Dear Dr. Presseau:

Thank you for considering our manuscript, “Why is announcement training more effective than conversation training for introducing HPV vaccination? A theory-based investigation” (#IMPS-D-17-00436), for publication in Implementation Science.

Below we provide responses to the reviewer’s and associate editor’s comments. We believe that our paper has been further strengthened by this revision, and we thank the reviewer and associate editor for another thorough review.

We look forward to your publication decision.
AE = associate editor; R2 = reviewer 2
Page numbers refer to the version of the manuscript with tracked changes.

1. AE, comment #1: The title: The title still feels too ‘definitive’ given the design limitations of the uncontrolled before/after nature of the study, and still does not sufficiently convey (to a reader who has not yet read the abstract or the paper) that two types of training are being evaluated. The authors may have been hasty in removing the term ‘process evaluation’ from the title as it is indeed reporting aspects of what other papers in the field would classify as a process evaluation (ie evaluating mechanisms of change). I suggest a revised title: “Investigating why announcement training is more effective than conversation training for introducing HPV vaccinations: a theory based process evaluation”, which more closely aligns with the process evaluation aims of the manuscript and the focus on the training itself (which is also more closely aligned with the remit of the journal).

The main purpose of our paper is to report registered secondary outcomes related to provider self-report for our clinical trial. We also had process data that fit nicely with the secondary outcomes data. We worry that framing the paper as solely a process evaluation misses one of its main strengths as an outcome evaluation. In addition, the theoretical aspect of the measures based in TPB was for outcome but not really for process evaluation. Finally, we want to keep the announcement term as close to the front of the title as possible; we suspect it is what will make people read and cite the paper. We propose the following title: “Why is announcement training more effective than conversation training for introducing HPV vaccination? A theory-based investigation.”
2. AE, comment #2: Intention: The lack of assessing intention from the TPB is a limitation and should be reflected in the limitations section; intention is arguably the key construct from the TPB and the added role of intention as a key mediator between attitude, subjective norm and behaviour represents one the theory’s main contributions to science. Irrespective of this study not aiming to test theory, if the study is claiming to use the TPB to investigate mechanisms of change, a missing construct should be listed as a limitation.

We assessed intentions at post-intervention and follow-up: “I plan to [use/routinely use] this communication strategy to recommend HPV vaccine for my adolescent patients.” It is heartening that intentions were fairly high (~4.5 of a 5-point scale) and did not drop over the follow-up period.

We did not see any way to assess intentions meaningfully at pre-test, and not contacting control clinics meant that we could not compare to this trial arm. The limitations section now addresses that we did not survey providers in the control arm:

“While it is encouraging that intentions to use the training approach was high and did not drop over the 1-month follow-up period, the absence of a baseline assessment meant we could not compare these measures to before we taught the communication approach. We also did not assess the broader construct of intentions to recommend HPV vaccination to all eligible patients.” (p. 18-19)

3. AE, comment #3: Clarify measures to promote replicability: The ‘Perceptions of the communication strategy’ description on page 11 would be difficult for another researcher to replicate without more detail. Please clarify more specifically which constructs are being assessed and by how many items for: ‘easy to do’, ‘saves time’, ‘helps to make HPV vaccination a part of routine care’, ‘helps them address parent concerns’, ‘helps them emphasize HPV vaccination as a way to prevent cancer’, and ‘increases HPV vaccination in their practice’. It seems these may be a combination of items that tap Attitude (or at least behavioural beliefs) and Perceived Behavioural Control (or at least control beliefs) rather than being completely distinct. Also, this index is slightly better described in the results section on page 13 but it would help to be more consistent between the sections.
The verbatim items assessing providers’ perceptions of the communication strategy appear in Table 3. These items assessed the acceptability of the training, which is distinct from the TPB constructs that assessed the impact of the training of providers’ attitudes about HPV vaccination. To clarify this distinction, we have edited the Methods as follows:

“TPB constructs. Pre- and post-training surveys included 6 items that assessed TPB-related constructs so as to understand the impact of our training on providers’ HPV vaccine-related perceptions; one-month follow-up surveys also assessed 3 of these items. These items assessed providers’ HPV vaccine attitudes (2 items), subjective norms about HPV vaccination (2 items), and self-efficacy to recommend HPV vaccination (which is an aspect of perceived behavioral control, 2 items). We evaluated one additional construct, behavioral intentions, at post-training and one-month follow-up with a single item that assessed intentions to use the recommendation strategy taught in the training. For all TPB items, the 5-point response scale ranged from strongly disagree to strongly agree.” (p. 11)

“Perceptions of the communication strategy. To evaluate the acceptability of the communication trainings, post-training and one-month follow-up surveys assessed perceptions of the recommendation strategy taught in the training (7 items).” (p. 11)

We also have added a supplemental table of survey items mapped onto HPV vaccine recommendation behaviors, theoretical constructs, and perceptions of the communication strategy. We now direct readers to the supplemental table:

“Surveys are available at http://www.unc.edu/~ntbrewer/hpv.htm and in the supplemental table.” (p. 9)

4. AE, comment #4: Consider the relative patient-centredness of each intervention in discussion: At the discretion of the authors, it may be worth a point in the discussion that even though ‘announcement training’ was better perceived by the health providers and they feel more confident in using that strategy, arguably it is a less patient-centred approach or may be perceived as such. In a time where greater patient participation and shared decision making are recommended, it may be worth discussing whether the findings could inform future training that recognizes that health professionals are less confident in the participatory conversation
intervention but with training may lead to more patient-centred care and decisions. Without this paragraph, it feels a little like we are cutting out the role of patients/parents in decision-making because the health providers feel more positive about announcing than discussing. A more nuanced discussion on this could be worth considering but I leave it at the discretion of the authors.

We agree that additional research is needed to understand the impact of various communication approaches on parent-level factors such as satisfaction and trust. Because a parent-level evaluation was beyond the scope of the present study, we are hesitant to speculate about how parents perceived the announcements. It may be that parents appreciate the efficiency of announcements, which save them time for discussing more complex, family-directed behaviors. Given that the field is still coming to terms with how to define patient-centered communication in the context of routine preventive services, we believe that these points are best made in terms of areas for future study:

“Future studies are needed to understand how communication training affects the experience of adolescent patients and their parents; like providers, families may appreciate spending less time on routine preventive services so as to focus on more complex health issues, such diabetes, asthma, and depression.” (p. 19)

Finally, decision aids and shared decision making are appropriate in the presence of clinical equipoise. Vaccination is a very different situation. National immunization authorities have established clear clinical guidelines for adolescent vaccines, and pediatric organizations have endorsed these recommendations as best and ethical practice. Providers may harm patients’ health by treating some vaccines differently than others (announcements are by far the norm for childhood vaccines); by having a long conversation that singles out, for example, HPV vaccine in a way that suggests risk where none exists; and forcing parents to have a discussion that many don’t want. The idea that announcements eliminate discussions is a false dichotomy. Parents can and do ask questions, and the training gives a specific approach for addressing them (the EASE approach). We respectfully disagree that our approach is anything but highly patient-centered.

We added text to the methods to clarify that we also trained providers to address parents’ questions and concerns.
“In the second section, the physician educator taught participants a strategy for delivering effective HPV vaccine recommendations by starting with either an announcement or conversation strategy and then, as needed, addressing parent questions using the EASE approach, and recommending the vaccine. The EASE approach to addressing questions was to Elicit the parent’s main concern, Acknowledge the concern without judgment, Share a commitment to vaccination and the child’s health, and Explain what the science says.” (p. 9)

5. AE, comment #5: Implications for Implementation Science: The added discussion point on pages 20-21 is useful. The authors may want to consider enhancing their interpretation of the utility of the theoretical approach by highlighting that while TPB results did not differ between arms, had a control group been included, differences may have been observed (and flag this for future research). The lack of control arm remains a limitation that should be added to the limitations section, as other TPB-based process evaluations alongside trials do also collect pre-post data from health professionals in the control arms. Please add this to the limitations.

We agree that a control arm would have been a useful addition and have added this to the limitations section:

“Finally, future studies should consider collecting survey outcomes and process data from providers in the control arm. These data would offer additional insight into how the trainings acted on the TPB constructs.” (p. 19)

6. AE, comment #6: ‘Norms’ terminology: RE: the authors justify their decision to stick with ‘social norm’ over ‘subjective norm’ as the term by citing Fishbein and Ajzen’s Reasoned Action Approach. However, in the RAA, the term used for this construct is ‘perceived norm’. For the sake of consistency, if they authors are saying that they operationalized the TPB, please use the TPB’s construct names (including subjective norms). The literature is already replete with multiple terms for similar constructs and it is important to remain consistent with terminology in order to build a cumulative science.

As requested, we have changed all instances of “social norms” to “subjective norms.” Some benefit could accrue for the field to update terms to match the current science, especially when we have the authors’ own words to guide us with respect to the problems with the old
nomenclature. Thank you for pointing out the use of perceived norm as the preferred term in the RAA. Fishbein and Ajzen use perceived social norm, perceived norm, and social norm frequently in the text, and we had missed their preferred use of perceived norm.

7. AE, comment #7: Minor point: Figure 2’s Y axis title has a typo on the word ‘discussion’

Thank you for alerting us to this error. We corrected it.

8. AE, comment #8: Minor point: in figure 2, it would help to describe in parenthesis what units of measurement the Y axis is referring to so that it is a standalone figure (ie it is not clear that the 1-5 is a response scale as it could be seen as raw number of times)

We have updated Figure 2’s Y-axis to read “Length of discussion (minutes).”

9. AE, comment #9: Minor point: The abstract only states that t-tests were used; but so were ANOVAs. please clarify.

We removed the names of the statistical tests from the abstract. For a reader to understand what we did, they would need more information than we can provide in the space of the abstract.

