Author’s response to reviews

Title: A qualitative assessment of factors influencing implementation and sustainability of evidence-based tobacco use treatment in Vietnam health centers

Authors:

Nancy VanDevanter (nvd2@nyu.edu)
Milkie Vu (milkie.vu@emory.edu)
Ann Nguyen (ann.nguyen@nyulangone.org)
Trang Nguyen (nttrang@isms.org.vn)
Hoang Van Minh (Hvm@huph.edu.vn)
Nam Truong Nguyen (ntnam@isms.org.vn)
Donna R Shelley (ds186@nyu.edu)

Version: 1 Date: 12 Jun 2020

Author’s response to reviews:

Dear Dr. Flottorp,

Thank you for the opportunity to respond to the reviewers’ comments. The main critiques appeared related to confusion about the terminology related to intervention vs implementation strategies which we acknowledge required revisions. We have also reorganized the results section to respond to the recommendation from more than one reviewer to more concretely outline the domains and constructs. We are willing to add a table describing the implementation strategies that were tested if that would add clarity and to make additional edits were suggested. We also made significant edits to the Discussion, again to address reviewers’ comments. Below we include the reviewers’ comments and our responses.

Reviewer #1: The methodology used seems rigorous and was reported with sufficient information. The study findings were also reported with sufficient details, and well discussed. My only comment to authors is to perform a language revision of their manuscript before its publication.

Response to Reviewer #1: We appreciate the reviewer’s comments and recommendations. The request for a language revision that is mentioned by two reviewers seemed related to a lack of clarity and consistency on our part in the use of the term intervention vs implementation strategy. There was also confusion about the use of the term implementation effectiveness. We have made a number of edits throughout the document to address any inconsistencies in the terms.
Reviewer #2:
The manuscript throughout also requires a thorough English language revision.

Response: See response to Reviewer 1 above and responses below.

Title: Could the authors shorten the title and keep it precise.

Response: We edited the title as suggested and hope this is responsive to the suggestion.

Abstract and conclusion: This section could benefit from summarizing the key findings and highlighting the implications of the study.

Response: We believe that the conclusion describes key findings and implications of the study. “Our findings offer insights into how a multicomponent implementation strategy influenced changes in the delivery of evidence-based TDT. In addition, the results illustrate the dynamic interplay between barriers and facilitators for sustaining TDT at the policy (i.e., outer settings) and community/practice-level, particularly in the context of centralized public health systems like Vietnam’s. Sustaining gains in practice improvement and clinical outcomes will require strategies that include ongoing engagement with policymakers and other stakeholders at the national and local level, and planning for adaptations and subsequent resource allocations, in order to meet the World Health Organizations’ guidelines for promoting access to effective treatment for all tobacco users.”

Background:

* Page 4; Line 7: Provide some examples on what kind of evidence-based smoking cessation services are being referred to here, to support the statement ‘…evidence-based smoking cessation services ?? are still not….

Response: The statement is supported by the references cited and described in the next paragraph. However, we have added the following sentence that outlines the core components of evidence-based tobacco dependence: “Evidence-based guidelines for tobacco dependence treatment (TDT) include asking all patients about tobacco use, advising smokers to quit, assessing readiness to quit, and providing cessation assistance (e.g., counseling) (i.e., the 4As). The literature also demonstrates that multisession behavioral counseling is associated with higher abstinence rates compared with written material and/or brief advice.”

* Page 4; Line 10-11: Again, provide examples to support the statement -"There are effective strategies ?? for implementing guideline….”

