Author’s response to reviews

Title: Implementing cardiovascular disease prevention guidelines to translate evidence-based medicine and shared decision making into general practice: Theory-based intervention development, qualitative piloting and quantitative feasibility

Authors:

Carissa Bonner (carissa.bonner@sydney.edu.au)
Michael Anthony Fajardo (michael.fajardo@sydney.edu.au)
Jenny Doust (jdoust@bond.edu.au)
Kirsten McCaffery (kirsten.mccaffery@sydney.edu.au)
Lyndal Trevena (lyndal.trevena@sydney.edu.au)

Version: 2 Date: 27 May 2019

Author’s response to reviews:

Dear Dr Presseau,

Thank you for the opportunity to revise and resubmit this paper again. We have revised the manuscript in response to the helpful comments of the editor and reviewers, including:
1. adding a more detailed flowchart to more clearly explain the scope of this paper in the context of the larger program of research it is part of
2. restricting all analyses to the follow-up sample of n=98 (including outcomes assessed at baseline where total n=123)
3. revising the discussion to explain implications of specific low risk results relating to de-implementation and broader issues for the field
4. more consistent use of terms and stages throughout

We have addressed each point below and hope it is now suitable for publication in Implementation Science.

Kind regards,

Carissa Bonner on behalf of all authors

Associate Editor's comments:

1- The added text on ‘implications for the field of implementation science’ does not add any discussion
on implications for the field, but rather only reiterates the aims and broad methods used, which are already described elsewhere in the manuscript. Please add a more considered discussion on what the present study, in terms of methods, theory and/or findings adds to implementation science so that readers can better appreciate the broader contribution that this manuscript can make beyond the bounds of the study itself. A dedicated subsection in the discussion on 'implications for implementation science' should be considered.

We have added the subsection with broader implications.

Page 16: Implications for implementation science
Our results highlight a theoretical issue regarding the difference between implementation (prescribing for high risk) and de-implementation (not prescribing for low risk).[39] While addressing capability barriers to guidelines appeared to increase intentions for prescribing medication to high risk patients, there was no improvement in unnecessary prescribing for low risk patients. A recent synthesis of behaviour change theory suggests that behaviour substitution may be needed to address the latter situation, but there is little guidance in the literature for how to select such a behaviour at present.[39] More broadly, this project provides a model to other intervention developers for how to apply the theory-based Behaviour Change Wheel framework to identify behavioural barriers to the use of guidelines,[24] and co-design an evidence-based intervention with end users to address these barriers. In particular, it illustrates the value of an extensive qualitative evaluation to understand behavioural barriers amongst different targets (GPs and patients) and testing different strategies/formats before trialling an evidence-based intervention, as previous trials in this context had little impact on prescribing and failed to incorporate important knowledge (confusion about the role of different risk factors) and capability (doctor-patient risk communication) issues. The iterative co-design process for website development shows how GP and patient feedback can be incorporated into intervention design, but the timeframe required for this process meant that the qualitative analysis was pragmatic rather than formally thematic. Future intervention designers may benefit from: 1) considering implementation and de-implementation components separately as different behavioural strategies may be needed; and 2) long term planning to allow time for detailed exploration of behavioural barriers initially and more in-depth analysis of purposively sampled user feedback during development.

2- The authors have not quite addressed my previous point about the varying sample sizes (point 12). If the design is a pre-post, then the same ‘pre’ participants need to be compared with the same ‘post’ participants. Otherwise, those that only completed the ‘pre’ may be inflating the overall ‘pre’ responses relative to 'post'. It would be much more robust to present findings with the same sample size across all analyses (in other words, for all analyses in all tables, only include the n=98 participants that have completed all data points at both time point and discuss limitations related to attrition, or present a robust missing data imputation solution).

Different sample sizes were reported because different outcomes involved different time points: the baseline survey involved assessing knowledge pre- and post-viewing the website (n=123 for both pre and post measures; therefore 123 seemed appropriate to report); while the follow-up survey involved assessing self reported use after 1 month (n=98). However, we have now restricted analyses for all outcomes to n=98 as requested as this was our intended sample size and we think this will reduce confusion given it is a very complex manuscript.

