Author’s response to reviews

Title: An electronic registry to improve adherence to active surveillance monitoring among men with prostate cancer at a safety-net hospital: protocol for a pilot study

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(Please see attached document for responses to reviewer and editor comments. The text is pasted below as well)

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Dr. Gillian Lancaster
Dr. Lehana Thabane
BMC Pilot and Feasibility Studies

Dear Drs. Lancaster, Thabane, and the BMC Pilot and Feasibility Studies Editorial Board,
Thank you for your review of our manuscript entitled “An electronic registry to improve adherence to active surveillance monitoring among men with prostate cancer at a safety-net hospital”. Below, I outline our responses to the reviewer comments and include the location of the revised text. The additions and clarifications are presented here in this letter indicated in italicized font in response to reviewers comments in bold.

Our study has multiple authors. None of us have any competing interests. We all meet the uniform criteria for authorship. All authors have seen and approved of the final revised manuscript and participated in design and/or execution of the study. The content of this manuscript has not been published or submitted elsewhere. Thank you for your consideration.

Sincerely,

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Reviewer 1:

1. I thought this was an interesting protocol that addresses a very pragmatic issue that affects patient care and ongoing treatment outcomes. Whilst I felt overall that the protocol gave a clear overview of the work to be undertaken, there are some points of clarification that I would wish to see addressed.

The Background section could be made more applicable to an international audience if a couple of sentences of explanation were included for those not familiar with the US healthcare context. For example in line 99/100 - is increased uptake of conservative management by those of low socioeconomic status due to active treatment having increased monetary costs?

Thank you for the suggestion to clarify and add context. It is unclear why this population of men receives conservative management more frequently. Active treatment may be more costly for uninsured populations, but in this care setting cost differences are unlikely to play a role. Prior work suggests that men of lower SES may be less likely to opt for surgery because of lack of trust.1

1Tomic K, Ventimiglia E, Robinson D, Haggstrom C, Lambe M, Statin. Socioeconomic status and diagnosis, treatment, and mortality in men with prostate cancer. Nationwide population-
2. In the Study Design section it is not made clear whether the newly diagnosed men are being added into your newly developed system, or whether you are just following them to get an understanding of usual care. Similarly are existing patients being added to the system or are you simply following their usual care. I suspect you are using your system, because you mention in line 176 that you will be looking at how well the registry has been integrated, but this needs to be made more explicit at the start of the study design section.

Thank you for catching this omission. We agree that it was not clear how patients would be followed so we have clarified both newly diagnosed men and existing patients will be added to the electronic registry. The following text has been added:

“This study is a prospective non-randomized pilot study that will add newly diagnosed men with prostate cancer who choose AS based on shared decision making as an initial management strategy to the registry and follow them. We will also continue to track men who are already on AS at ZSFG, adding them into the new system.”

3. It is also unclear how people are being added to your registry and who is responsible for adding them (hospital staff?)? Do you need consent from individual patients or is this covered by being a study on healthcare implementation and therefore covered by consent at a hospital level? Again this may vary between countries so it might not be evident to all readers.

We appreciate your pointing out that there should be a description of how patients are added to the registry. We have added the following sentences detailing the procedure:

“Patients will be entered into the registry by involved healthcare providers. A team of care managers, including a nurse practitioner and medical residents, will perform registry enrollment and maintenance.”

The requirement for informed consent was waived by the UCSF IRB (12-09658) as this protocol describes a quality improvement initiative implemented at the clinic-level to improve patient safety.

4. I appreciate that wordcount might be short but it would be nice to have a bit more info about the staff interviews as an outcome measure. Which staff are you hoping to interview and how many interviews - what proportion of the staff would these represent? Staff come and go so might it be helpful to build in exit interviews for staff who may have been there during the setup period, or are you planning on doing all the interviews at the end of the project?
Thank you for allowing us to elaborate. We agree that more detail on the interviews would help readers understand the process better. We have added the following explanation:

“We will interview at least one clerk responsible for scheduling, one registered nurse, one nurse practitioner, and at least three urologists. We would not be aiming for a specific proportion of staff, but rather representation of all types of staff. The interviews would be conducted once the registry has been in use for 6 months. If staff who have been involved with the system leave the team, we will conduct exit interviews to ensure their voices are included.”

5. Overall I feel that whilst the study at the HIT system are well discussed, the protocol paper is missing the human element. In many studies, particularly in healthcare settings, this is a major source of bias or of studies failing to meet their initial expectations. Currently it reads as if the system is simply running by itself with no human involvement. As mentioned above, I would like to see more attention given to who is adding people to the registry, whether or not staff are being trained in its use, is there somebody double-checking to ensure patients do not fall through the net or are deliberately not added (or is this an outcome you want to evaluate), are you accounting for staff leaving or being on long-term leave and building in opportunities for repeating the training. It is also not clear of the researcher involvement throughout the study, for example in providing training and support, and how data is being gathered and sent back to the researchers during the project. Currently this makes the staff interviews for outcome measures seem a little redundant as it is not apparent that staff have any involvement at all.