Response: This statement is cited, however, we have again, added the following sentence to provide some examples. “These include training and coaching, embedding reminders in clinical workflows to prompt providers to screen for tobacco use, creating systems for task sharing that may include referrals to national smoker’s Quitlines which allows providers to delegate more in-depth counseling.”
Response: We cited the protocol paper and another outcome paper that describe the intervention in detail, and we provided a description in the background (ref 13, 14). Although this paper is reporting on provider and staff perceptions of the strategies, as well as the evidence-based intervention (TDT), we thought it was appropriate to provide a brief overview of this information in the text rather than a figure. However, we have further edited that part of the background section and added additional detail that we hope responds to the reviewer’s suggestion: “To address this gap, we conducted a cluster randomized controlled trial (RCT), referred to as VQuit, that compared the effectiveness of two multi-component strategies to increase implementation of TDT guidelines (i.e., the evidence-based intervention) in commune health centers (CHCs) in Vietnam. Arm 1 included provider training and a tool kit with patient educational brochures and a provider materials (i.e., a poster that outlined the 4As and desktop decision support) to remind and support providers to deliver the 4As. Arm 2 included Arm 1 components plus a system for providers to refer patients to a trained VHW to receive three sessions of in-person cessation counseling. The referral system included a form that was completed by providers and picked up by VHWs during their weekly visits to the CHCs.”

If the editor prefers, we can provide appendices with photos of the materials in the tool kit or a table that outlines the Arm 1 and Arm 2 strategy components: Arm 1 Training and took kit (Patient brochures and Provider reminder system (poster recommending 4As and decision support (desktop flipchart)), Arm 2 Arm 1 plus referral to VHW (referral form, VHW 3 session counseling)

Response: The CFIR is a well-established framework for both informing the development and evaluation of implementation research. (see ref 20-22) We do not think this requires more justification than the references we provide as it is one of the most commonly applied frameworks in implementation research. We have also referenced our two prior publications in Implementation Science (ref 13,15) which described this framework as well. We do not believe that a more detailed definition of this framework belongs in the background section. The data collection and measures section outlines each domain with examples of the major constructs that emerged in the analyses.

Response: Thank you for pointing out the spelling error. We decided to delete this term and edited that sentence for clarity.
* A paragraph leading up to the rationale of the study will be helpful for readers.

Response: The rational for the study is described at the beginning of the Background section.

Methods:

* Page 6; Line 67-68: Describe the two strategies 'effectiveness of two strategies…'?

Response: The study design section focuses on the design of the qualitative analysis which is the purpose of this paper. We have provided more information on the strategies in the background, as per the reviewer’s suggestion. We agree that this information was important to set up the purpose of this analysis. However, it would be redundant to repeat this information in the methods section, and again, the study design section was written to reflect the design of this paper analysis.

* Page 7: Data Analysis: This is a very important section in a qualitative paper and currently it lacks rigor.

Response: As reviewers 1 and 3 noted, this paper meets SRQR guidelines for qualitative research. However, we have revised this section and inserted additional details.

Results: It may be worth restructuring the results by first highlighting all the key themes and subthemes. Add a sentence or two to describe each theme and link them with CFIR. Then under each theme, discuss each subtheme as a separate paragraph and insert quotes for each subtheme with some discussion. In the below sections, start by explaining the domain in a couple of sentences and then present each theme and sub-themes with their quotes. Also try to have standalone theme/sub-theme heading.

Response: We agree that the results, in particular the description of findings under the first two domains, could be clarified. We have revised the results section to respond to the reviewer’s suggestion by starting with an explanation of the main areas we explored (i.e., implementation effectiveness/process and sustainability). We believe we have also clarified how, for example, intervention characteristics assesses both the characteristics of the evidence-based intervention (TDT), and the implementation strategies. We realize that the terminology in Implementation Research can be confusing and tried to clarify the difference between the evidence-based intervention (TDT) and the implementation strategies (training, tool kit, referral option). We have also separated Intervention Characteristics and Individual characteristics into separate sections. CFIR domains do interact, by definition, to impact implementation effectiveness but we agree that this was confusing.

We are trying to balance explaining CFIR for those readers not familiar with the model but not providing so much detail that it detracts from the findings. Readers can go to the references to obtain more information about each domain and all of the constructs. We do not believe that it is helpful to describe every one of the 39 constructs, but rather we focus on those that emerged during the interviews. The constructs described under each domain were the ones that emerged
as the major themes driving implementation effectiveness. We have outlined each domain in the study design section and in parentheses offered an example of constructs within each domain.

