewards versus immediate rewards showed that the subjective value of a reward decreases when there is a delay in providing the reward.<sup>24,25</sup> In addition, smokers are more likely to choose a small and immediate reward rather than a larger reward that they will receive later.<sup>26</sup> This implies that a delay in providing incentives may be less effective. Success will also depend on the nature of the incentive. For example, a simple pen is unlikely to encourage sufficiently toward smoking cessation. It is thus important that there is a reasonable base for expecting that women will in fact be encouraged to quit smoking with the intended incentive. All such aspects need to be taken into account, as informed by existing evidence on the topic when designing the incentive-based intervention.

### Criterion 2: Does the Incentive Support a Healthy Lifestyle?

To maximize beneficence, the chosen incentives should ideally support a healthy lifestyle (eg no smoking, no alcohol use, sufficient exercise, minimal sedentary behavior, and a healthy diet), for example with healthy incentives such as fruit, vegetables, or sports activities instead of unhealthy food. Or by providing incentives that can be expected to increase maternal well-being, such as a beauty treatment.

### Criterion 3: Is the Intervention Considered a Motivator by the Target Population?

Before developing an incentive-based intervention for smoking cessation during pregnancy it is advised to consider the target population and adjust the intervention and incentives to the preferences of the target population. It has been shown that pregnant women appreciate incentives that increase maternal well-being, and baby and pregnancy-related incentives.<sup>27</sup>

### Nonmaleficence

The principle of nonmaleficence requires that an intervention does not harm the target population.<sup>21</sup> Typically, this entails that the intervention's benefits outweigh its burdens (proportionality) and that the least intrusive intervention is chosen to achieve the intended health improvements (subsidiarity).<sup>21</sup>

Although public health interventions are designed to improve health, unintended adverse consequences may occur. To ensure that the intervention does not harm the target population, the

intervention should not stimulate unhealthy behavior and the risk for negative attitudes toward participants and the intervention should be minimized.

#### **Criterion 4: Does the Intervention Avoid Stimulating Unhealthy Behavior?**

To ensure that an intervention is not harmful to participants, the incentives should not stimulate unhealthy behavior. It should not be possible to buy unhealthy items like cigarettes, unhealthy food items, or alcoholic beverages with the incentives.

A potential unintended consequence of the implementation of an incentive program for smoking cessation is that individuals may take up smoking in order to become eligible for the intervention to subsequently earn incentives.<sup>17</sup> To avoid this, the inclusion criteria should ideally specify the duration of the participants' smoking. The challenge lies in how the duration of smoking prior to start of the intervention might be confirmed. It could for example be helpful if only health care providers can refer women to the intervention. Health care providers such as general practitioners and midwives are more likely to have been aware of the woman's smoking status for longer and are therefore able to identify actual long term smokers. It is also possible to use a biochemical test to identify long term smokers at inclusion, such as hair nicotine levels.<sup>28-30</sup>

#### **Criterion 5: Is the Risk for Negative Attitudes Toward Participants and the Intervention Minimized?**

Medicalization can be described as "a process by which non-medical problems become defined and treated as medical problems."<sup>31</sup> It is in this regard essential to note that smoking is an addiction rather than merely a lifestyle and that it carries a risk for developing many adverse health consequences for mother and child. It should therefore be considered as a medical issue, and public support for incentive-based interventions may be enhanced by framing smoking during pregnancy as an addiction, hereby avoiding medicalization.

Incentives for uptake of healthy behaviors are more likely to be supported by the general public when they are considered effective and cost-effective.<sup>32</sup> This suggests that the support toward incentives for smoking cessation during pregnancy might be increased by education and media advocacy. Projects implementing incentives for smoking cessation during pregnancy should therefore consider to share information on their costs, success rates and considerations for applying the intervention and to participate in the (inter)national discussion concerning this subject.

Stigmatization is the process of assigning certain disfavored characteristics to a specific person or group.<sup>33</sup> Because it has been demonstrated that stigmatization causes lower cessation intentions, especially among smokers with lower income and less self-efficacy,<sup>34</sup> all interventions should avoid stigmatization. This can be achieved for example, by ensuring that the incentives offered do not give away the fact that the recipients are women who smoke so to avoid feelings of blame and shame.

#### **Respect for Autonomy**

Personal autonomy encompasses self-rule that is free from limitations and controlling interferences that prevent choice.<sup>21</sup> Respect for autonomy is an important ethical principle and can be infringed upon in case of interventions that aim at steering behavior, even if this steering is aimed at attaining health benefits.