3- In stage 5 results, it would help to add the actual ’n’ next to each % of the sample reported on.

We have added this detail.
Reviewer reports:

Reviewer #1: I would like to congratulate the authors on the strength and clarity of the revised manuscript. There are a few more areas that require attention that would significantly strengthen the manuscript's contribution to the literature. On an unrelated note, I would also like to commend Mr. Fajardo for supporting this submission while Dr. Bonner was on maternity leave- this is an uncommon gesture (in my experience) with immeasurable impact.

Thank you for your kind comments, and noting the team support during leave – we all agree!

Major Revisions

4. The authors regularly refer to an audit and feedback exercise as part of the intervention, but this is not well-described. It is clear that the intervention provides feedback on risk classification, but what is the audit component? The 'audit' aspect of audit and feedback refers to the measurement of an individual's professional practice or performance, which is then compared to professional standards or targets. It would appear that the intervention provides feedback on performance (in the absence of an audit).

The audit and feedback details are provided in Figure 1 and the supplementary material, but this component was already familiar to GPs so was not the subject of the piloting/feasibility study. For this reason it has not been reported on in as much detail. Nevertheless we have added some further description of the audit component to clarify what is involved in that component.

Page 5: Audit and feedback programs on this topic were already available to GPs involving audit of 10 patients with feedback comparing performance to guidelines and peers.

Page 10: Self-directed audit & feedback including cases that GPs find challenging for CVD risk assessment and communication [16, 17], and comparison of management to guidelines [23], using evidence-based behaviour change techniques [32]; based on existing audit and feedback tools familiar to GPs (involving audit of 10 patients with feedback comparing performance to guidelines and peers).

5. Page 4, end of final paragraph - why have these interventions not been translated into clinical practice nationally? Are the ineffective? This seems like a critical insight that relates to the feasibility of future implementation for the current intervention.

The interventions increased CVD risk assessment but had limited impact on guidelines-based prescribing; presumably this is why they have not been implemented nationally. We suggest this is due to key behavioural barriers not being addressed. We have added a comment on this.

Page 5: This project identified barriers that had not been addressed in previous trials that had little impact on prescribing

Page 16: In particular, it illustrates the value of an extensive qualitative evaluation to understand behavioural barriers amongst different targets (GPs and patients) and testing different strategies/formats before trialling an evidence-based intervention, as previous trials in this context had little impact on prescribing and failed to incorporate important knowledge (confusion about the role of different risk factors) and capability (doctor-patient risk communication) issues.
6. Page 7-8 - The methodological description for Stage 2 is lacking. Were any instructions given to the knowledge broker service to guide recruitment? How were the qualitative data analyzed? Were rationale and associated changes documented (it would appear from the results that they were)?

More detail has been added to this section.

Page 7: Two GP groups were included as they were running discussions at the time of the study. The qualitative data were analysed through field notes to document any suggested changes or problems identified by users, with audio recordings used to clarify field notes if needed. A summary of each group discussion was written, and this document was scanned to identify changes to be made for the next website version.

7. Page 11, Stage 2 results - More detail is required here. What were the demographic characteristics of the GPs? What themes were captured across the notes? Please provide an example of the feedback received during this stage.

The GPs involved in user testing were a convenience sample with no purposive sampling strategy employed, therefore demographic details were not recorded. Rather than formal themes, this stage involved only a summary of main suggestions in order to make changes. We have provided more detail about how this influenced the inclusion of decision aid options in text and table, but have also acknowledged this convenience/pragmatic method as a limitation of the study.

Page 11: The website content and format was discussed with two practices involved in the ASK-GP CRE (n=18 GPs), including feedback on examples of evidence summaries, decision aids and CVD risk calculators. Changes were made to the evidence summaries to incorporate more practical issues such as cost and inconvenience to patients. GPs asked about complementary and alternative medicine options (fish oil, antioxidants and multivitamins), which were subsequently included in the risk calculator/decision aid even though they had no effect on CVD outcomes, as the GPs felt it would be helpful to show this to patients in order to direct them to more effective options.