* Page 7, line 108: In the background section, the authors state that the aim this study was to 'identify factors' but here they say that 'We present participants' perceptions about factors that influenced….' It is not clear whether the authors were already aware of the factors and undertook this study to understand perceptions or were they trying to do both??

Response: This section has been edited to align with the background section.

* Page 8, Line 115-116: Revise the themes for clarity. For example: '1) relative advantage of the intervention.' could be revised by highlighting the advantage of the intervention itself. Make the themes standalone as it lacks meaning in its current form.

Response: These themes are the names of the constructs in CFIR and the results section provides additional information that the reviewer is requesting with supportive quotes. However, we appreciate this comment and have expanded on the language used to denote each construct. For example, we now describe complexity in the following way: “relative advantages of implementation strategies as compared to current practice and resources and complexity of the evidence-based intervention, TDT”.

At the start of the Results section we have also added the following sentence: Throughout, the results reflect participants’ responses to questions about both the intervention (i.e., TDT) and the implementation strategies.

* Page 9, Line 165-166: Please revise and clarify each subtheme. For example, '1) tension for change..' could be revised as 'need for capacity building/ or lack of organizational capacity to deliver TDT'; '3) compatibility…' (of what, with what??) this could be revised as 'Mixed compatibility of the intervention (state the intervention?)'… Please do the same throughout the results section.

Response: Our analysis was conducted using the specific CFIR constructs as a guide. Revising these terms would require reanalyzing the data. We have chosen quotes that were most representative of these constructs and we edited the language leading into the quotes, where necessary, to add clarity.


Response: We have edited this sentence as recommended.

* Page 11, Line 203: Revise the theme 'Process' (of what??) and why is there no sub-theme under Process?

Response: We have decided to delete this section to reduce the complexity, and thus the confusion, that this domain is creating. The process was not explicitly explored in the interviews but rather what we presented emerged in the analysis. The team concurred that these quotes were
describing some components of this domain as defined by the CFIR. However, the Process domain does include a number of constructs that we did not explore. We believe, in reviewing the paper again, and considering the reviewer comments, that this section did not add significantly to the findings.

* Page 11, Line 215: Should there be a broad theme on barriers and facilitators under sustainability. You could then have several sub-themes under barriers and facilitators. For example, 'incompetent policy environment, inadequate funding etc.' could be the sub-themes under barriers. Consider doing the same for 'facilitators'

Response: We have revised this section as recommended to outline each domain separately. This was challenging as these domains are interrelated and this was particularly true for sustainability.

* Overall, there is a need to better integrate the CFIR framework with your findings. Findings need a more thorough discussion and must be adequately supported by the literature.

Response: The CFIR guided our analysis and is therefore reflect in the findings in the results section which we think is now made clearer with the revisions that respond to the reviewer’s recommendation. The CFIR constructs and domains are infused throughout the discussion without necessarily referring concretely to those domains and constructs. We believe that the discussion does place the findings in the context of the larger literature on policy and system strategies to facilitate implementation of TDT in public health systems in Vietnam, and more broadly in other LMICs. We suggest areas for further research and specifically address the CFIR’s relevance as a framework for assessing barriers and facilitators of sustaining changes in practices. This is an important addition to the literature which is lacking in real world data, particularly in LMICs, on factors influencing sustainability.

* Page 14, Line 284: 'Task shifting the more…..' sentence needs to be revised for clarity.

Response: Task shifting is a well-established term describing the sharing of responsibilities to improve care. We referenced the WHO recommendation which we think made this clear. However, we have made a slight edit believe that the meaning is now clear in the sentence in which it is used.

* Page 14, Line 292-294: 'Moreover, reframing this approach to reflect a need for greater task sharing as opposed to task shifting’… this sentence is somewhat contradictory to the sentence in line 284. Please clarify.

