PEER REVIEW HISTORY

ARTICLE DETAILS

TITLE (PROVISIONAL)	SAFety, Effectiveness of care and Resource use among Australian Hospitals (SAFER Hospitals): A protocol for a population-wide cohort study of outcomes of hospital care
AUTHORS	Ranasinghe, Isuru; Hossain, Sadia; Ali, Anna; Horton, Dennis; Adams, Robert; Costa, Bernadette; Bertilone, Christina; Carneiro, Gustavo; Gallagher, Martin; Guthridge, Steven; Kaambwa, Billingsley; Kotwal, Sradha; O'Callaghan, Gerry; Scott, Ian; Visvanathan, Renuka; Woodman, Richard

VERSION 1 – REVIEW

REVIEWER	Seth Freedman Indiana University O'Neill School of Public and Environmental Affairs United States
REVIEW RETURNED	24-Jan-2020

GENERAL COMMENTS	This protocol describes tracking trends and variation in hospital-based adverse events, mortality, and re-hospitalizations in Australia. The study will link hospitalization records to subsequent re-hospitalizations and mortality records within each state or territory. This study will provide the ability to track past data on hospital quality and build an infrastructure to continue tracking these data into the future. Below are a few comments and suggestions I have to improve the protocol. 1. The protocol states that the administrative data includes all public and 80% of private hospital in Australia. It would be helpful to discuss why 20% of private hospitals are missing from the data. For example, do some states report data for private hospitals and some do not, or do some private hospitals selectively choose not to report data? It will help the interpretability of the results to understand this selection. In addition, what fraction of hospitalizations are the excluded hospitals expected to represent? 2. The protocol also states that cost data is available from >400 public and private hospitals. What fraction of each type of hospital does this represent and how representative is the sample of hospitals reporting costs compared to the full sample? 3. I think the protocol should include more details about the linkages. It currently reports that accuracy exceeds 99%, but it was not clear if this is for linking hospitalizations over time, for linking hospital records to mortality records, or both. To the extent that the data linkage process has already occurred, I would find it helpful if the protocol included a table that reported linkage rates by type of

	linkage and by state to understand if there is any systematic variation in linkage quality. 4. Aim 1 describes estimating national incidence of adverse events, deaths, and unplanned hospitalizations. Assuming that these outcomes will be tracked over time, I think they should be risk adjusted to account for any changes in underlying population health over time. The other described aims do discuss case mix adjustment, and I think this should be applied to Aim 1 as well.

REVIEWER	Catherine Grenier French National Authority for Health France Interests for developing outcomes measurement of hospital care in France
REVIEW RETURNED	28-Jan-2020

GENERAL COMMENTS	It would be relevant to more discuss the use of the hospital outcomes you will find out: control, public reporting, pay for performance.

REVIEWER	Donald S Shepard Brandeis University, USA
REVIEW RETURNED	05-Feb-2020

GENERAL COMMENTS	I am writing as an American health economist who had the privilege of spending a semester in Adelaide under an Australian-American Fulbright award. I commend the SAFER study as a very promising contribution to health policy, both for Australia and globally. This article's description of the study's goals, approach, strengths, and limitations is generally clear and well written. My main comment relates to several potential enhancements that, at relatively little additional effort, could substantially increase the value of this study. If some these elements are already part of the study plans, the authors may wish to clarify those strengths. The first enhancement relates to obtaining characteristics of a hospital. One obvious characteristic is the hospital's geographic location. Figure 1 depicts that based on the hospital's location in Geographical Region. Another similar categorization worthy of consideration, is the Australian Bureau of Statistics' Accessibility and Remoteness Index of Australia (ARIA). Breakdowns by state or territory, controlling for case mix, would also be informative. Further breakdowns jointly by combinations of state or territory, lower administrative regions, remoteness (e.g. major city, inner region, etc.) would also provide indicators of variability. The study could also indicate the variation of costs per capita across these geographical regions, both for total hospital costs and avoidable hospital costs. Such analyzes would further raise the study's profile for policy makers. In an effort to identify policies that might improve hospital quality generally, the investigators may wish to consider adding additional independent variables to their data which can be obtained from existing data. In addition to location-based variables, important characteristics include ownership (public or private), degree of

university affiliation, types of residency program, size of the hospital, scope of services offered, accreditation status from the Australian Council on Healthcare Standards, clinical quality indicators, etc. They could then regress outcomes such as risk (RSOR) against these characteristics. Such analyzes would help to inform systematic strengths and areas for improvement within the Australian hospital system. In addition, outliers could be identified controlling for these systemic characteristics on top of patient case mix.

