Author's response to reviews

Title: Measuring the Costs of Outreach Motivational Interviewing for Smoking-Cessation and Relapse-Prevention Among Low-Income Pregnant Women

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Author's response to reviews: see over
Dear BioMed Central Editorial Team,

Thank you for the opportunity to revise and resubmit our manuscript (MS 1188259889258996) entitled, “Measuring the Costs of Outreach Motivational Interviewing for Smoking-Cessation and Relapse-Prevention Among Low-Income Pregnant Women,” for further consideration. As requested, herewith we submit our revised manuscript and this cover letter with point-by-point responses to the reviewers’ comments and details on changes made to satisfy each comment or rebuttals. Please do not hesitate to contact us if you require further information.

Sincerely,

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Responses to Reviewers’ Comments:
MS 1188259889258996, “Measuring the Costs of Outreach Motivational Interviewing for Smoking-Cessation and Relapse-Prevention Among Low-Income Pregnant Women”

Editors

1. It appears that there was a misunderstanding regarding our original request to you on citing the randomized controlled trial from which you have taken data for analysis. We ask that you please provide a citation for this in your article.

Thank you for this comment. We have included the name and NIH Grant number for the randomized controlled trial from which we take the data for analysis. There are only a few articles that have come from this trial and they are noted herewith and we have cited the relevant ones in our revised paper.


In response to Reviewer 1 (see below), we have also added several paragraphs to the methods section with information about the RCT.

Reviewer #1

1. The present article uses a micro-costing system to estimate resource costs of outreach motivational interviewing for smoking-cessation and relapse-prevention among low-income pregnant women and report results from a randomized controlled trial employing the method. This paper can potentially make significant contributions to the literature, but there are several significant weaknesses that need to be addressed.

Thank you for this comment. We also think that this paper can potentially make a significant contribution to the literature and have provided point-by-point responses to the following comments and revised the paper where relevant. We see the micro-costing methodology as quite innovative, as well as the cost estimation.

2. The literature review is weak. There are publications on costs associated with smoking as well as detailed methods on how to estimate costs when conducting RCT. Moreover, this paper is on cost measurement and the authors seem to ignore most of the economic literature on costs issues.

Thank you for this comment. As the reviewer recognizes, this is a cost analysis, employing a novel micro-costing methodology to rigorously examine the costs of the
smoking cessation among low income pregnant women. The study is not, however, an
effectiveness study, nor is it a cost-effectiveness study. The micro-costing methodology is
so new and innovative and so rigorous in its application in this paper, that it is necessary
to focus solely on this research.

The reviewer is correct that there is a literature on costs associated with smoking, but
most of this literature is in the form of cost-benefit analyses, some cost-effectiveness
analysis, but none of it is in the form of micro-costing. In fact, our research group has
recently done an extensive literature review on economic evaluations of smoking
cessation. We scoured the literature on this, which is why the study reported in this
paper is important to the field; there really aren’t micro-costing studies in smoking
cessation. In terms of citations and review of the literature on the cost-benefit and cost-
effectiveness of smoking cessation in general and among pregnant women in specific,
that literature is well reviewed and cited in our previous work, (Ruger JP, Weinstein
MC, Kearney MH, Hammond K and Emmons, KM. Cost-Effectiveness of
Motivational Interviewing for Smoking Cessation and Relapse Prevention Among
Low-Income Pregnant Women: A Randomized Controlled Trial, Value in Health,
2008; 11(2): 191-198.), but those other studies have little relevance for the
paper at hand.

Moreover, we have added to the revised paper the following paragraphs
regarding our findings from our comprehensive and exhaustive review. We added
the following:

“Despite recent work on economic evaluation in clinical trials however, which focuses,
for example, on econometric techniques for the analysis of cost distributions, little, if any,
research has been conducted on micro-costing in health and medicine, particularly in
conjunction with randomized controlled trials. Cost analyses in many areas of public
health and medicine, including smoking cessation, have not typically been conducted
uniformly and standardized so as to compare cost estimates across studies. Many have
not included future costs, patient time and travel, and set-up or implementation costs.
Incomplete and inadequate cost analyses can have a significant effect on final cost
analyses (especially where real costs are underestimated), and on cost-effectiveness and
cost-utility analyses. Cost analyses require standardized methodology as recommended
by the Panel on Cost-Effectiveness in Health and Medicine (hereinafter, the Panel). The
lack of standardized or uniform methods in estimating costs is problematic in terms of
limiting our knowledge of the most efficient and equitable resource allocation to reduce
smoking. This article aims to address these gaps in the literature.”