Table 2: GP focus group: Is it possible you need to quote something along the lines of ‘no evidence regarding dose or exact dose’ or something? Cos patients ask you a lot of ‘how much should I take?’… It could be good with a bit of extra information and a little bit more about the doses and the side effects and costs and so on”

Page 17: The main limitations are: 1) the use of pragmatic qualitative analysis methods (i.e. documenting issues in field notes/summary documents to facilitate quick feedback to website developers rather than formal thematic analysis)

8. Page 14 - Much of the data reported from the quantitative feasibility study (Stage 5) would be more clearly presented in a table vs. written out in text (i.e., efficacy, acceptability, demand, and other outcomes).

Since there are already a large number of tables we decided against adding another one, and have instead clarified the text. We have included the frequency for each percentage and restricted the analysis to the final sample of n=98 at the request of the editor, which we hope will reduce confusion. We have also provided data for website feedback and quantitative capability changes in tables, including revisions to Table 2 to show examples of user feedback from all 5 stages to make the overall results clearer.
9. Page 16, Table 5 - This table demonstrates that the decision aid increased the user's capability to correctly identify the patient's risk category. For patients with moderate to high risk, this resulted in a decrease and increase in prescribing recommendations, respectively. However, for the low risk category, prescribing recommendations remain largely unchanged. The authors highlight overprescribing to low-risk patients as a target of the intervention in the introduction, therefore this finding warrants attention in the discussion (perhaps in the last paragraph on Page 18). Why do the authors think this evidence-practice gap still persists? Why might providers think differently about this group of patients?

We agree this is an important result to highlight, and have added further discussion of this in the abstract, results and discussion sections. Thank you for this suggestion.

Abstract: but prescribing to low risk patients remained similar (from 19% to 22%; n=37).

Page 13: From 37 GPs who selected a low risk case, prescribing was similar before (19%, n=7) and after (22%, n=8) using the risk calculator.

Page 16: Our results highlight a theoretical issue regarding the difference between implementation (prescribing for high risk) and de-implementation (not prescribing for low risk).[39] While addressing capability barriers to guidelines appeared to increase intentions for prescribing medication to high risk patients, there was no improvement in unnecessary prescribing for low risk patients. A recent synthesis of behaviour change theory suggests that behaviour substitution may be needed to address the latter situation, but there is little guidance in the literature for how to select such a behaviour at present.[39]

10. Page 17, outlining the three suggestions- For the first two suggestions, please add an explanation as to why the authors feel the addition of a motivation-focused feedback exercise or a decision aid to address capability is likely to make a previously unsuccessful method successful (as you have for the third suggestion).

We have revised these sections to focus more clearly on the benefit of the new component (the risk calculator/decision aid).

Page 14: This method has been trialled previously in Australia for CVD risk assessment using a waiting room method [15], but without the additional support of a risk calculator/decision aid that addressed capability barriers around understanding and communication of risk models. Existing risk calculators did not explain the role of assessment vs management factors, and no decision aids were available that matched 5 year Australian CVD risk guidelines.

Page 15: This approach has been trialled previously in Australia [13, 14], but access to the risk calculator was restricted to license holders and did not have the additional support of a decision aid to address communication of risk models. Existing tools were inaccessible or did not match Australian guidelines.

11. In the conclusion section, there is no need to re-state the project methods. Please highlight the preliminary impact the intervention had on correctly identifying risk categories and the subsequent influence on treatment decisions and focus on the feedback you received from users that likely optimized the intervention's impact. Please align the conclusion section of the abstract as well.
We have revised these sections.

Abstract/Conclusion: Following a theory-based development process and user co-design, the resulting intervention was acceptable to GPs with high intentions for use, improved identification of patient risk categories, and more guidelines-based prescribing intentions for high risk but not low risk patients. The effectiveness of linking the intervention to clinical practice more closely to address implementation barriers will be evaluated in future research.