The authors might consider combining the four groups of hospital readmissions described on p 14 to create a robust overall index. An initiation combination might define "expected avoidable rehospitalizations" as the sum of 100% of group 1, 50% of group 2, 25% of group 3, and none of group 4. The weighting could be refined by the project's advisory committee using existing literature, or, if desired, reviewing an anonymous random selection of readmission cases from each group.

The limitations should endeavor to assess and discuss how well the existing data capture socio-economic characteristics. In major cities in the United States, for example, homelessness, is a major risk factor for readmission. While ICD9 and ICD10 coding provide a possibility of entering this risk factor into the patient's medical record and thus into the discharge summary, it is used sporadically and inconsistently in the US. Often, clinicians do not specifically ask the patient status or follow up if a patient gives the address of a homeless shelter as his/her residence. This generally leads to under-counting. Occasionally, the code may be a relic of the patient's earlier status, but not updated if the patient moved into stable housing. Tests of social indicators in claims against other sources could examine their validity.

Finally, this reviewer would suggest the authors check a few formatting refinements. Where they mention dollars, they should be explicit and add currencies to specify Australian (AUD) or US dollars (USD). Most references followed the preferred style of sentence capitalization for the title of an article and Title Capitalization for the journal's title. However, references 15 and 31, for example, did not apply Title Capitalization to journal titles, whereas references 28 and 32 did not apply sentence capitalization of article titles.

VERSION 1 – AUTHOR RESPONSE

Reviewer 1

This protocol describes tracking trends and variation in hospital-based adverse events, mortality, and re-hospitalizations in Australia. The study will link hospitalization records to subsequent re-hospitalizations and mortality records within each state or territory. This study will provide the ability to track past data on hospital quality and build an infrastructure to continue tracking these data into the future.

Below are a few comments and suggestions I have to improve the protocol.

1.   The protocol states that the administrative data includes all public and 80% of private hospital in Australia. It would be helpful to discuss why 20% of private hospitals are missing from the data. For example, do some states report data for private hospitals and some do not, or do some private hospitals selectively choose not to report data? It will help the interpretability of the results to understand this selection. In addition, what fraction of hospitalizations are the excluded hospitals expected to represent?

Response

Tasmania, South Australia and the Northern Territory of Australia do not release private hospital data to researchers. We have clarified based on estimated that the number of private hospitals in these states amounts to about 14% (85 out of 624) private hospitals in Australia in the 2014-15 financial year based on the Australian hospital statistics (please note that the 20% stated in the manuscript was incorrect. This has been corrected in the revised manuscript and we have cited the

appropriate government report with the exact number of hospitals). We do not know the exact proportion of hospitalisations represented by these private hospitals, but we anticipate the proportion to be small because (1) acute care in Australia is predominately provided by public hospitals; and (2) Tasmania, South Australia and the Northern Territory collectively represent only 10% of the Australian population.

In response to the reviewer comments, we have added the following statements to the methods and limitations sections.

Methods (study design):

"Private hospital data are not available to researchers from South Australia, Northern Territory and Tasmania which collectively contain about 14% of all private hospitals in Australia.19"

Limitation:

"South Australia, Tasmania and the Northern Territory do not release private hospital data to researchers although the impact on the study is likely to be small as most acute care in Australia is provided by public hospitals and these states only account for about 10% of the overall population."

2.   The protocol also states that cost data is available from >400 public and private hospitals. What fraction of each type of hospital does this represent and how representative is the sample of hospitals reporting costs compared to the full sample?