Response: We deleted that sentence

* Page 16, Line 335: Add reference to support your claim.

Response: We don’t have a reference. This is from our interactions with our colleagues and from the CHC provider interviews. However, we edited it to clarify that the conclusions is based on our findings. “The findings also point to a need to further engage with the MOH to explore why,
despite having a Tobacco Law and Fund, and actively implementing other FCTC policies, based on our interviews, the MOH has not yet made cessation a priority program for CHCs.”

* In the limitations section, it may be worth discussing, what measures did the authors put in place to minimize the limitations. Such as the social desirability bias?

Response: There was a risk of a social desirability bias in responses however, participants were willing to share weaknesses in the current system for supporting tobacco cessation and we reached saturation with responses in this large sample. We have added this to the limitations section.

Reviewer #3: Overall, this paper uses strong qualitative methods in accordance with SPQR guidelines and addresses an important problem. However, revisions are needed to improve conceptual clarity and to highlight the paper's contribution to the implementation research literature.

Introduction

Page 4, Lines 18-23: The intervention and the implementation strategy are not clearly delineated in this block of text. Is the "4As" program considered the intervention? Training and a tool kit are referred to as the implementation strategy in the control sites- can the authors map their approach to the ERIC taxonomy or other guidance for specifying implementation strategies?

Response: We have edited the paper to better clarify what is the intervention vs the implementation strategy. We referenced Powell in the article and the strategies are aligned with those reported in that paper and the literature on implementation strategies tested to specifically implement TDT. We now delineate those strategies in the background section.

Results: The current structure and reporting of results raises some questions to be addressed by the authors. Lines 113 Intervention Characteristics (Implementation Strategies) and Individual Characteristics. The parenthetical construction here seems to imply equivalence between intervention characteristics and implementation strategies, which is confusing. Further, no rationale is given for grouping intervention characteristics and individual characteristics in this section.

Response: We have separated intervention and individual characteristics as described above (Reviewer 2). We have clarified that the Intervention Characteristics referred to both the intervention and implementation strategies. For example, we asked about both the complexity of providing TDT and their reactions to the design of the strategies like the training. We have deleted the parentheses.

Page 8, Lines 114-116
114 …The main themes that emerged under the intervention characteristics 115 domain were: 1) relative advantage of the intervention, 2) perceptions about intervention
116 complexity, 3) strength of the evidence, and 4) design quality and packaging. The authors appear to have selected a set of 4 CFIR subheads under intervention characteristics as main themes. (The full set of CFIR subheadings includes internal or external origin, evidence quality and strength, relative advantage, adaptability, trialability, complexity, design quality and presentation, and cost.) Individual characteristics comprise another set of potential themes (Individual Identification with Organization, Individual Stage of Change, Knowledge &Beliefs about the Intervention, Other Personal Attributes, and Self-efficacy).

Response: We report only on the main constructs that emerged during the analysis. We explain above (Reviewer 2) that we did not think it was relevant to describe each construct regardless of whether it emerged as relevant to the aims of the analysis. The constructs and representative quotes reflect the most commonly noted discussion points and issues that the participants raised.

The emergence of main themes noted in this section seems arbitrary, given the quotes provided. What is the justification for not including elements grouped under characteristics of individuals, one of CFIR’s primary domains, as main themes? For instance, a statement like "I got more knowledge on how to advise our patients to quit smoking" on line 121 would seem to relate to self-efficacy.

Response: We have separated Individual Characteristics and Intervention Characteristics and made clearer that the Individual Characteristics the main constructs that emerged under this domain were a gain in knowledge and associated gains in self-efficacy.

As another example, Lines 151-152 state:
151 Although a few patients were willing to purchase products, for most,
152 the cost was a barrier in rural areas where "people are not able to afford the medicine"

If this quote is included in the text, why isn't cost mentioned as a theme under characteristics of the intervention?

Response: We have now explicitly noted cost as a construct.

By contrast, the following section on inner setting is logically structured. The reviewer suggests splitting and restructuring the section on intervention and individual characteristics to address previous comments, and to be consistent with the construction of the inner setting section.