Minor Revisions

12. Abstract - please revise the first sentence in the methods to read "Stage 1 involved the identification of evidence-based solutions using the…” to avoid confusion.
This has been revised.

13. Abstract - please refer to the intervention in Stage 3 as a 'prototype website' to ensure consistency with reference to the website in Stage 4.
This has been revised.

3. Abstract - in the results section, revise to 'Stages 2-4 iteratively improved…”
This has been revised.

4. Abstract - throughout the results section, please include the total number of respondents in addition to the percentage
This has been revised.

5. Introduction - there are several sentences in the introduction which could be tightened considerably. For example "Despite available guidelines, absolute risk is often not assessed and when it is assessed, is not necessarily used to guide management decisions". Later in the paragraph "The evidence-practice gap has been estimated…” (instead of 'failure to implement the absolute risk approach).
This has been revised.

6. Please review the manuscript to ensure you use consistent language throughout to refer to the intervention at various stages. For example, for stage 1, either use the term 'intervention' or 'prototype'. If using prototype, consider calling it a prototype website so it logically flows when using the term website later on. Please also change the subheading if required
This has been revised throughout – we now refer to the prototype website, functional website and final website.

7. Page 7 - Suggest revising the subheading to read "Qualitative piloting and iterative website development" (or whatever term you choose)
This has been revised.

8. Page 13, Table 3 - Please include independent columns that identify the respective stage and intervention version number to help orient the reader.
We have now used more consistent terms between table and text to clearly identify each stage in the methods, results and table.

Reviewer #2: Thank you to the authors for their careful consideration and integration of proposed
revisions. As a result, the manuscript is improved with the addition of an informative summary of the team's prior work leading up to this project, the presentation of the sequential approach to intervention development, piloting and feasibility testing, and greater details about the theoretical framework used. Yet, from my perspective, a few issues remain, mostly around clarity of process and ideas. I offer some additional areas where I believe the manuscript could be strengthened.

Thank you for your helpful comments.

Abstract:

Background:
- Could the authors state directly in the background what the intervention is? As it currently reads, we only find out by Stage 4 in the methods section that the intervention is a website. This has been revised.

- Similarly, could the authors state that the "new content" is a decision aid? This has been revised.

Methods:
- Stage 1 involved analysis of behavioral barriers and identification of evidence-based solutions…

Conclusion:
- Add: "address behavioral barriers to guideline use amongst GPs"

Manuscript

1. The chronology of the overall study process remains unclear in some areas. For example, it is not immediately clear at which point the risk calculator, audit and feedback was developed/adopted, and the decision aid added in relation to barrier identification. A figure showing a flowchart of overall study processes would be helpful, including previously completed steps that have informed this study such as barrier identification and the future planned effectiveness study. Perhaps the figure could show the overall intervention development and testing processes of components (if any) with citations for completed steps and a box around the portion of the study described here with the flow of study processes for the work represented in this manuscript presented in finer detail.

Thank you for this helpful suggestion, we agree a flowchart could help explain this complicated process and have substantially revised Figure 3 to address this. We have also clarified where prior research was used in relation to stage 1 with references, in the revised table 2 (see row 1). References to audit and feedback have been clarified throughout the manuscript to better explain that this component was already available to GPs so the pilot focused on the new risk calculator/decision aid.

Table 3:

EXAMPLE USER FEEDBACK
Healthy Heart Study GP interview: The calculator of course doesn’t include certain factors…if someone does do a lot of exercise I would…think their risk is probably lower. [16]
Healthy Heart Study patient interview: The visual presentation of the result…because it’s a picture instead of numeric, I think I’ll take more interest…when you see red and green…that seems to have more of a impact on me, you know…the numbers don’t, you know? [30]

MAJOR CHANGES MADE
Develop new risk calculator to more clearly explain risk factor roles in assessment versus management guidelines (psychological capability), supported by links to existing audit and feedback strategies (reflective motivation)

Link risk calculator to patient decision aid with colour coded icon arrays to help GPs explain probability of CVD event to patients (psychological capability) and access up-to-date intervention effects on their risk (physical opportunity)

Methods

2. Stage 1: The three determinants could be further explained as such: opportunity (physical and social environment), capability (physical and psychological ability), and motivation (automatic and reflective mechanisms) - mostly because physical appears twice. The delineation between physical environment and physical ability would be helpful.