“Currently available economic evaluations of behavioral counseling services for
smoking cessation provide limited evidence on costs to determine optimal resource
allocation strategies. With some notable exceptions, few studies have been performed in
accordance with U.S Panel on Cost-Effectiveness in Health and Medicine
recommendations grounded in economic theory. While such limitations hinder comparisons
among programs, they also represent an opportunity for future analyses to better adhere
to sound and consistent methodologies. A lack of economic studies is common in public
health and medicine, however, especially in the area of prevention services. Despite these limitations, efforts to sort out the finer methodological challenges in the cost elements of economic evaluation will eventually lead to more uniformity in reporting. For example, efforts to enumerate cost categories will improve the generalizability and comparability of the results of economic evaluations. In combination with established standards, such efforts will help in the development of an analytic framework for making future studies more comparable. Moreover, efforts to design and conduct economic evaluations of drug abuse treatment, smoking cessation and relapse prevention, would ideally be planned prospectively and apply standardized methods.”

The proposed research project adheres to Panel recommendations and meet quality standards in several ways. First, it conducted an economic evaluation in conjunction with a randomized clinical trial in which all inputs consumed in the interventions have been measured and valued in conjunction with the clinical trial to enhance the reliability and validity of intervention costs. Second, costs were collected by a standardized methodology and those collected included those necessary to reproduce the intervention in a non-research setting and such inputs include time spent by clients for intervention delivery and follow-up.

In terms of the economic literature on cost issues, the reviewer is also correct that there is a significant literature on this. Indeed at least two of the authors on the current paper (Drs. Ruger and Weinstein) are quite familiar with this literature having used much of it in the courses they teach or co-teach. That said, much of this literature would not be relevant for the much more specific application that is the focus of this study. Two other literatures are worth discussing here, the first is the literature on the economics of addiction and the second is the literature on economic evaluation in clinical trials.

In terms of the literature on the economics of addiction, noted scholars ranging from Michael French, Gary Zarkin, Jody Sindelar, Pierre Alexander, Don Shepard and more have written extensively in these areas. None, however, have done work in micro-costing, per se, as specified by the Panel on Cost Effectiveness in Health and Medicine. One of the authors on the current paper, Milt Weinstein, was on the Panel and is very familiar with this literature. It would be too difficult and far afield to review all this literature for the current paper. That said, in the revised paper, we have included some of this literature in the discussion section in discussing the micro-costing methods strengths and weaknesses and relations to other methods.

In the revised paper, we note, “Like the CCC’s Cost Allocation Methodology, noted by the ADSS (Alcohol and Drug Services Study) Cost Study, micro-costing is a highly detailed and intensive method. Finally, a number of limitations exist (e.g., differences in recruitment costs, scheduling issues, etc.) in translating cost estimates obtained through a randomized controlled trial to real world clinical practice.”
“There are other substance use treatment costing methods, such as the use of the Drug Abuse Treatment Cost Analysis Program (DATCAP), and Substance Abuse Services Cost Analysis Program (SASCAP) However, these instruments tend to focus primarily on the institutional level in inpatient and outpatient treatment programs, aggregating and generalizing over the site of care delivery for typical costs of services. For the specific purposes of this study, they are less appropriate due to the use of cost integrated services such as behavioral counseling and due to the need to cost in detail these promising treatment services in conjunction with a randomized controlled trial. In the proposed study, rather, we aimed to employ micro-costing to reflect the ideal of identification, measurement, and valuation of resources, guided by a theoretical framework that identifies all consequences of adopting different interventions.”

We have added the following citations to the paper:


Department of Health and Human Services. Substance Abuse and Mental Health Services Administration Office of Applied Studies. The ADSS cost study: costs of substance abuse
In terms of the literature on economic evaluation in clinical trials, a recent book has been written, entitled, “Economic Evaluation in Clinical Trials” by Henry Glick, Jalpa Doshi, Seema Sonnad, and Daniel Polsky. In that book there is one chapter on costs and it has a completely different focus from the current paper. There is no mention of micro-costing and the focus tends to be on analyzing data once one has it, rather than on the methodology necessary to collect valid and reliable data in the first place. That said, we have added this reference (Glick HA, Doshi JA, Sonnad SS, Polsky D. Economic Evaluation in Clinical Trials) to the paper, noting the highly different emphasis of this more recent work from ours.