Response

We use cost data from the National Hospital Cost Data Collection (NHCDC) published by the Independent Hospital Pricing Authority (IHPA). NHCDC has been collected since 1995 and its primary function is to enable Activity Based Funding for Australian Hospitals. IHPA undertakes major areas of work to inform the Australian health departments regarding the costs of healthcare according to the hospital types, sizes, geographical location, and care provided. It also uses a sampling strategy to ensure a minimum number of hospitals are sampled to ensure the accuracy and representativeness of data collected. Thus, we believe this data collection is representative of the full range of Australian hospitals. The number of

4

hospitals sampled varies from year to year. Therefore, we have not provided an exact number although this information is publicly available from the IHPA website which we have cited.

3.	I think the protocol should include more details about the linkages. It currently reports that accuracy exceeds 99%, but it was not clear if this is for linking hospitalizations over time, for linking hospital records to mortality records, or both. To the extent that the data linkage process has already occurred, I would find it helpful if the protocol included a table that reported linkage rates by type of linkage and by state to understand if there is any systematic variation in linkage quality.

Response

Assessing linkage accuracy requires manually checking large numbers of records. Australia has been a pioneer in the development of linkage infrastructure and such analyses were performed when data-linkage infrastructure was initially set up. For example, Western Australia has operated a

linkage unit since 1995. When constructing the linkage in Western Australia, a wide range of potential matches (~24,000 linkages) was manually checked across the range of linked health care data sets. The proportions of invalid (false positives) and missed links (false negatives) were both estimated at 0.11% (Holman CD et al. Aust N Z J Public Health 1999;23(5):453-9).

Since linkage units across Australia have adopted the methodology developed in Western Australia and since similar datasets are used, these validation studies have not been repeated in the literature. Thus, we are unable to report a linkage accuracy for every region and dataset. Nevertheless, Data Linkage Units undertake linkage quality checks as a part of their quality assurance activities. Moreover, recent studies that have reported the accuracy of more complex multi-jurisdictional linkages (i.e. across regions rather than linkage within regions) have also reported high (>99%) matching across multiple datasets from multiple regions (Boyd et al. BMC Health Services Research (2015) 15:312, now cited in the manuscript). Therefore, we believe the linkage to be highly accurate across Australia.

4.	Aim 1 describes estimating national incidence of adverse events, deaths, and unplanned hospitalizations. Assuming that these outcomes will be tracked over time, I think they should be risk adjusted to account for any changes in underlying population health over time. The other described aims do discuss case mix adjustment, and I think this should be applied to Aim as well.

Response

We have modified the text to indicate that we will adjust for temporal change in baseline characteristics.

"Outcomes will be adjusted for temporal change in baseline characteristics to account for changes in underlying population characteristics over time."

Reviewer:2

1.	It would be relevant to more discuss the use of the hospital outcomes you will find out: control, public reporting, pay for performance

Response

Thank you for the suggestion. We have the following paragraph in the discussion as a succinct summary of the potential benefits of measuring these outcomes in our study. We anticipate further discussions of the implications of these outcome measures when we publish the study findings.

"The SAFER Hospitals study purports to answer these questions and benefit the Australian community by (1) informing and prioritising target conditions for large-scale quality improvement efforts; (2) developing and supporting the implementation of standardised methods for hospitals to routinely measure these outcomes; and (3) facilitating policy changes such as public reporting efforts and innovative funding models to incentivise safer and more effective care."

Reviewer: 3

I am writing as an American health economist who had the privilege of spending a semester in

Adelaide under an Australian-American Fulbright award. I commend the SAFER study as a very promising contribution to health policy, both for Australia and globally. This article's description of the study's goals, approach, strengths, and limitations is generally clear and well written.

1.   My main comment relates to several potential enhancements that, at relatively little additional effort, could substantially increase the value of this study. If some these elements are already part of the study plans, the authors may wish to clarify those strengths. The first enhancement relates to obtaining characteristics of a hospital. One obvious characteristic is the hospital's geographic location. Figure 1 depicts that based on the hospital's location in Geographical Region. Another similar categorization worthy of consideration, is the Australian Bureau of Statistics' Accessibility and Remoteness Index of Australia (ARIA). Breakdowns by state or territory, controlling for case mix, would also be informative. Further breakdowns jointly by combinations of state or territory, lower administrative regions, remoteness (e.g. major city, inner region, etc.) would also provide indicators of variability.