Response: As recommended, we have separated the two domains.

The section on process does not follow the structure of the preceding sections and does not clearly tie quotes to elements of process in CFIR (Planning, Engaging, Executing, Reflecting &Evaluating).

Response: We addressed this above (Reviewer 2). We did not purposively evaluate process. Rather, the one construct of engagement emerged from the interviews. We acknowledge that this could have been evaluated in more depth but was not explicitly explored in the interview guide. We have decided to delete this section as explained above.
Discussion

Lines 325-326
325 Our findings are consistent with the current literature on determinants of implementation effectiveness and sustainability. The references listed here are, by and large, descriptions of frameworks without specific things to say about the study at hand. As such, this statement is not very informative - "our findings are consistent" in what sense? The contribution that this study makes is not clear and could be more clearly articulated.

Response: We agree that this was vague and have edited that paragraph. We have made significant edits to clarify how we think the paper adds to the literature and the implications for informing future research. The discussion does note that the findings contribute to a greater understanding of opportunities for intervening at multiple levels to increase implementation and sustainability of TDT. We expand on the contribution the paper makes by demonstrating the application of CFIR to assess sustainability and by identifying other domains in other frameworks that would add to these types of analyses. We have edited the discussion to make more explicit that these findings can inform context specific strategies for increasing the translation of Article 14 guidelines into public health practice globally.

More discussion on how Vietnam compares to other countries would be helpful to understand the generalizability of the results, implications for other countries seeking to implement smoking cessation interventions, and applicability of the results to other interventions.

Response: The discussion includes a statement that this may be applicable to countries with similar political and health system infrastructure.

Minor comments

The abstract closes with the phrase: "in order to meet Article 14 goals" - "Article 14" is not a widely known term to a general reader of this journal.

Response: We have deleted mention of article 14 in the abstract. Its not described until the background.

* These statements in Lines 44-50, related to the parent trial from which this study derives, are not very informative without seeking out the original papers. More quantitative detail, including effect sizes, would be useful in this segment.

Response: We have added the p values in the background.

* Statements from lines Lines 51-52: and then in the study design are inconsistent (one year post intervention vs at the end of the intervention period.
Response: We have edited this to be more consistent.

*There are more acronyms in the paper than are listed in the acronym key. For example-Vietnam Steering Committee on Smoking and Health (VINACOSH). Please spell out all acronyms beyond these 6.

Response: Additional acronyms have been added.

Reviewer #4: Throughout the paper, the authors seem to confuse the focus on the intervention, which I understand to be TDT, and the strategies used to promote the implementation of the intervention, which I understand to be the 4As and 4As+R. Most of the text makes it sound as though the authors are interested in understanding the influence of the strategies on adherence to TDT, but there were many, many places where I wasn't so sure. Examples include the objective of the paper: "to identify factors that influenced the implementation and the potential for sustainability of this effective model (implementation strategies???) for improving adoption and implementation of TDT guidelines in Vietnam CHCs."

Response: Thank you for this helpful comment. This was an issue for the other reviewers and we have tried to clarify this issue throughout the paper. We have also removed reference to 4As+R because we think this created some of the confusion.

In the methods section, the interview guide is described as being based on the CFIR, and some examples of its application suggest that interview questions related to the implementation strategies, but some suggested that interview questions related to the intervention. If, for example, the authors asked in interviews about e.g., relative priority of addressing tobacco use, then they're asking about TDT and not about implementation strategies as I think they intended to do, and thus they haven't answered their research question. This is also confusing in the results section.

Response: In the results section we have clarified that we explored the relevance of the CFIR constructs for both the intervention (TDT) and the implementation strategies. This approach applied only when relevant to both.

How were the adaptations done to avoid compromising what made the implementation strategies effective in HIC?