3. The title of the paper refers to … low-income pregnant women. When allocating salaries and wages to estimate time costs for patients, it is important to have socio-economic data on the individuals, including age, education, employment, etc. The authors should provide a section describing the samples of the study. We also need to know more about the RCT; at least the authors should provide published references where we can read more about the RCT.

Thank you for this comment. We have included the name and NIH Grant number for the randomized controlled trial from which we take the data for analysis. There are only a few articles that have come from this trial and they are noted herewith and we have cited the relevant ones in our revised paper.


In terms of the randomized controlled trial participants, we focused in the paper on the micro-costing study and provided relatively no description on the participants in the original version of the paper. In the revised paper, we assessed where we might add the following information on the participants, and added several sections within the METHODS section. We think this is fine here. We have added the following to the revised paper:

“Recruitment, Design, and Sample of Randomized Controlled Trial”
Potential study participants were recruited from a large number of community-based health-care practices and community health-care centers that provided prenatal care. To be eligible, women had to be less than 28 weeks pregnant, and either current smokers or recent quitters (i.e., quit during previous three months). They also could not be in drug addiction treatment, and they spoke English or Spanish.

During routine prenatal visits, health care providers described the study and assessed women’s interest in participating. Study personnel then received contact information and called interested women for further explanation of the study. Trained research assistants visited the women in their homes to answer questions, obtain informed consent, conduct the baseline survey, and complete other study assessments.

The health care providers referred 549 women to the study. Of those, 65 did not meet eligibility requirements, and 68 could not be located. Of the remaining 416 women, 114 refused participation. The final sample at baseline was 302 pregnant women (73% of known eligible women).

After the 302 women gave their consent and completed the baseline assessment, they were randomly assigned to either UC or MI. Follow-ups were conducted 10 weeks after baseline (prenatal assessment) and 4 to 6 months after the baby’s birth (postnatal assessment). At each assessment visit, passive sampling dosimeters were placed in the home (kitchen and living room) for 7 days to assess air nicotine concentrations. Feedback about nicotine levels was provided as part of the MI intervention.

**Intervention Conditions**

*Usual Care*

After UC participants completed the baseline survey, a letter was sent to their prenatal care providers indicating the patient’s study participation and recommending that the provider discuss the patients’ smoking with her. A description of the study, a tip sheet for providers based on the Agency for Health Care Policy and Research (AHCPR) guidelines and a pamphlet describing ways of dealing with nicotine withdrawal symptoms were included with the letter. Participants in this condition received their usual prenatal care from their providers.

*Motivational Interviewing*

In addition to their usual care, MI participants received monthly visits from a Public Health Nurse until one month post-partum. The intervention was designed to address social contextual factors that might influence responses to the smoking intervention. The nurse was available to help with all aspects of pregnancy, including prenatal education, gaining needed social services, smoking cessation and secondhand smoke reduction. Two of the monthly visits were devoted primarily to the smoking intervention, however.
The intervention was based on motivational interviewing\(^\text{ii}\), which emphasizes the woman’s choice, personal responsibility for change, and enhancement of self-efficacy.

The MI component was designed to increase motivation and self-efficacy for smoking cessation and to provide support and skills-training. Thus, the sessions explored the participants’ perceptions and concerns about smoking, increasing their awareness of the pros and cons of smoking and clarifying conflicting motivations governing decision-making. The goals of the MI session were: (1) provide information about the impact of smoking on the mother and fetus and the impact of secondhand smoke on newborns; (2) to help participants re-evaluate their smoking behavior; (3) to increase perceived self-efficacy for the ability to quit smoking; (4) to educate the participants about mechanisms for reducing secondhand smoke exposure and to set goals for changing smoking habits; (5) to provide feedback about the impact of changes on household nicotine levels. These MI components were tailored to each client’s stage of readiness.