Thank you for your comment. We agree that the human element is a necessary component and deserves further explanation. We have added the following text to the Study Design section to elaborate on this topic, including which providers are involved and how CipherHealth offers ongoing support:

“Patients will be entered into the registry by involved healthcare providers. A team of care managers, including a nurse practitioner and medical residents, will perform registry enrollment and maintenance. As the team of medical residents rotates, the study group conducts recurring training sessions to ensure all users are able to access and use the tool. In our case, this is approximately every four months. When the residents return to the Urology clinic on rotation, they can engage in peer-training. The study team and CipherHealth provide ongoing support for the clinical staff. CipherHealth offers a data portal for the study team to be able to capture real-time metrics, such as number of patients enrolled, tasks completed, and outcomes. The registry provides automated reminders to prompt follow-up activities (e.g. visits, testing, check-ins).”

Reviewer 2:

6. 1.1. Background
The background provides a good understanding of the topic and reasons for wanting to do the study, which I think is always appreciate to other scholars in the field and general readers at large. However, there some areas that I wish the authors could give some explanation on. For instance, why in one study “biopsy follow up was discordant in 54% of men in the first two years and in another study the numbers decreased to <13% beyond two years? See line 88-90 of the manuscript. Why in ZSFG hospital there was a high rate LTFU, 17% men on AS out of 18.3%? Line 113-114. Similarly, line 100-102, what sort of socioeconomic statuses that are likely to have contributed to LTFU based on the reported percentages? Additionally, how this proposed study plan to deal with such socioeconomic status challenges. In line 105-107 perhaps the authors may wish to provide at least one reference.

The aim of the proposed study is clearly defined.

We appreciate the comments asking for why biopsy rates decline after the initial two years. We have clarified the wording to show that fewer biopsies are done beyond the beginning of active surveillance. Further, the authors of those studies do not specify why this drop-off occurs. We can speculate that this drop-off after 2 years is LTFU or the patient thinking surveillance is no longer necessary given the lack of progression, for example. However, we were unable to identify literature which describes underlying causes for declining biopsy rates.

As clarification, at ZSFG 18.3% of men on AS showed upgrade, and 17% of men on AS were LTFU (not 17% of 18.3%). The reason for high LTFU may be related to the reasons provided about at-risk populations who ZSFG serves (see patient population characteristics in Methods, “Vulnerabilities included…” on page 6, and “The racial composition…” on page 9). Ballas et al (2018)1 showed that lower SES was associated with likelihood of being LTFU.

It is an important observation to ask how to deal with the socioeconomic challenges affecting our patient population. Unfortunately, the registry does not directly address these barriers. The hope is that instituting a more rigorous system to track and enforce AS timeline events will minimize other factors that lead to LTFU or less effective management.


7. 1.2. Methods

I find the methods of the proposed study to be appropriate and the authors have provided sufficient information.

1.3. Outcomes

This section is clearly explained.
Figures and tables: I find these to be well presented and easy to interpret. Having said that, in figure 1, I am clear with the last three points except the first one (Manual). To add, the last three points in this figure are mentioned in line 152-154 of this manuscript. In table 1, the second domain (Social history), I think it would be better to add "employment history" as a forth data due to low socioeconomic status reported in this population. But it is up to the authors.

Thank you for your comment. We have clarified the meaning of Manual by adding the text

“Aside from the automatic feed of data from Openlink, manual data entry by clinical staff is also possible.”

We also agree that it would be beneficial to incorporate employment history and have added as recommended.

8. 1.4. Analyses

This section is well explained. However, it is not clear how the semi-structured interview will be analysed.

Thank you for your comment. We agree that further explanation of the interview structure and analysis would be helpful. We have updated the text to elaborate on these points. We have added the following:

“Using a grounded theory approach, we will analyze semi-structured interviews abductively, integrating inductive and deductive reasoning to explore and describe emergent themes within structured domains of interest. Within each domain, we will iteratively open-code, analyze, and theorize until we have reached saturation and no more themes emerge. Finally, we will see if the can integrate themes across domains for a unified theory.”

9. 1.5. Discussion

The findings are well described. Significant potential challenges are properly discussed.

Additional comments

The whole manuscript talk about African American. But in line 186, I noticed that the authors talk about African American/Black. Is there any difference between the two? If so, it would be helpful to provide a definition. If not, I think authors could just use one.

Line 131, I think there should be "Active" just before surveillance.

Line 110, Country instead of "county". I think it is a typing error.
Thank you for your comment. We have opted to use the term “African American/Black” for consistency’s sake. Patients may self-identify differently, which is why there are two categories (African American and Black). E.g. not all people who are Black identify as African American. We have added “active” before surveillance. We have removed “county” as well, given the confusion. County generally refers to a public hospital funded by a county, a geographic area that may or may not be composed of one city.