Response

The dataset contains information on hospital type (public/private) and geographical region based on the Standard Australian Geographical Classification which will allow us to assess outcomes by geographical locality. We have modified the method to indicate the geographical variables collected and the intention to analyse by geographical region.

The study could also indicate the variation of costs per capita across these geographical regions, both for total hospital costs and avoidable hospital costs. Such analyzes would further raise the study's profile for policy makers.

Response

Thank you for the comment. We agree that this would be a useful comparison and we do intend to compare variation in costs by region.

6

In an effort to identify policies that might improve hospital quality generally, the investigators may wish to consider adding additional independent variables to their data which can be obtained from existing data. In addition to location-based variables, important characteristics include ownership (public or private), degree of university affiliation, types of residency program, size of the hospital, scope of services offered, accreditation status from the Australian Council on Healthcare Standards, clinical quality indicators, etc. They could then regress outcomes such as risk (RSOR) against these characteristics. Such analyzes would help to inform systematic strengths and areas for improvement within the Australian hospital system. In addition, outliers could be identified controlling for these systemic characteristics on top of patient case mix.

Response

We thank the reviewer for the thoughtful comment. We agree that such analyses would be extremely beneficial. However, we have received de-identified data. In some states and territories, this includes de-identified hospital labels. Hospital names and unique identifies are replaced with a dummy identifier so that hospital-level analyses are possible, but we cannot identify the hospital

or link to external datasets that contain hospital-specific data. As a result, we have limited the study protocol to the description of analyses that can be performed for all hospitals. Nevertheless, we anticipate being able to perform analyses such as suggested by the reviewer in a subset of states and territories.

The authors might consider combining the four groups of hospital readmissions described on p 14 to create a robust overall index. An initiation combination might define "expected avoidable rehospitalizations" as the sum of 100% of group 1, 50% of group 2, 25% of group 3, and none of group 4. The weighting could be refined by the project's advisory committee using existing literature, or, if desired, reviewing an anonymous random selection of readmission cases from each group.

Response

We appreciate the reviewer's suggestion. However, we did not find a robust rationale for weighting the hospital readmission categories as suggested by the reviewer in the literature. As the reviewer may understand, there is considerable debate about what constitutes a "preventable" or "avoidable" readmission with considerable disagreement among clinicians and studies. This becomes even more challenging when analysing readmissions using coded administrative data. For this reason, the literature has used unplanned readmissions as the most consistent and robust summary endpoint as it is readily identifiable using administrative data. We have chosen to breakdown this further into the categories described in our method which we believe will help the reader make more sense of the data although we are uncertain of committing to a weighted index without further testing using the data especially in the absence of widespread use of such an approach. We do thank the reviewer for the suggestion, and we intend to explore this option when evaluating the study outcomes.

The limitations should endeavor to assess and discuss how well the existing data capture socio-economic characteristics. In major cities in the United States, for example, homelessness, is a major risk factor for readmission. While ICD9 and ICD10 coding provide a

possibility of entering this risk factor into the patient's medical record and thus into the discharge summary, it is used sporadically and inconsistently in the US. Often, clinicians do not specifically ask the patient status or follow up if a patient gives the address of a homeless shelter as his/her

residence. This generally leads to under-counting. Occasionally, the code may be a relic of the patient's earlier status, but not updated if the patient moved into stable housing. Tests of social indicators in claims against other sources could examine their validity.

Response

Unfortunately, robust socioeconomic data are not collected in the Admitted Patient Data Collection. Homelessness is also not captured in a robust fashion in these datasets. We have indicated this as a study limitation.

"Socioeconomic status may influence patient outcomes although socioeconomic characteristics are not routinely collected in the hospital admitted patient data collections."