The first counseling session focused on increasing motivation, in part by addressing ambivalence associated with the decision to quit smoking. The nurses began the counseling session by presenting results from household nicotine assessments. If the woman was interested, the nurse discussed ways to either reduce the nicotine levels in the home or, if levels were low, ways to prevent them from increasing. Smoking cessation was discussed with women who were interested. Additionally, the nurses worked with the participants on setting goals in other areas of their lives (e.g., employment, education, parenting skills, social service needs). When appropriate, the relationship between these other goals and smoking was explored. The first counseling session placed a strong emphasis on goal setting. Progress toward those goals was the focus of the subsequent intervention visits.”

4. Throughout the paper the authors refer to the societal perspective of the estimation. The relevance of the discussion is not clear. Are the estimates based on that perspective? Future costs savings discussed on page 13 do not seem to enter the results calculations and I do not understand the relevance. Something seems to be missing. On page 10, there is discussion about extending the cost analysis to the societal perspective by including next resource costs, but it does not seem to incorporate any of these items into the results

Thank you for this comment, it is very helpful and it also identifies an inadvertent error on page 13 of the original paper where we left a dangling sentence and did not clarify future costs. The relevance of the mention of the societal perspective and the future costs savings is to describe the conceptualization of a full cost analysis, of which the micro-costing on the direct costs, is a part. This is the conceptualization based on recommendations from the Panel on Cost Effectiveness in Health and Medicine, as such, in the context of this micro-costing study, we conceptualize all costs as set out by the Panel. We have revised this to clarify, by adding several sentences in different parts of the paper. We note, for example, in the introduction of the revised paper that, “Thus, in
this micro-costing study, we include the patient’s costs as well as the providers’ costs and we conceptualize future savings that could offset initial costs.” In the methods section of the revised paper, we note, for example, that “These costs are included in the overall cost analyses reported from the societal perspective, but are not reported in the following tables of direct program costs.” Moreover, we significantly revised the paper to include an overarching theoretical framework within which the micro costing fits (discussed below).

5. Finally, it might help to conduct a sensitivity analysis of the results and if this is not important please discuss.

Thank you for this comment and suggestion, it is very helpful. We do think it is useful to conduct a sensitivity analysis and so we have significantly modified the paper to include the results of this analysis. In the revised paper we included the following revisions. In the introduction of the revised paper, for example, we included the following. “We conclude with sensitivity analysis of the robustness of these estimates to changes in key cost components.” In the methods section of the revised paper, we included a separate section/paragraph as follows,

“Sensitivity Analyses
Sensitivity analyses were conducted to analyze the variation in total costs according to uncertainties in key cost categories, such as intervention delivery, staff travel, and analysis of nicotine samples.”

Moreover, we added to the results section the following: “We conducted a sensitivity analysis to examine the variation in our total cost estimates as a result of variation in key parameters. We were most interested in examining the effects of uncertainties in key cost categories for MI: intervention delivery, staff travel, and analysis of nicotine samples. As shown in Table 5, we varied the intervention delivery costs to a 25% decrease and increase, resulting in a range of total costs from $284 to $335. For staff travel, we reduced and increased the costs by 30% resulting in a range of total cost per person of $291 to $327. Finally, decreasing and increasing the costs of analyzing the nicotine samples by 35% resulted in a range of total costs per person of $297 to $321.”

Finally, we added Table 5: Sensitivity Analysis on page 25.

Minor Issues

6. Background section: Provide reference for “Smoking imposes … life at low costs”

Thank you for this comment. In the revised paper, we have added two references for this statement.

These references include:


7. Not sufficient to note that for low-income women, we used the minimum wage. Please report the number used.

   Thank you for this comment. Yes, we agree that it is not sufficient to note that for low-income women we used the minimum wage without reporting the number used. This figure is actually reported on page 14 of the original paper as we note, “At a minimum wage of $5.15 per hour”

8. Page 14; use ‘adjusted’ instead of ‘updated’

   Thank you for this comment. In the revised paper, we have made the change from “updated” to “adjusted” in the text of the paper on page 17.

9. Discussion: please discuss policy implications of the findings

   Thank you for this comment. We have added a few sentences to the discussion regarding policy implications. Moreover, we have significantly revised the discussion section to further explain the implications of the micro-costing methodology for research on cost estimation.

Reviewer #2

1. The scope of the paper should be defined and presented more clearly. The focus is simply on a method of estimating costs of delivering a behavioral intervention to a defined panel of participants. The paper should briefly review the more general framework of cost-effectiveness and cost-benefit analyses and more directly explain that the costing procedure demonstrated would be one step in a broader analysis. For the benefit of typical readers, the introduction should clearly distinguish between the procedure presented and the cost-effectiveness analyses more commonly encountered in the clinical research literature.