#### **Criterion 6: Is Personal Autonomy Sufficiently Respected?**

Incentive-based interventions interfere with the decision-making process by stimulating women to participate in an intervention, in potential conflict with a participant's autonomy. Interventions using incentives should always inform women about the procedure and goal of the intervention. Also, the informed consent of women should always be obtained before participating in the intervention. This ensures autonomy is respected despite the intervention being aimed at influencing behavior.

To make an informed choice, a participant needs to have all the right information. Information can be overstated, oversimplified, incomplete, subjective, unclear, or even wrong. For example, research showed that women who smoke have a 50% lower chance of becoming pregnant within the next 5 years.<sup>35</sup> This does not necessarily imply that smoking cessation doubles the chance of getting pregnant within 5 years for an individual patient.<sup>35</sup> Providing false information to persuade participation violates autonomy by denying someone an informed choice and should therefore be averted by those who offer the intervention to potential participants.

#### **Criterion 7: Does the Intervention Also Address Intrinsic Motivation?**

Intrinsic motivation is motivation based on internal rewards, such as health and desire for self-control.<sup>36</sup> Extrinsic motivation is driven by external rewards such as incentives or social influence.<sup>37</sup> Extrinsic motivation can be a "nudge" in the right direction, but in order to maximize sustainability after the intervention has ended and maintain autonomy an intervention should not solely rely on extrinsic motivation (by using incentives) but also intrinsic motivation.<sup>37,38</sup> This can be achieved by (1) a non-coercive character of the enrolment so only women who do have intrinsic motivation will participate, (2) not giving incentives of excessive value (eg a shopping voucher worth a 1000 euros instead of a shopping voucher worth 50 euros) so women feel they cannot refuse, and (3) providing information about the health benefits of smoking cessation to mother and child thereby increasing intrinsic motivation.

#### **Criterion 8: Is Privacy Respected?**

The incentives, vouchers for example, should not be sensitive to being openly associated with having received support to promote smoking cessation during pregnancy. This means that store owners and others who see the vouchers should not be able to link these to a person having been a smoker or being pregnant.

In addition, neither name, photos nor other personal information should be accessible or released without the participant's consent.

#### **Justice**

The ethical principle of justice requires a fair, equitable and appropriate treatment and distribution of benefits and burdens.<sup>21</sup> It is important in incentive-based interventions for smoking cessation that justice is preserved. This means that the intervention: (1) is fair toward non-smokers, (2) allocates the incentives to those who deserve them, (3) is cost-effective, and ideally also (4) improves the health of those whose health is most impaired.

#### **Criterion 9: Is the Intervention Fair to Non-smokers?**

A potential drawback of interventions using incentives to encourage smoking cessation during pregnancy is that they may be perceived as being "unfair" to women who do not smoke,<sup>18</sup> because they do



not receive incentives despite displaying healthy behavior; that is, not smoking. This sense of unfairness might be diminished by not using luxury products or products with an excessive value as an incentive.

Another way to justify incentivizing smoking cessation because of a pregnancy is that society in the broader sense benefits from smoking cessation. When a woman quits smoking during pregnancy, the health of mother and child can benefit,<sup>9</sup> which may eventually save money on health care spending. Also, when more people quit smoking, less people are exposed to passive smoking. This is also beneficial for the health of non-smokers, including other children in the family, who are particularly vulnerable.

#### **Criterion 10: Does the Intervention Allocate the Incentives to Those Who Deserve It?**

Participants who fail to quit smoking but still want to receive an incentive might claim they have quit smoking. To prevent the possible misuse of the incentives, smoking cessation should be biochemically validated. The National Institute for Health and Care Excellence guidelines recommend a carbon monoxide breath test to validate smoking cessation among all pregnant women.<sup>39</sup> Downside of using this carbon monoxide breath test is that it may not detect low levels of smoking or infrequent smoking because of the short half-life of 1–4 h.<sup>40</sup> Quantifying cotinine (a metabolite of nicotine) levels in blood or urine is also commonly used for testing,<sup>41</sup> because of the longer half-life of 9 h in pregnant women.<sup>42</sup> However, this method is more invasive and more expensive as compared to the carbon monoxide breath test. Another benefit of the carbon monoxide breath test is that it provides an immediate reading, thereby avoiding delay in providing the incentive which may decrease effectiveness of the intervention.<sup>25</sup>

#### **Criterion 11: Is the Intervention Cost-Effective?**

Smoking during pregnancy is responsible for significant health care spending.<sup>39</sup> Smoking cessation during pregnancy decreases the risk of common and potentially severe adverse perinatal outcomes and as such has the potential to reduce health care costs. Spending public money on interventions that encourage pregnant women to quit smoking using incentives is therefore justifiable, but each incentive-based intervention should ideally be supported by a formal cost-effectiveness analysis. This will also help assess whether the intervention may be considered fair to non-participants (as discussed in criterion 9).