This has been revised as suggested.

3. Stage 1: The way in which the BCW steps are listed (p.7), do not clearly map onto the steps outlined in Table 2. It would be clearer if consistent terminology was used.

We have now made sure the 5 stages are described consistently in the methods, results and tables. We have clarified that the BCW process was the first stage of the paper; and Table 3 now outlines all 5 stages of the paper including this first stage. If it is of sufficient interest to the editors to go into more detail for stage 1 we can provide the entire BCW document but it is very long and includes many options we did not choose to pursue; we have therefore omitted further detail on this stage to avoid additional complexity and confusion to the reader. Instead, we have added more detail to Table 2 as follows.

Table 2:
• Psychological capability (understanding role of risk factors, risk communication) [16-18]
• Physical opportunity (access to updated evidence on risk/benefit in line with Australian guidelines) [16, 21, 22]
• Reflective motivation (attitude towards using guidelines for perceived low/high risk cases) [16, 18]

4. Stage 2-4: - Details about the qualitative data analysis are still lacking. How was the data analyzed? The authors mentioned use of thematic analysis from interview notes and recordings but without neither elaboration, nor citations to support the approach used.

The data collection was based on a “concurrent and retrospective verbal protocol” think aloud process, for which we have now provided a method reference. The qualitative data were analysed only through field notes (MF and CB) to document themes in terms of any suggested changes or problems identified by users, with audio recordings used to clarify field notes if needed. A summary of each GP group discussion/interview was written, and the resulting document was scanned to identify changes to be made for each website version. Rather than formal themes, this stage involved only a summary of main suggestions and issues encountered with the website in order to make changes. We have acknowledged this as a limitation of the study. More formal qualitative analyses were conducted in related studies, now outlined in table 1 and the new flowchart.

Page 7: Two GP groups were included as they were running discussions at the time of the study. The
qualitative data were analysed through field notes to document any suggested changes or problems identified by users, with audio recordings used to clarify field notes if needed. A summary of each group discussion was written, and this document was scanned to identify changes to be made for the next website version.

Page 8: After the GP17 conference, the functional website was developed iteratively based on semi-structured “think aloud” user interviews [25] to improve acceptability. More detailed Framework Analysis had been conducted in 1 GP interview study and 2 patient think aloud studies prior to this stage (see Table 1); so thematic analysis for this stage was limited to notes taken during the interviews (CB and MF) and from audio recordings, to identify areas to improve. Interviews were conducted at the University of Sydney, via Skype or at the participants’ residence/workplace, and were audio-recorded to supplement field notes on intervention features to improve. This involved a concurrent and retrospective verbal protocol where users were asked to think aloud as they used the website, followed by prompting for feedback by the interviewer (CB) [26].

Page 17: The main limitations are: 1) the use of pragmatic qualitative analysis methods (i.e. documenting issues in field notes/summary documents to facilitate quick feedback to website developers rather than formal thematic analysis

5. Stage 4: I think the following passage is a repetition of the same information provided a sentence above it "were audio-recorded to supplement field notes on intervention features to improve."

This process was used for both stage 2 and stage 4; so the phrase has been repeated. We have described the different stages more clearly in this version.

6. Stage 5: The name of the outcomes (e.g. acceptability, demand) do not fully align with what is reported. Acceptability measures usually refer to ratings regarding the comprehensibility of intervention components, its length, amount of information, and overall suitability for its intended purpose; and demand usually refers to person's willingness to purchase/use a particular good during a given period of time. In my view, the use of the terms currently used in parentheses', namely "intended use", "actual use" and "appropriate guideline-based recommendation for risk category" are a better representation of the outcomes that are actually reported.