   Thank you for this comment it is very helpful. This comment helps us reflect on the nature of micro-costing in the context of the broader clinical research literature. In the revised paper, we have modified the abstract and introduction to place this study in the context of the clinical research literature and economic theory, for example, by recognizing the reach and limitations of recent work on economic evaluation in clinical trials, which has been virtually silent on micro-costing and the direct collection of valid
and reliable cost estimates. Moreover, we’ve now emphasized these gaps in the literature noting the problematic nature of the lack of standards and uniformity in costing in clinical research. Furthermore, we provide theoretical grounding for the micro-costing methodology we develop, which places the cost estimation in the context of overarching economic evaluation.

In the revised paper, we added the following sentences to the abstract, “Economic theory provides the theoretical foundation for valuing costs in judging medical and public health interventions.” and “Methodological standards in cost analysis are necessary for comparison and uniformity in analysis across interventions.”

We also revised the abstract’s conclusion to read as follows:

“Grounded in economic theory, this methodology systematically identifies and measures resource utilization, using a process-tracking system and calculates both component-specific and total costs of outreach MI. The methodology could help improve collection of accurate data on costs and estimates of the real resource costs of interventions alongside clinical trials and improve the validity and reliability of estimates of resource costs for interventions targeted at underserved and hard-to-reach populations.”

In the revised paper, we have added several paragraphs to the introduction, which aim to address some of these issues.

We note in the revised paper, in the introduction, that:

“Economic theory provides the theoretical foundation for valuing costs in judging medical and public health interventions. Resources used in, and saved as a result of, medical and public health programs must be measured in terms of their monetary costs, to understand the overall implications of such interventions. Under economic theory, the opportunity cost of a resource – or its value in its next best or alternative use – is the real cost of that resource to society. Under ideal circumstances (e.g., perfect competition, absence of market failures such as externalities and public goods and absence of market distortions such as insurance) the price of a resource can be taken as its opportunity cost. However, medical and public health programs rarely operate under ideal market conditions. Thus, we cannot rely on prices to value resources in the economic evaluation of medical and public health interventions, although prices are almost always used for cost estimates. Rather, we need a systematic methodology for measuring costs grounded in the theory and process of identifying, estimating and valuing resource costs. This method can be described as micro-costing.”

Later in the revised paper, also in the introduction, we note the following:

“Despite recent work on economic evaluation in clinical trials, however, which focuses, for example, on econometric techniques for the analysis of cost distributions, little, if any, research has been conducted on micro-costing in health and medicine, particularly in
conjunction with randomized controlled trials. Cost analyses in many areas of public health and medicine, including smoking cessation, have not typically been conducted uniformly and standardized so as to compare cost estimates across studies. Many have not included future costs, patient time and travel, and set-up or implementation costs. Incomplete and inadequate cost analyses can have a significant effect on final cost analyses (especially where real costs are underestimated), and on cost-effectiveness and cost-utility analyses. Cost analyses require standardized methodology as recommended by the Panel on Cost-Effectiveness in Health and Medicine (hereinafter, the Panel). The lack of standardized or uniform methods in estimating costs is problematic in terms of limiting our knowledge of the most efficient and equitable resource allocation to reduce smoking. This article aims to address these gaps in the literature.”

“Currently available economic evaluations of behavioral counseling services for smoking cessation provide limited evidence on costs to determine optimal resource allocation strategies. With some notable exceptions, few studies have been performed in accordance with U.S Panel on Cost-Effectiveness in Health and Medicine recommendations grounded in economic theory. While such limitations hinder comparisons among programs, they also represent an opportunity for future analyses to better adhere to sound and consistent methodologies. A lack of economic studies is common in public health and medicine, however, especially in the area of prevention services. Despite these limitations, efforts to sort out the finer methodological challenges in the cost elements of economic evaluation will eventually lead to more uniformity in reporting. For example, efforts to enumerate cost categories will improve the generalizability and comparability of the results of economic evaluations. In combination with established standards, such efforts will help in the development of an analytic framework for making future studies more comparable. Moreover, efforts to design and conduct economic evaluations of drug abuse treatment, smoking cessation and relapse prevention, would ideally be planned prospectively and apply standardized methods.”

