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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Author’s response to reviews:

July 22, 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” (FAMP-D-16-00109R2). We appreciate your comments and the change to clarify several points in 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.

Editor's comments:

1. We note that your study was conducted as part of Project ReD CHiP. Please can you include the trial registration number and date of registration of Project ReD CHiP in a 'Trial
Registration” section at the end of the Abstract. If registration took place after the first participant was enrolled, please state also “Retrospectively registered” at the end of this section.

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.

Please ensure that the abstract in the system has also been updated with any changes.

Our response: Thank you. Please note there were no changes needed to the abstract.

2. In the Ethics approval and consent to participate section we note that you state that you obtained survey consent to participate from all participants. Please could you clarify whether this consent was written or verbal. If verbal, please state the reason and whether the ethics committee approved this procedure. Please could you also clarify whether you obtained consent from clinical staff members to be observed as well as taking part in the survey. 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 could you also clarify in the Ethics approval and consent to participate section whether you also obtained informed consent, written or verbal, from all patients who were observed. If verbal, please state the reason and whether the ethics committee approved this procedure. If any of the patients were minors please clarify whether informed consent was obtained from their parent/legal guardian. 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: Thank you for raising this important question. Per the IRB approved protocol for this study, the research procedures in this piece of the study including the survey and the observations were classified as quality improvement and therefore written consent was not obtained. We have changed the wording of the “ethics, consent, and permissions” and the “Ethics approval and consent to participate” sections to clarify these points.

The survey questions were preceded by the following statement, “Please rate the following statements about the automated blood pressure machines (Omron devices) and the blood pressure
measurement protocol. Your answers to these questions are confidential and will not affect your final score.”

The IRB protocol wording regarding observations of clinic staff is below. As the procedures were classified as comprising quality improvement and no identifying information about clinic staff were collected, and to minimize the Hawthorne effect, written consent was not obtained from clinical staff during the observation portion of the data collection.

“Data will also be collected via observation of the Certified Medical Assistants as they collect blood pressure readings to ascertain level of BP measurement protocol adherence, an essential mediator of many of the outcomes in this study. In order to minimize the effect of observation on their normal protocol adherence, this aspect of data collection will be communicated to the Certified Medical Assistants as an observation of clinic flow. To ensure that there are no penalties associated with protocol adherence, the identities of the CMAs observed will not be recorded in any way, patient identifiers and patient data will not be observed or collected, and the data collected on protocol adherence will be aggregated by clinical site. Observation will be carried out by a physician-trainee who already has clinical privileges at JHCP, and who will strictly follow HIPAA policies and research ethics protocols from training that he or she has already received. Aggregated data collected before and after the release of the blood pressure training videos will be used to evaluate whether the videos change BP measurement behaviors among CMAs.”

Similarly, as per our IRB-approved protocol, patients were approached to ask their permission to be followed during the observation procedures, but the objective of the study was not disclosed to patients to minimize disruption of normal workflow. The IRB-approved script for introducing the observation to patients is below:

“SCRIPT FOR JHCP PATIENTS

Hello ________.

I am ________. We are running a small research project at the Johns Hopkins Outpatient Centers to observe workflow - basically what the check-in experience is for the patients who are seen here. If you don't mind, I'd like to follow you to document your experience. I'll be asking you a couple of questions such as your age range and medical history, but we won't collect your
name, or use any information to identify you specifically. Would you mind if I followed you until your check-in is completed?”

We have changed the wording of the “ethics, consent, and permissions” and the “Ethics approval and consent to participate” sections to clarify these points as below:

Methods (page 7): “This study was approved and HIPAA waiver granted by the Institutional Review Board at Johns Hopkins University School of Medicine (NA_00037622) and the Johns Hopkins Community Physicians Education Committee. As the procedures were classified by the IRB as comprising quality improvement endeavors, written consent was not obtained.”

3. Please clarify whether the pre- and post-intervention surveys used in your study were developed for this study or have previously been published elsewhere. If they have been published elsewhere please provide a reference to them in your manuscript, if they were developed for this study please include the surveys as supplementary files. Please note that when you include a supplementary file you need to provide, after the References, a section titled “Additional files” where you list the following information about your supplementary file: * File name (e.g. Additional file 1), * Title of data, * Description of data. Please ensure also that the additional file has been cited in the main manuscript.

Our response: The surveys used in our study were novel and developed for this study. We have included the surveys as an Appendix. Please note that in Part 1, the selected answer for Question #4 is incorrect. It should have been C. In Part 2, the same question (#13) has the correct answer marked.

Supplementary files (page 17): “Appendix - Pre- and post-intervention surveys are the questionnaires used to assess knowledge and attitudes of clinical staff before and following completion of the continuing education program.”

4. Please could you also clarify whether the online educational program used in your study can be made available and if so please include details of how to access the program in the
Availability of data and materials section. If the program cannot be made available please state this with a justification.

Our response: Thank you for asking this important question. The videos were novel and were developed for this study. We are happy to share the videos with interested readers. Posting the videos on a publically available website is difficult because of funding constraints and because the videos have been updated significantly since the data for this study were collected. We added this information to the Availability of data and material section.

Availability of data and material (page 16): “Training videos are available upon request submitted to the corresponding author.”

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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