Finally, this reviewer would suggest the authors check a few formatting refinements. Where they mention dollars, they should be explicit and add currencies to specify Australian (AUD) or US dollars (USD). Most references followed the preferred style of sentence capitalization for the title of an article and Title Capitalization for the journal's title. However, references 15 and 31,

for example, did not apply Title Capitalization to journal titles, whereas references 28 and 32 did not apply sentence capitalization of article titles.

Response

Thank you for your suggestion. We have specified the currencies and fixed the capitalisation in references.

VERSION 2 – REVIEW

REVIEWER	Seth Freedman Indiana University
REVIEW RETURNED	14-Apr-2020

GENERAL COMMENTS	I appreciate the authors' responsive revision. I have only one remaining comment. I would suggest clarifying in the text that the data linkages are being performed by "linkage units" and not the authors themselves, as described in the response to my original comments.

REVIEWER	Donald S. Shepard Brandeis University, USA
REVIEW RETURNED	06-Apr-2020

GENERAL COMMENTS	This reviewer thanks the authors for their clear and thoughtful response and resulting valuable improvements to the manuscript.

8

However, this reviewer feels that the manuscript would be improved further by incorporating many of the insights and suggestions in the authors' response memo into the manuscript itself.

These additions will further highlight the value of the planned study, initiate further discussion among researchers, perhaps encourage jurisdictions to release additional data for this type of study, and increase the credibility and significance of results of these analyses by showing that they were planned beforehand and not post-hoc analyses that would by susceptible to cherry picking.

Specific comments, linked to the authors' response letter, follow:

Authors' response, P1, item 1.
South Australia, Tasmania and the Northern Territory do not release private hospital data to researchers although the impact on the study is likely to be small as most acute care in Australia is provided by public hospitals. These states only account for about 10% of the overall population and their private hospitals contain only xx% of Australia's total hospital beds ."

Reviewer's comment:
It would be helpful to quantify the assertion that the limitation is minor, thereby increasing the usefulness of this study. The bolded last sentence above seeks to do this.

Authors' response, P5.
Thank you for the comment. We agree that this would be a useful comparison and we do intend to compare variation in costs by region.
Reviewer's comment.
It would be helpful to add this and other planned analyses to the objectives in manuscript.

Authors' response, P5.
In some states and territories, this includes de-identified hospital labels.
Reviewer's comment.
This reviewer believes that it would be useful to create a section called "supplementary analyses" planned for the subset of states that provide de-identified hospital data. It would be useful to indicate the share of hospital beds represented by the data from these states and to specify the supplementary analyses planned in that subset of states.

Authors' response, P6.
We do thank the reviewer for the suggestion, and we intend to explore this option when evaluating the study outcomes.
Reviewer's comment.
As with the previous comment, it would be helpful to add this and other planned analyses to the objectives in manuscript.

VERSION 2 – AUTHOR RESPONSE

Reviewer Name: Donald S. Shepard
Institution and Country: Brandeis University, USA
Please state any competing interests or state 'None declared': None declared.

Please leave your comments for the authors below
This reviewer thanks the authors for their clear and thoughtful response and resulting valuable improvements to the manuscript. However, this reviewer feels that the manuscript would be improved further by incorporating many of the insights and suggestions in the authors' response memo into the manuscript itself.

These additions will further highlight the value of the planned study, initiate further discussion among researchers, perhaps encourage jurisdictions to release additional data for this type of study, and increase the credibility and significance of results of these analyses by showing that they were planned beforehand and not post-hoc analyses that would by susceptible to cherry picking.

Specific comments, linked to the authors' response letter, follow:

1. Authors' response, P1, item 1.
   South Australia, Tasmania and the Northern Territory do not release private hospital data to researchers although the impact on the study is likely to be small as most acute care in Australia is provided by public hospitals. These states only account for about 10% of the overall population and their private hospitals contain only xx% of Australia's total hospital beds ."

   Reviewer's comment:
   It would be helpful to quantify the assertion that the limitation is minor, thereby increasing the usefulness of this study. The bolded last sentence above seeks to do this.