The proposed research project adheres to Panel recommendations and meet quality standards in several ways. First, it conducted an economic evaluation in conjunction with a randomized clinical trial in which all inputs consumed in the interventions have been measured and valued in conjunction with the clinical trial to enhance the reliability and validity of intervention costs. Second, costs were collected by a standardized methodology and those collected included those necessary to reproduce the intervention in a non-research setting and such inputs include time spent by clients for intervention delivery and follow-up.

And further in the revised paper we note,

“No the Panel on Cost-Effectiveness in Health and Medicine recommended micro-costing in the late 1990s, it suggested breaking the production and delivery of an intervention into discrete work-steps, which could be analyzed separately; however, it gave little guidelines on how to implement a micro-costing study, in general, and no guidelines or procedures on how to do so in particular studies. It provided no
procedures for assessing costs on an outreach basis in order to better access underserved and hard-to-reach populations. For each step, all inputs, including personnel/patient time and supplies/equipment, are inventoried and measured. The costs of each step are summed to determine the intervention’s total cost. The straightforward micro-costing methodology described here was grounded in economic theory and undergirded by the Panel’s recommendations, which we modified and applied to an outreach MI program. The detailed cost information collected by this methodology is essential for understanding the levels and types of resources necessary for effective implementation of smoking-cessation and relapse-prevention programs. As an input to cost-effectiveness and cost-benefit analyses, it could enable benefits to be weighed against costs to facilitate rational allocation decisions.”

2. The discussion should come back to this point, clearly explaining that the estimates derived by the costing procedure are simply for delivery of the intervention to the designated participants and do not incorporate consideration of intervention effect; it should be made clear that the result reported is not an estimate of cost per quit.

Thank you for these comments. Yes, the reviewer is correct that this paper reports results of a micro-costing study, and the importance of developing a standardized and uniform methodology for micro-costing that can be employed across studies in multiple areas of health and medicine. The aim of this paper is not to report a cost per quit. In the revised paper, we have highlighted in the discussion that the cost estimates derived from this methodology are necessary for understanding the types and levels of resources necessary for implementing smoking cessation and relapse prevention programs and that they are in input to cost-effectiveness and cost-benefit analysis.

We note in the revised paper:

“Thus, despite the noted limitations, the detailed cost information collected by this methodology is essential for understanding the levels and types of resources necessary for effective implementation of smoking-cessation and relapse-prevention programs. As an input to cost-effectiveness and cost-benefit analyses, it could enable benefits to be weighed against costs to facilitate rational allocation decisions. Effective policy analysis and implementation of medical and public health programs relies on valid and reliable estimates of the costs and benefits of such programs. Micro-costing can help in providing such information.”

In the introduction, we also note, “Incomplete and inadequate cost analyses can have a significant effect on the final cost analyses (especially where real costs are underestimated), and on cost-effectiveness and cost-utility analyses.”

Moreover, in the revised paper, we have more explicitly described the economic theory and foundation for the micro-costing methodology and its relation to other aspects of economic evaluation. In the methods section, for example, in the revised paper, we included the following:
“Economic Consequences of Public Health and Medical Programs

Figure 1 illustrates the economic consequences of health interventions as recommended by the Panel. While a comprehensive review of the components of Figure 1 is beyond the scope of this article and can be found elsewhere, it is worth noting briefly the role of cost estimation (Box E,F,G,H) plays in the broader framework of cost-effectiveness (CEA) and cost-benefit analysis (CBA). It should also be noted that cost estimation and analysis need not be confined to use in CEA or CBA, but may be relevant as a stand-alone measure of economic impact, as an element of cost-minimization analysis (CMA) and as a component of a larger theory of health and social justice. In Figure 1, however, we can see that Box E (Changes in use of Health Care Resources), Box F (Changes in Use of non-Health Care Resources), Box G (Changes in Use of Informal Caregiver Time) and Box H (Changes in Use of Patient Time (for Treatment)) represent the factors in cost estimation. Indeed for the purposes here, the key factors relevant for measuring costs are located in the numerator of the illustration.”

3. The paper should more clearly and thoroughly explain the differences between the demonstrated costing procedure and alternative approaches. What is the unique information that justifies publication? Perhaps background information an the rationale used by the national panel in recommending this cost procedure would be presented in more detail.

