Author’s response to reviews

Title: Promoting sustainability in quality improvement: An evaluation of a web-based continuing education program in blood pressure measurement

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Version: 4 Date: 30 Oct 2017

Author’s response to reviews:

October 30, 2017

Dear Dr. Aronin and Reviewers,

Thank you for your helpful review of our manuscript, “Promoting sustainability in quality improvement: An evaluation of a web-based continuing education program in blood pressure measurement” (AMP-D-16-00109R3). We appreciate your comments and the chance to improve elements of our paper. Please find below editor comments as well as our response to each comment, and text identifying changes that have been made in response to the comments. An updated paper is attached to this application for your review.

1. Thank you for providing more detail regarding consent to participate for your study and for clarifying that written consent was not obtained. However, we require some additional details to be included in the manuscript.

Regarding the participation of the clinical staff members: please can you clarify whether verbal consent was obtained from these participants to take part in the survey and to be observed and if
the IRB approved this procedure. If the need for consent was waived by an IRB or is deemed unnecessary according to national regulations, please clearly state this, including the name of the IRB or a reference to the relevant legislation. Please clearly state your response in the Ethics approval and consent to participate section of the Declarations.

Our response: As per our IRB approved CMA Observation Protocol, we did not receive consent from the MAs to observe them. The IRB and the JHCP Research Committee approved the observation as it fell under QI. We included this information in the Ethics approval and consent to participate section of the Declarations.

Ethics approval and consent to participate (page 16), “As per the IRB approved CMA Observation Protocol, we did not receive consent from the MAs to observe them.”

Regarding the participation of the patients: we note that you have stated in the Methods “if the patient agreed to being observed”. Please can you clarify whether verbal consent was obtained from the patients to be observed and if the IRB approved this procedure. If the need for consent was waived by an IRB or is deemed unnecessary according to national regulations, please clearly state this, including the name of the IRB or a reference to the relevant legislation. Please clearly state your response in the Ethics approval and consent to participate section of the Declarations.

Our response: Verbal consent was obtained from the patients who were observed during intake. We had an IRB approved patient script for asking for permission to observe. The Johns Hopkins University School of Medicine IRB approved this procedure. We included this information in the Ethics approval and consent to participate section.

Ethics approval and consent to participate (page 16), “Verbal consent was obtained from the patients who were observed during intake. We had an IRB approved patient script for asking for permission to observe.”

Please can you also clarify in this section whether the IRB specifically waived the need for written consent for your study and include the full name of the IRB in this statement.

Our response: We received IRB approval for a "Waiver of HIPAA Privacy Authorization." Due to the QI nature of the study, there was no feasible way for us to consent the 60,000+ JHCP patients that might participate in the study.
Ethics approval and consent to participate (page 16), “The IRB waived the need for written consent since the study was classified as quality improvement.”

2. Thank you for providing the TRN for Project ReD CHiP. As your study was part of Project ReD CHiP we require the trial registration number and date of registration of Project ReD CHiP to be included in a ‘Trial Registration’ section at the end of your Abstract. If registration took place after the first participant was enrolled, please state also “Retrospectively registered” at the end of this section. Please ensure that the abstract in the system has also been updated with any changes.

Our response: Thank you; the ClinicalTrials.gov registration number for this study was NCT01566864. The registration was retroactively received March 22, 2012, while first patient enrollment took place on April 19, 2011. We added this information to the abstract.

Abstract: “Trial registration: Retrospectively registered with ClinicalTrials.gov on March 22, 2012; registration number NCT01566864.”

3. We note that you have stated that the videos were developed for your study. Please can you clarify whether you obtained informed consent, written or verbal, from all participants in the videos. If verbal, please state the reason and whether the ethics committee approved this procedure. If the need for consent was waived by an IRB or is deemed unnecessary according to national regulations, please clearly state this, including the name of the IRB or a reference to the relevant legislation.

Our response: In terms of our video, all of the clinical staff members in the videos were medical assistants. All signed media release forms for participating in the videos. We included this information in the Ethics approval and consent to participate section of the Declarations.

Ethics approval and consent to participate section (page 16): “All of the clinical staff members signed media release forms for participating in the videos.”
4. Thank you for providing your surveys as supplementary material. We note that in your response you have stated that in Part 1 of your survey the selected answer for question #4 is incorrect. Please can you include a note in the appendix stating this.

Our response: We have added a note to the Appendix specifying the incorrect answer. As noted in the paper, we did not include this question in data analysis.

Appendix (page 58): *The pre-test answer to question #4 was incorrectly listed as “The patients should hold his/her arm away from the body during blood pressure measurement.” The correct answer is “The patient’s back should be supported during blood pressure measurement.”*

5. In the Methods section please provide a reference to the national guidelines (page 6, line 22) and the AHA guidelines (page 6, line 25).

Our response: These references were both to the AHA 2005 guidelines. We included a reference to the original manuscript in the indicated places in the Methods section and changed the wording to indicate we referred to the same guidelines in both places in the text.

Methods (page 6): In 2011, approximately two years prior to this study, we trained clinic staff to use the Omron HEM-907XL automated blood pressure measurement devices in a manner consistent with AHA guidelines [21]. As part of the practice network’s protocol, staff had been instructed to position patients in accordance with AHA guidelines, to rest patients for three minutes and then to obtain three consecutive blood pressure measurements using the automated features of the device [21].

6. We note that two email addresses have been included for the corresponding author on the title page “lblock2@northwell.edu” and “Lblock2@nshs.edu”. Please provide an explanation for this and ensure that the same email address for the corresponding author is provided. Please note that if you change the email address for the corresponding author the information in the system will also need to be updated.

Our response: The email address of the corresponding author was changed by her employer as the name of the health system changed during this time interval. The new corresponding author email is lblock2@northwell.edu. This information has been updated in the system.

We look forward to hearing from you and are happy to make any further changes as recommended by your team.
Best regards,

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