Response: Although the reviewer raises an important IS methodological issue, our findings indicate that the strategies were effective in addressing CFIR constructs (e.g., increased knowledge and confidence among providers) and our main outcome analysis demonstrates a remarkable improvement in adherence to the TDT guidelines. We very clearly defined the core functions for each implementation strategy as per Jolles et al (Core Functions and Forms of Complex Health Interventions: A Patient-Centered Medical Home Illustration J Gen Intern Med. 2019 Jun;34(6):1032-1038) and very clearly documented the way each strategy was adapted to maintain the core function. For example, the CHCs didn’t have charts so we used a poster to prompt providers to remember to implement the 4As rather than embed an alert as we might have done if sites had electronic health records (EHRs), or even a paper chart. Similarly, the
referral system included a paper form rather than a direct data exchange that we use in the US where EHRs are the norm. We believe that it is beyond the scope of this article to describe the adaptation process in detail. The goal of this paper is to present the participants’ perspectives on the implementation strategies and potential for sustainability.

There are several things in the methods that would benefit from clarification: (1) Much of the study design section has information that belongs in a separate sample section and in the data collection section.

Response: As we explained above, we believe the study design should only include information about this paper. We have included the study design for the parent grant in the background as recommended by the previous reviewer.

(2) Where were the participants interviewed? How did they promote confidentiality? We note that his study was IRB approved therefore all measures were taken to safeguard confidentiality

Response: As the reviewer notes, this study was approved by two IRBs. Our prior experience suggests that this type of detail regarding human subjects is not needed given the IRB approval statement.

(3) Methods described on p7 line 96-99 don't relate to external validity.

Response: We have deleted this.

(4) Describe Standard for Reporting Qualitative Research (SPQR) and why it's important/helpful.

Response: We are required to include this in the paper as per the Journal guidelines. We do not feel this requires further explanation. We added reference to SPQR.

(5) In the results section, but ostensibly relating to methods, why do only some domains apply to implementation and other domains apply to sustainability? Was this a coincidence, or was this by design (i.e., only some domains asked about with respect to one or the other of these outcomes)?

Response: We have revised the sustainability section to separate the domains and constructs under those domains that emerged in relation to sustainability. The guide specifically asked participants about what they believed would facilitate or impede sustainability and we coded those responses within relevant domains and constructs as we did in the implementation effectiveness analysis. It is not necessarily surprising that the relevant constructs might differ. Responses were not exactly aligned under the main heading of implementation and sustainability. Therefore, the domains and constructs we describe under each are not necessarily the same. We allowed the data to drive the findings.

Minor considerations
Consider renaming 'implementation effectiveness' to 'implementation success" or similar bc of confusion with intervention effectiveness. Header implementation effectiveness p7 line 112 is confusing bc that's the outcome and the subsections below it are determinants of implementation, not subsets of implementation.

Response: We agree that the quotes are describing determinants of implementation or implementation effectiveness (why implementation of TDT increased). We also agree this language, which is consistent with implementation science terminology, can be confusing. We have edited the heading but we are open to other suggestions if this needs further clarification.

* 'Adoption' p5 line 53 - if it's a trial, don't they mean potential adoption in context of theoretical scale up?

Response: We deleted mention of adoption in this sentence.

Need to define sustainability and explain why it's important in this context. Is there reason to believe that it will be a concern, maybe.

Response: Sustainability is receiving increased attention in implementation science because it remains understudied. It’s clear that simply achieving short-term implementation outcomes does not necessarily ensure sustainability (i.e., longer term sustained adherence to TDT, in the case of this project). Few studies have examined either long-term sustainability of outcomes or factors that influence (independent variables) sustainability in the context of a real-world pragmatic trial. As per Chambers’ paper on the Dynamic Sustainability Framework, cited in this paper, sustainability requires an iterative process of assessment and adaptation to address contextual barriers. Our assessment of sustainability was meant to provide actionable data to the MOH to inform additional funding and other resource allocation to optimize both implementation and ensure that improvements in outcomes were sustained. We believe it is the information on sustainability in the results and discussion sections that provides the most important contribution to the literature.