Thank you for this comment. The reviewer is correct that the rationale for using this approach stems from the recommendations of the Panel on Cost Effectiveness in Health and Medicine and it stems from economic theory. As noted above, we have significantly revised the paper to include the theoretical framework and grounding for the study and to place micro-costing within the broader economic evaluation framework. Please note the additions cited above.

Moreover, in the revised paper, the following excerpt from the Methods section reads as follows:

“Micro-Costing Methodology

The theory and process of valuing costs through a micro-costing methodology rests on a three-step approach: identification, measurement, and valuation of resources used. While the Panel recommended following this theory and process, it provided no guidelines on implementing a micro-costing study, in general, and no procedures on how to do so in specific studies. Because micro-costing uses primary data on the exact number and type of resources consumed by each client, it is most accurate when it tracks resource consumption as it occurs, thereby enhancing the validity and reliability of cost estimates. Once resource utilization is measured, the quantity of each type of resource consumed is multiplied by unit costs, and the results are summed to obtain total component-specific costs and overall cost. Total and component-specific costs can then be divided by the number of clients to determine expected costs per client.
The Panel also recommended that future costs and savings attributable to an intervention be included in cost analyses from the societal perspective, in addition to micro-costing of intervention costs. Many interventions, especially preventive ones, for example, can result in future savings that offset initial costs. Analyses performed from the perspective of a provider or payor would include only those costs and savings that they bear or realize. Thus, in this micro-costing study, we include the patient’s costs as well as the providers’ costs and we conceptualize future savings that could offset initial costs. We conclude with sensitivity analysis of the robustness of these estimates to changes in key cost components.”

In terms of alternative approaches, we have added a paragraph to the discussion section regarding alternative approaches and have added several additional references (see above). The new paragraph reads as follows:

“There are other substance use treatment costing methods, such as the use of the Drug Abuse Treatment Cost Analysis Program (DATCAP), and Substance Abuse Services Cost Analysis Program (SASCAP) However, these instruments tend to focus primarily on the institutional level in inpatient and outpatient treatment programs, aggregating and generalizing over the site of care delivery for typical costs of services. For the specific purposes of this study, they are less appropriate due to the use of cost integrated services such as behavioral counseling and due to the need to cost in detail these promising treatment services in conjunction with a randomized controlled trial. In the proposed study, rather, we aimed to employ micro-costing to reflect the ideal of identification, measurement, and valuation of resources, guided by a theoretical framework that identifies all consequences of adopting different interventions.”

4. Reference to “gross-costing of clinical events prevented” (p.6) is confusing and probably inappropriate; if necessary, this could be presented as part of the more general framework noted in point 1.

Thank you for this comment. We can see how this could be unclear, so, in the revised paper in the introduction, we have added a parenthetical to explain the general idea of gross-costing, without going into to much detail on it. It is worth noting here in contrast to micro-costing, but we do not want to spend a lot of time going into gross-costing or its methodological differences with micro-costing.

5. An entire paragraph on p. 10 is devoted to the cost saving side of a comprehensive analysis, yet this is not in the scope of the current paper. Similarly, an entire paragraph on p. 13 addresses hypothetical cost savings resulting from smoking cessation; this issue is not in the scope of the current paper.

Thank you for these comments. Now that we have revised the paper to include the general overarching theoretical framework, grounded in economic theory, these costs fit in
better, so thank you for the suggestion on the framework. We modified several sentences in this section of the paper to clarify that the micro costing fit into a broader framework. Also, we have added a sentence at the end of this section to clarify that they are not included in the micro costing, but are included in the overall cost analysis from the societal perspective. We also corrected the dangling sentence, which left the reader wanting to know where this was going, so thank you for catching this. Our sentence is: “These costs are included in the overall cost analyses reported from the societal perspective, but are not reported in the following tables of direct program costs.”

Moreover, as noted above, with the significant additions regarding the theoretical grounding, the conceptual framework is more clear.

6. There is a gap between the costs considered in this paper and the costs that might be incurred if a similar intervention were to be implemented in a typical clinical situation. This paper focuses on costs of intervention delivery to a group of women who consented to participate in a research study. Recruitment costs would be incurred in a clinical situation. The resulting set of participants likely would not be as committed to the intervention program resulting in higher scheduling costs, such as reduced availability and missed appointments. This issue would certainly affect the main estimate as well as the scaling example presented on p. 15. Although the focus is on the costing procedure and not the specific example, these issues should be acknowledged as limitations in the discussion.