There is no consistent way to operationalise these concepts in the literature; and many of these specific measures (e.g. comprehensibility, length) were covered qualitatively rather than quantitatively in our study. We have retained this description as we did consider these concepts when deciding on our measures, but have been clear to explain the difference between the feasibility concepts and the operationalised measures in the methods.

Results

7. Stage 1: The BCW process revealed that psychological capability, physical opportunity and reflective motivation were the most important behavioral barriers (Table 2). In the summary of the Healthy Heart Study initiatives completed to date, these three barriers were identified in prior GP interviews. It is my understanding that these barriers are the starting point for this piloting and feasibility study. Although the identification of these barriers from prior GP studies is noted in the background, this is not reiterated in the results (Stage 1) which made me wonder if this step had been repeated in the context of this study. Could the authors remind the reader of their Stage 1 starting point and how they are building upon these previously identified barriers. A figure as proposed above could
help, and adding citations to the studies in Table 2 for column "Behavioral components (barriers?) served by intervention functions."

We agree this is unclear and have added a flowchart and citations as suggested – please see figures and tables 2-3.

8. Stage 1 results: By completing the BCW process the authors "identified the need to develop a new tool." In previous parts of the manuscript the authors state that the decision aid component was the only new component. The way in which the three key features of the new tool are currently presented, it doesn't distinguish the previously available features from the new one. Additional detail about how existing components were available and used by GPs and how this new tool was built using these existing components would be helpful.

The decision aid incorporates a modified risk calculator to address GP knowledge barriers about the role of risk factors in assessment vs management; this information creates the tailored decision aid report. So both the risk calculator and decision aid are new but they are combined into the one tool. The audit and feedback component is not new as it is based on existing tools in Australia. We have clarified that we reviewed available A&F tools as well as existing DAs/risk calculators in the new flowchart figures, tables 2-3, and throughout the manuscript.

9. Table 2: Based on the narrative text, it appears social comparison is missing from Table 2, column 3.

We have revised this as you are correct, social comparison is incorporated into the audit and feedback component.

10. Stage 5: Open feedback - Remove required - if it was required I would have expected to see 100% response rate.

This was a compulsory question but was often answered with N/A or similar. We have revised this for clarity.

Discussion

11. The sentence "The pilot findings suggest several directions for implementation that have already been trialled in the Australian primary care context, which may be effective if combined with the existing intervention" (p.17). It is not clear that the suggestions provided from GPs and patients refer to these "directions" or if the suggestions need to be addressed before the directions can be followed.

These directions come from the summary table for the results – they are based on GP feedback primarily. We have elaborated on this in the new version of table 3 to make this clearer, as they came out in both stage 4 and stage 5. The table provides specific quotes to further illustrate this:

Table 3, stage 4b changes
• No further changes made to GP website or linked resources
• Implementation suggestions still need to be addressed:
  1. auto-population of risk factors from patients’ electronic record;
  2. low health literacy version of decision aid;
  3. pre-consultation access to risk calculator/decision aid
Table 3, stage 5 changes
• Feedback generally positive with some contrasting views on format preferences
• Confirmed implementation issues identified in stage 4b:
  1. auto-population of risk factors from patients’ electronic record
  2. low health literacy version of decision aid;
  3. pre-consultation access to risk calculator/decision aid

Table 3, stage 5 example feedback
GP open response comments reflecting key implementation issues:
• If it could be somehow linked to practice software so I remember to do it and the values are prefilled that would be ideal.
• Needs to have some in different languages to show people outcomes for those with poor English understanding.
• More time to be scheduled to counsel patients on lifestyle modification and CVD risk calculator use.

12. Could Figure 3 be organized using the same stage numbers used throughout the manuscript?

We have revised this as suggested; see new flowchart version and more consistent terms for each stage throughout the manuscript. Thank you for this helpful suggestion.