PEER REVIEW HISTORY

ARTICLE DETAILS

TITLE (PROVISIONAL)	'Presumptively Initiating Vaccines and Optimizing Talk with Motivational Interviewing' (PIVOT with MI) trial: A protocol for a cluster randomized controlled trial of a clinician vaccine communication intervention
AUTHORS	Opel, Douglas; Robinson, JD; Spielvogle, Heather; Spina, Christine; Garrett, Kathleen; Dempsey, Amanda; Perreira, Cathyrn; Dickinson, Miriam; Zhou, C; Pahud, Barbara; Taylor, James; O'Leary, Sean

VERSION 1 – REVIEW

REVIEWER	Katie Attwell University of Western Australia, Australia
REVIEW RETURNED	11-May-2020

GENERAL COMMENTS	This protocol is clearly explained and leaves almost no relevant questions unanswered. Publishing it will be of immense use to researchers undertaking similar studies globally. One brief question - page 7 pre-study information - is it worth comparing clinician case load across all sites, as time available to spend with patients may also be influencing success of intervention. I am not a statistical expert and thus I have not been able to provide expert review of the analysis methods and sample size considerations.

REVIEWER	A/Prof Margie Danchin Murdoch Childrens Research Institute and University of Melbourne
REVIEW RETURNED	14-May-2020

GENERAL COMMENTS	Thank you for the opportunity to review this protocol for an innovative and promising intervention to improve childhood vaccine uptake - MI needs further evaluation to address VHPs so this is a welcome study Abstract - Suggest add critical to "improve" vaccine uptake Introduction - Suggest adding that presumptive initiation format is not suitable if the clinician already knows the parent is highly VH or refusing – for example this cannot be used in specialist immunisation clinics where parents attend to discuss vaccine concerns, such as we have in every tertiary paediatric hospital in every State in Australia Aims: very simple and clear Methods: well described and clear

	A few questions - The treatment of the control cohort is not well-explained – what do these clinicians and practices receive? Why do they receive MOC part 4 credits at then end f they have not been trained? - For the intervention group – with BL training and then a refresher at 3 and 6 months – do you think there should be a refresher at 12 months – this could be done online to limit face to face requirements? - How will you ensure that all clinicians attend the face to face training - the MOC part 4 credits are an incentive but when will these be scheduled and how will you capture clinicians who can't attend? For most clinicians, attendance for face to training is becoming increasingly difficult – did you consider an online version as well? There could still be coaching, audit and feedback? - Will be interesting to see if the presumptive initiation format upsets very highly VH or refusing parents and if this inhibits the MI approach in subsequent visits ie the clinicians would not use this approach for the next visit if they already know the parent is VH - The assumption of 10% VHP is consistent with our estimates of VHP in Australia – the sample size calculations seem feasible This is well written and clear protocol and I look forward to seeing the results of the study

VERSION 1 – AUTHOR RESPONSE

Reviewer 1 Concerns:

3) One brief question - page 7 pre-study information - is it worth comparing clinician case load across all sites, as time available to spend with patients may also be influencing success of intervention.

> *This is an interesting point. We agree that the time available to spend with patients is an important variable. Though we are not collecting information on clinician case load, we are asking all clinician participants in both study arms to complete a pre- and post-study survey regarding the amount of time they spend discussing childhood vaccines with typical parents as well as with parents who have substantial vaccine concerns. This will allow us to assess not only for baseline differences that may need to be accounted for in analyses but also to assess the effect of the intervention on this variable. We have added this information to our 'Outcomes' section on page 9.*

Reviewer 2 Concerns:

4) Abstract: Suggest add critical to "improve" vaccine uptake

> *Thank you for this suggestion. We have revised this sentence to now read: "Improving clinician communication with VHPs is critical to increasing childhood vaccine uptake."*

5) Introduction: Suggest adding that presumptive initiation format is not suitable if the clinician already knows the parent is highly VH or refusing – for example this cannot be used in specialist immunisation clinics where parents attend to discuss vaccine concerns, such as we have in every tertiary paediatric hospital in every State in Australia.

> *Thanks for this comment. We certainly acknowledge that use of the presumptive initiation format in these scenarios does not seem intuitive, and more so, may not be feasible or appropriate in specific settings. That said, we are not aware of any evidence that use of the presumptive format in these scenarios is not suitable. In fact, in our preliminary work, we*

found less verbal resistance to vaccine recommendations when clinicians used the presumptive (vs. participatory) format even among VHPs. We have therefore added a sentence to the introduction to explicitly note this existing evidence to better substantiate our intervention. Indeed, we have designed the PIVOT with MI communication strategy to involve use of the presumptive initiation format with all parents at every vaccine visit. We also provide explicit instruction in our training curriculum regarding how to use this format even with parents who have previously refused vaccines or in scenarios when the provider knows the parent is vaccine-hesitant. This design is also driven by the inclusion of motivational interviewing techniques in our PIVOT with MI communication strategy; in situations where parents are highly hesitant or previously have refused, pivoting from the presumptive format to MI can occur more quickly to be responsive to parental concerns.

6) The treatment of the control cohort is not well-explained – what do these clinicians and practices receive? Why do they receive MOC part 4 credits at the end if they have not been trained?

We have elaborated on what we mean by control clinicians providing usual care: specifically, that control clinicians will not receive any communication training and simply continue to communicate with parents about childhood vaccines as they are accustomed. This has been added to the 'Study overview and setting' section on page 6. We have also revised the section on 'Participant retention' on page 10 to denote that control clinicians will only receive MOC at the conclusion of the study and after completing the PIVOT with MI curriculum.

7) For the intervention group – with BL training and then a refresher at 3 and 6 months – do you think there should be a refresher at 12 months – this could be done online to limit face to face requirements?

Thank you. We had actually previously made this change and did not update Table 2. This is now corrected to reflect refresher trainings at 3-6 months and 9-12 months.

8) How will you ensure that all clinicians attend the face to face training - the MOC part 4 credits are an incentive but when will these be scheduled and how will you capture clinicians who can't attend? For most clinicians, attendance for face to training is becoming increasingly difficult – did you consider an online version as well? There could still be coaching, audit and feedback?

We are logging attendance and making MOC contingent on completion of the training. For the uncommon (but real) circumstances when a participating clinician cannot make an in-person training, we have an online version of each training available that we can track to ensure it is viewed. This is only used in exceptional circumstances as coaching, audit and feedback are not as effectively provided through this version as they are during in-person trainings. We have added mention of these online training versions to Table 2.

9) Will be interesting to see if the presumptive initiation format upsets very highly VH or refusing parents and if this inhibits the MI approach in subsequent visits ie the clinicians would not use this approach for the next visit if they already know the parent is VH.

Agree!

VERSION 2 – REVIEW

REVIEWER	A/Prof Margie Danchin Murdoch Childresn Research Institute and University of Melbourne
REVIEW RETURNED	Thank you for submitting a revised version of the trial protocol - I believe that the authors have adequately addressed all the questions that arose on initial review and that the protocol should be accepted for publication. I wish the authors all the best for the conduct of the trial and will look forward to the results.