Thank you for this comment. Yes, the reviewer is right that, even though we have excluded research costs from the cost analysis, as is typically the case with clinical research, there will often be differences between the work done in a clinical trial and in another setting. Thus, a typical clinical situation might differ from the intervention, most notably, as we state explicitly in the paper text, our intervention has been delivered on an outreach basis, so this is quite different.

In terms specifically of the comments about scheduling costs, and missed appointments, these costs actually are included in the analysis. The scheduling costs are included in the administrative costs noted as scheduling costs and the missed appointments are included as travel and time costs for the nurses. The reviewer is right that these issues certainly would impact implementation in another setting, in the revised paper we have noted this in the limitation section. Thank you for pointing this out to us.

Also in the revised paper, we have included a sensitivity analysis to provide a better sense of the changes in the total costs as a result of differences in cost estimates for particular cost components.

Minor Revisions

7. The detailed background information on motivational interviewing is not necessary, and possibly misleading since the details are largely irrelevant to the example illustrated in methods and results.
Thank you for these comments. The information about MI was included so as to emphasize the aspects of MI that lend themselves to the micro-costing (a step-by-step approach). Given the close link between the nature of MI and the micro-costing, we do need to keep information on MI in the paper to provide enough background for the cost estimates as they relate to the production function.

8. Footnote Table 2 to explain “TC”

Thank you for this comment and for catching this. We have added the explanation to the footnote in Table 2.

9. Examples of the process tracking form and other worksheets would help to clarify the presentation.

Thank you for this comment. Due to the voluminous reams of worksheets and tracking logs, and the differing aspects of the different forms, it isn’t feasible to provide the process tracking form or other worksheets.

10. The discussion of micro-costing strengths and weaknesses is valuable and could be extended. This is where the case can be made for investing resources in this procedure. A single packed paragraph may not be adequate.

Thank you for this comment, it is very helpful. In the revised paper, we have added a paragraph to the discussion section (as noted above) to highlight the strengths and weaknesses of the micro-costing relative to other costing approaches.

11. The abstract and introduction sections focus on the importance of economic analyses of smoking cessation interventions. Are there examples of alternative interventions costing procedures in the smoking cessation literature to which the micro-costing procedure might be compared?

Thank you for these comments. Our group conducted a rigorous and thorough literature review on the subject of costing procedures in the smoking cessation literature. We scoured the literature on this, which is why the study reported in this paper is important to the field; there really aren’t micro-costing studies in smoking cessation. In terms of citations and review of the literature on the cost-benefit and cost-effectiveness of smoking cessation in general and among pregnant women in specific, that literature is well reviewed and cited in our previous work, (Ruger JP, Weinstein MC, Kearney MH, Hammond K and Emmons, KM. Cost-Effectiveness of Motivational Interviewing for Smoking Cessation and Relapse Prevention Among Low-Income Pregnant Women: A Randomized Controlled Trial, Value in Health, 2008; 11(2): 191-198.), but those other studies have little relevance for the paper at hand.

Moreover, we have added to the revised paper the following sentences regarding our findings from our comprehensive and exhaustive review. We added the following: “Despite recent work on economic evaluation in clinical trials however, which focuses, for example, on econometric techniques for the analysis of cost
distributions, little, if any, research has been conducted on micro-costing in health and medicine, particularly in conjunction with randomized controlled trials. Cost analyses in many areas of public health and medicine, including smoking cessation, have not typically been conducted uniformly and standardized so as to compare cost estimates across studies. Many have not included future costs, patient time and travel, and set-up or implementation costs. Incomplete and inadequate cost analyses can have a significant effect on final cost analyses (especially where real costs are underestimated), and on cost-effectiveness and cost-utility analyses. Cost analyses require standardized methodology as recommended by the Panel on Cost-Effectiveness in Health and Medicine (hereinafter, the Panel). The lack of standardized or uniform methods in estimating costs is problematic in terms of limiting our knowledge of the most efficient and equitable resource allocation to reduce smoking. This article aims to address these gaps in the literature.”

Finally, as noted above, we have added a paragraph to the discussion section regarding alternative approaches to costing in the literature.

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i Fiore, M.C., et al., Treating tobacco use and dependence. 1996, UD Department of Health and Human Services: Rockville, MC.