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Title	The role of hospital characteristics in patient safety: A protocol for a national cohort study
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Reviewer 1	Dr. Christopher Fernandes
Institution	Hamilton Health Sciences/McMaster University
General comments (author response in bold)	This study aims to define and study hospital characteristics that may affect patient safety. The protocol is ambitious but needs further refinement. **We thank the Reviewer for taking the time to review our manuscript and provide feedback to improve the manuscript.** Abstract--Why were these 4 domains chosen? Why were 90 hospitals chosen? **We have provided the rationale for these domains – through a combination of literature review and expert consultation, on page 8, paragraph 3: "Our four exposure variables were identified through a review of the literature and through consultation with our steering committee that includes hospital leaders and researchers with expertise in the area of patient safety. Inventories and validated surveys will be used to measure our outcome variables."** **Ninety hospitals was a convenience sample chosen because we have secured interest in participation from 72 hospitals and 90 hospitals represents 35% of eligible hospitals. We have conducted a power calculation to show that with at least 90 hospitals we will be sufficiently powered to detect a 20% change in the rate of adverse events across the study period. Page 12, paragraph 3: "Data analysis: A sample size of at least 90 hospitals is a convenience sample based on the commitment of 72 hospitals to participate and based on the representation of 35% of eligible Canadian acute care hospitals. Using AEs as the outcome variable, based on the author's previous work that indicates an AE rate of 10% (standard deviation=5),(4, 14) to detect a 20% decrease in the rate of AEs using a sample size of 90 we will 79% power."** Introduction--p.4, lines 47-54--it might be worth explaining why these 4 domains were chosen. **Thank you for providing an opportunity to expand on our rationale for choosing these domains.** **These four domains were chosen based on a review of the literature and expert consultation. We have clarified in the introduction and have also described in greater detail in the methods.** **Page 8, paragraph 3: "Our four exposure variables were identified through a review of the literature and through consultation with our steering committee that includes hospital leaders and researchers with expertise in the area of patient safety. Inventories and validated surveys will be used to measure our outcome variables."** p.5, lines 10-17--repetitive of the previous paragraph. **We agree that there is a some repetition from the previous paragraph, but believe the emphasis on the limitations of existing studies is warranted here.** Methods--p. 5,line 47--why were 90 hospitals chosen?

	Thank you for highlighting that the rationale for the sample size is missing. We have provided a power calculation. **Page 12, paragraph 3: "Data analysis: A sample size of at least 90 hospitals is a convenience sample based on the commitment of 72 hospitals to participate and based on the representation of 35% of eligible Canadian acute care hospitals. Using AEs as the outcome variable, based on the author's previous work that indicates an AE rate of 10% (standard deviation=5),(4, 14) to detect a 20% decrease in the rate of AEs using a sample size of 90 we will 79% power."** p. 6, line 36--how are these hospital-level decision-makers chosen? This is a weak point of the paper. Is the chosen individual an actual decision-maker or a delegate who happens to have time on their hands to do the survey? **We have clarified how the hospital-level decision-maker is chosen in our recruitment strategy. Our research team, including our steering committee which includes hospital leaders, will identify the most responsible hospital leader. Due to issues related to feasibility, the hospital leader may assign a delegate to complete the survey.** **Page 7, paragraph 1: "The hospital-level decision-maker (or delegate) will be identified by our research team; we will screen the organizational charts of the eligible acute care hospitals to identify the most responsible hospital-level decision-maker. The hospital-level decision-maker will then nominate the most appropriate leader within each clinical area to participate. The clinical area leader will facilitate recruitment of frontline staff by sending emails to all frontline staff within their clinical area as well as posting recruitment materials on websites and in physical spaces within hospitals."** p. 7, lines 6-10--why are emergency departments not included? Many of the key safety decisions are being made here e.g. to discharge sick patients so as to avoid tying up a bed. **Emergency departments are not included because data from emergency department visits are not included in our data source. Similarly, we are interested in hospital adverse events and in the Canadian healthcare system, an emergency department visits is not considered a hospital admission until they are assigned a hospital bed, which is why these data are not included in the hospital data.** p. 7, lines 42-47--this is a weakness of the study. How can you ask participants that have not been able to improve patient safety to now comment on a survey that examines these very strategies? **While not all participants have been involved in quality and safety improvements, we are interested in examining their perceptions of the presence or absence of evidence-based quality improvement strategies. It may be that certain safety strategies are implemented in hospitals (e.g. hand hygiene) but are not perceived by frontline staff.** p.7, line 47-p. 8, line 6--many of these variables are not really strategies. **Thank you for providing an opportunity to clarify. We have revised this section on page 9 paragraph 1: "Participants will be asked to rate adoption and fidelity of evidence-based safety strategies within their hospital. In**