10. AE, comment #10: Minor point: the authors have the option of publishing their measures as online additional materials which would facilitate replication in a more straightforward manner than linking to a personal website. but this is at the discretion of the authors.
We agree. In addition to hosting the surveys on our professional website, we have uploaded the surveys as online additional materials.

11. R2, comment #1: (1) Investigating acceptability as an aim: In the aims of the study, Line 117-120 suggests that you will evaluate 'process measures such as acceptability' - this term is not used again until the discussion; which measures does this refer to?

We now clarify the measures of acceptability in the methods. Please see our response to AE, comment #3.

12. R2, comment #2: (18) Time period between data collection: My reservation is less with comparisons between pre-training and one-month follow on, but with those made between pre- and post-training (e.g. for the two attitude items and one social norm item). The influence of collecting data immediately after intervention delivery warrants caution in interpretation.

We agree, and we also point readers to a commentary by Williams and Dunsiger that argues for immediate post-intervention evaluations are being valuable because they are not affected by the changes in behavior that result from the intervention. We revised the limitations section as follows:

“Evaluating changes in constructs after the intervention but before providers had an opportunity to change their behavior can disentangle the impact of the intervention from subsequent behavior which might also cause changes in these constructs [24].” (p. 18)

13. R2, comment #3: (22) TPB item development: Given the availability of item development guidance for the TPB it would be useful to provide additional detail about the process by which items were developed and justification in text for only including two items per TPB construct. It
is unclear if these measures would demonstrate validity, other than clinical face validity based on the revised text (e.g. how was the theoretical validity of the items ensured)

The limited items reflect the clinical reality of providers’ limited time and disinclination to complete lengthy psychological instruments. We now note this as a limitation:

“Our surveys were brief, assessing TPB constructs with as few as two items, in an effort to be mindful of providers’ limited time and to increase the response rate. We cognitively tested our measures with four providers, but additional validation may be warranted in future studies.” (p. 18)

14. R2, comment #4: (27) Study design: Could the authors add a description of the study design?

We have added descriptions of our study design to the Abstract:

“… we evaluated intermediate outcomes and process measures from our randomized clinical trial …” (p. 3)

We also added several sentences to the beginning of the methods to orient the reader to the overall design. Some of the text had appeared in the methods but was, we agree, hard to put together into a coherent picture if you didn’t already know the trial.

“We conducted a randomized clinical trial to evaluate the impact of provider trainings on HPV vaccine communication (NCT NCT02377843). We randomly assigned clinics to one of two intervention arms (announcement training or conversation training) or to a waitlist control arm, and then we recruited the clinics to meet our quota. This article focuses on the 20 clinics that received the communication trainings; we did not provide training to clinics in the no-intervention control arm during the follow-up period. We described our methods previously [19] and thus describe them briefly below.” (p. 7-8)
15. R2, comment #5: (31) Title: The exploratory nature of the study hypotheses would indicate that a less clear-cut title may be more representative of the study aims and findings.

We have softened the title of the paper. Please see our response to AE, comment #1.

16. R2, comment #6: Findings/conclusions related to provider perceptions of strategies (incl. Table 3): Do more positive provider perceptions of the announcement strategy for introducing HPV vaccine provide a sufficient answer to the question posed in the title? While participants may have positive perceptions of an intervention, would this be sufficient to lead to changes in behaviour? How this might operate could be explore further given that no differences were observed between groups on TPB measures. Also, looking just at the mean differences in Table 3 regarding perceptions of the two communication strategies, while there are numerous significant differences, these relate to differences of 0.2-0.5 between groups - are these likely to represent clinically significant differences?

In the discussion, we speculate that providers’ positive perceptions (i.e., acceptability) of the announcement training may have led to higher adoption of announcements. It may be that positive perceptions had an additive effect with TPB constructs to drive the higher HPV vaccine coverage we observed in announcement training clinics:

“Trial arms showed few differences in TPB-related perceptions and self-reported recommendation practices, perhaps because the portions of trainings that were designed to affect these perceptions and practices were designed to be the same across arms. Instead, we observed differences by trial arm in perceptions of the communication strategy, with a fairly consistent pattern of providers reporting more positive perceptions of the announcement training. We speculate that providers perceived announcements as being more feasible, and therefore implemented that strategy more often. It may be that providers’ positive perceptions of the announcement training, along with TPB-related constructs, were needed to drive the higher HPV vaccine coverage we observed in announcement training clinics.” (p. 17)

The effect sizes for some psychosocial measures are small to moderate in size. Our trial impact on vaccination (5%) is moderate in size and clinically meaningful.
17. R2, comment #7: (42-43) Effect sizes: Some of the effect sizes in the manuscript appear implausibly large. This may, in part, be related to measurement reliability which may spuriously affect effect size (and measures of constructs using single/few items are less reliable).

Low reliability would make our effect sizes smaller rather than larger. We now note that measuring constructs using few items is a study limitation (please see #13).