#### **Criterion 12: Does the Intervention Improve the Health of Those Whose Health Is Most Impaired?**

In developed countries, smoking during pregnancy is highly associated with socioeconomic disadvantage.<sup>43</sup> Smokers with a low socioeconomic status more often have a lack of support to quit, lesser self-efficacy and lesser self-control causing a lower chance of successfully quitting and resulting in an inequality in health.<sup>43</sup> If health inequality is unnecessary, preventable and unjust, the health inequality is called health inequity and intervening is morally obligated.<sup>44</sup> A possible benefit of interventions using incentives for smoking cessation is that incentives might encourage smoking cessation especially among women with low socioeconomic status because this intervention delivers money instead of costing money, thereby potentially decreasing health inequity.<sup>45</sup> To increase the chance that the intervention reaches this group of women, it should be considered to tailor the intervention specifically to especially reach these women. This implies the intervention should, for example, be appealing and

understandable, and should be available without barriers (such as high costs for participation or long travel distances) for participants. The incentives themselves should also be appropriate for the target population.

Furthermore, smoking before or during pregnancy is more common among certain ethnic subgroups.<sup>46</sup> However in many health care interventions a language barrier withholds women from participation.<sup>47</sup> As a result, health inequalities may be sustained or even exacerbated.<sup>48</sup> To prevent this, it is necessary that participation in an incentive-based intervention is also easily available to women who do not speak the language fluently.

## **Discussion**

We have developed an ethical framework that can be used for the development and evaluation of interventions that use incentives to encourage women to quit smoking during pregnancy. Integrating this ethical framework in the developmental process of an incentive-based intervention for smoking cessation during pregnancy ensures that relevant ethical aspects are adequately considered so as to evaluate moral permissibility.

Strengths of this ethical framework are that it is practical and was developed according to relevant ethical principles. These abstract ethical principles were translated into a list of practically applicable criteria and questions that can be used to identify and help address ethical pitfalls when developing and implementing interventions.

Although the framework was based on a comprehensive literature review there is a possibility that certain relevant ethical aspects were not identified and that therefore some ethical issues may not be discussed. Also, opinions may differ as to whether all criteria are equally important. In addition, some criteria might seem in conflict with each other. It is in this respect important to note that the framework was developed as a guidance tool to *evaluate* moral permissibility, no to *establish* moral permissibility.

For this framework we specifically focused on the moral concerns regarding the use of incentives to encourage smoking cessation during pregnancy. Aspects of the framework may however also be applicable to a broader set of interventions. For example those addressing smoking outside of pregnancy or those providing incentives for promoting other healthy behaviors, although in those cases some potentially relevant aspects may be missed from this framework.

In 2010, ten Have et al. gave an overview of ethical frameworks in public health and evaluated whether these framework were supportive in the evaluation of programs to prevent overweight.<sup>49</sup> They concluded that the frameworks had limitations within their practical value because the frameworks present a set of abstract ethical principles without practical guidance. In our framework we present a list of well-defined criteria with practical implication, which we feel can be a helpful tool to establish and help address various ethical pitfalls.

To the best of our knowledge our ethical framework is the first to specifically focus on the development and evaluation of interventions using incentives to encourage women to quit smoking during pregnancy. Lynagh et al. previously identified “key conditions” that makes the use of incentives most likely to be effective and appropriate for improvement of public health outcomes.<sup>50</sup> As such there is some overlap with the framework presented here. We have however provided a more comprehensive and much more specific set of criteria, including additional criteria not specified earlier, for example those concerning the support of a healthy lifestyle, appropriateness for the target population, aversion of unhealthy behavior

and medicalization, and privacy aspects. There is now a need to evaluate the applicability of this framework in guiding the development and evaluation of future interventions involving incentives for encouraging smoking cessation among pregnant women.

In addition, future research concerning incentive-based interventions should not only focus on which (value of) incentives and incentive schemes give the best results on public health but also doing so without crossing ethical boundaries.

In conclusion, incentives for smoking cessation are a response to the responsibility to protect the unborn child. But interventions using incentives might have possible adverse effects. We present the first ethical framework to evaluate and address potential ethical pitfalls of interventions using incentives to encourage smoking cessation by pregnant women. It can be a practical tool in the development and evaluation of these interventions and in evaluating their moral permissibility.

## Supplementary Material

Supplementary data are available at *Nicotine and Tobacco Research* online.

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## Authors' Contributions

All authors substantially contributed to the writing (ie drafting and/or critical revision) of the manuscript. LB was responsible for the collection of the literature and takes responsibility for the integrity. All authors read and approved the final manuscript.

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