	addition to the evidence-based safety strategies, the survey will include questions regarding: [a] number of dedicated staff and FTE acting in safety jobs, [b] safety budget, [c] organizational membership in safety organizations (accreditation, other), [d] existence of audit and feedback of safety incidents (e.g., reporting and learning systems), and [e] number of ongoing patient safety strategies according to the list of safety strategies recommend for implementation(46) and refined in collaboration with hospital leaders." p.8, lines 45-50--staff are constantly changing jobs and departments, so how will you account for this? **We agree with the Reviewer that there will be considerable staff turnover over a three-year period. We will try to recruit the same frontline staff over the study period. If a frontline participant changes clinical departments, they will be invited to participate but we will seek another frontline participant from the other clinical department. If there is true attrition (a participant leaves the hospital) then another participant with the same or similar role will be invited to participate. We have added these details to our recruitment strategy on page 7, paragraph 2: "Given this is a longitudinal study, efforts will be made to minimize this risk of bias due to attrition. We will invite the same participants complete the survey every year; however, if they do not, they will be replaced by others in the same role. To ensure continued engagement from all participants we will enter participants into a draw for $5-$10 coffee gift cards (each survey completed will result in one ballot for the draw) which will be drawn within 3 months of survey completion at each hospital. Bi-yearly we will also provide, tailored audit and feedback reports and newsletters to participants."** References--many of these references are not relevant. You could probably reduce the number significantly. Why is reference 39 capitalized? **We have modified the references. Because we have added considerable text, the absolute number of references has not changed drastically.**
Reviewer 2	Ms. Qian Yang
Institution	Canadian Medical Protective Association
General comments (author response in bold)	The manuscript described a protocol to capture hospital-level safety factors. The authors successfully presented the argument for hospital-level patient safety characteristics, and provided data collection and analysis plans to establish a profile of hospital safety factors. Such profile would be helpful in understanding patient safety climate in Canadian hospitals and possibly identifying opportunities for improvement. **We thank the Reviewer for their thoughtful review of our manuscript.** While the title of the manuscript is "What role do hospital characteristics play in patient safety", and the objective of the study was stated as "to identify hospital-level factors that impact patient safety in hospitals", the plans presented in this manuscript did not seem to address this research question as it did not establish the impact of the hospital characteristics to patient safety. The authors mentioned a complementary study in the last paragraph of the manuscript and showed 3 aims of the HARM Evaluated project in the one of graphs. These seem to suggest that this would be one of a series of studies. If so,

	a full overview of such studies needs to be more explicitly explained to properly orient this protocol and to set clearer reader expectations. **We agree with the Reviewer. We have revised the manuscript throughout to include our measurement of adverse events and analysis to examine the association between adverse events and organization-level factors.** **For example, in the methods section, we have added details on how we will measure adverse events and our analysis plan.** **Page 11, paragraph 2: "Adverse events (Outcome). We will link AE data from CIHI, hospital characteristics and patient characteristics from a retrospective cohort of patients admitted to participating hospitals with prospectively collected data described in Aim 1. The rate of AEs in participating hospitals will be measured using validated International Classification of Disease-tenth revision (ICD-10CA) algorithms for identifying AEs using CIHI data.(17, 48)"** **And, on page 13, paragraph 2 : "The incidence of AEs will be described as a proportion of hospital admissions and patients and as rate (per patient days). The overall AE incidence and the incidence of each type of AE will be presented. The association between AE incidence and organization-level variables will be explored using logistic regression. To account for possible effect measure modifiers, we will include type of respondent, and hospital characteristics such as geographical location, teaching status, urban versus rural hospital and type of hospital in our model.** **We will also report response rates for each hospital for frontline staff – the numerator will be the number of survey responses and the denominator will be the number of staff for each of the clinical areas."** A few specific questions with regard to the protocol. 1. Patient safety strategies domain. Survey for appropriateness, sufficiency, adherence to the strategies. It is not clear exactly what survey questions would be asked about the safety strategies, e.g. appropriateness, effectiveness, sufficiency, or something else. **We agree that there was not sufficient detail on this survey in the original manuscript. We have added additional detail and have included a draft of this survey as an appendix (Appendix A).** **Page 9, paragraph 1: "[2] Patient Safety Strategies. There are no established measures of safety strategies therefore a de novo survey to measure patient safety strategies is needed. We (KMS, RB, CP) have co-developed a safety strategy survey with hospital leaders based on a narrative review of the evidence, using standard survey development methodology informed by existing materials.(43-45) Participants will be asked to rate adoption and fidelity of evidence-based safety strategies within their hospital. In addition to the evidence-based safety strategies, the survey will include questions regarding: [a] number of dedicated staff and FTE acting in safety jobs, [b] safety budget, [c] organizational membership in safety organizations (accreditation, other), [d] existence of audit and feedback of safety incidents (e.g., reporting and learning systems), and [e] number of ongoing patient safety strategies according to the list of safety strategies recommend for implementation(46) and refined in collaboration with hospital leaders. We will test the face validity of this survey with experts in patient safety and quality improvement prior to distribution."**

	2. Data analysis. Are the composite scores going to be created within each domain? Variables in the different domains could well be correlated, e.g. staff burn-out affects learning environment, leadership associated with safety strategies. This potentially could introduce confounding variables to any further analysis. However, without knowing how exactly these hospital-level factors will be used, it is difficult to comment on appropriateness of the data analysis plan, or the temporal nature of the data. **Thank you for the opportunity to expand our explanation of the analysis plan. We have revised the analysis section to include our regression analysis plan to account for potential confounds.** **Page 12, paragraph 2: "The incidence of AEs will be described as a proportion of hospital admissions and patients and as rate (per patient days). The overall AE incidence and the incidence of each type of AE will be presented. The association between AE incidence and organization-level variables will be explored using logistic regression. To account for possible effect measure modifiers, we will include type of respondent, and hospital characteristics such as geographical location, teaching status, urban versus rural hospital and type of hospital in our model.** **We will also report response rates for each hospital for frontline staff – the numerator will be the number of survey responses and the denominator will be the number of staff for each of the clinical areas."** 3. What are the 3 cross-sectional outcome measurements? **We will administer the battery of surveys and questionnaires once a year for three years. We have clarified our approach on page 10, paragraph 2: "Organization-level variables will be measured once a year for three years in each hospital, with the inception date being unique to the study start date for each hospital."**