We thank Dr Shepard for the comments. We are unable to report the exact number of private hospital beds in these regions (and therefore calculate the percentage requested by the reviewer) because number of private hospital beds in Northern Territory and Tasmania are not publicly released to protect the confidentiality of the small number of private hospitals in these regions. Nevertheless, we have modified the text to the following as suggested.

Revised Discussion (limitations section, page 19)

South Australia, Tasmania and the Northern Territory do not release private hospital data to researchers although the impact on the study is likely to be small as most acute care in Australia is provided by public hospitals. These states only account for about 10% of the overall population. Furthermore, private hospitals in these states encompass a small proportion of overall hospital beds. For example, those in South Australia form 2% of all hospital beds in Australia and the number of private hospital beds in Northern Territory and Tasmania are not publicly released to protect the confidentiality of the small number of private hospitals in these regions.[19]

2. Authors' response, P5.
   Thank you for the comment. We agree that this would be a useful comparison and we do intend to compare variation in costs by region.

   Reviewer's comment.
   It would be helpful to add this and other planned analyses to the objectives in manuscript.

We have modified the method (as below) to indicate variation in costs will be compared by region.

Methods (analysis section under aim 2, page 12).

10

"Costs will be assessed and compared by geographical region."

3. Authors' response, P5.
    In some states and territories, this includes de-identified hospital labels.

    > Reviewer's comment.
    > This reviewer believes that it would be useful to create a section called "supplementary analyses" planned for the subset of states that provide de-identified hospital data. It would be useful to indicate the share of hospital beds represented by the data from these states and to specify the supplementary analyses planned in that subset of states.

    We have added a supplementary analysis section as requested. We note that hospital identifiers are only available from New South Wales, Queensland and Tasmania and much of the hospital-specific data are only publicly available for public sector hospitals.

    Supplementary Analyses (page 15)

    In most regions, de-identified data are provided for analysis including de-identified hospital labels where hospital names and unique identifies are replaced with a dummy identifier so that hospital-level analyses are possible, but the hospital cannot be identified. In New South Wales, Queensland and Tasmania actual hospital identifiers are provided. In these regions, we will seek to further examine the association of hospital-specific characteristics with the outcomes using publicly available data from the National Public Hospital Establishments Database (NPHED) and the MyHospitals reporting portal. Using standardised data definitions, NPHED collects data on each hospital's revenue, staffing levels, expenditure, the number of available beds for admitted patients, geographical location, specialised service indicators and the type of non-admitted patient care. NPHED data is only available for public hospitals. The MyHospitals national reporting platform allows users to explore information about hospitals and publicly reports a selected number of hospital-specific performance process and outcome indicators such as healthcare associated infection rates, predominately from public hospitals. New South Wales, Queensland and Tasmania include 54% of the Australian population and New South Wales and Queensland encompass 52.8% of all Australian hospital beds. Hospital bed numbers in Tasmania are not publicly released to protect the confidentiality of the small number of private hospitals in Tasmania.

4. Authors' response, P6.
    We do thank the reviewer for the suggestion, and we intend to explore this option when evaluating the study outcomes.

    > Reviewer's comment.
    > As with the previous comment, it would be helpful to add this and other planned analyses to the objectives in manuscript.

    We have revised the study method as suggested by the reviewer

    Revised Method (analysis plan under aim 2, page 13)

    We will also explore the possibility of combining the four categories of hospital readmissions to create a robust overall index with the weighing of categories to be determined based on empirical testing, available literature and expert clinical opinion.

Response to Reviewer #1 Comments

Reviewer Name: Seth Freedman
Institution and Country: Indiana University
Please state any competing interests or state 'None declared': None declared

Please leave your comments for the authors below

1. I appreciate the authors' responsive revision. I have only one remaining comment. I would suggest clarifying in the text that the data linkages are being performed by "linkage units" and not the authors themselves, as described in the response to my original comments.

We thank Dr Freedman for the comments. We have revised the method to clarify that the all data linkages will be performed by designated data linkage units within each region.

Revised Method (page 11)

All data linkages will be performed by designated Data Linkage Units within each jurisdiction using probabilistic matching using multiple patient identifiers (such as age, sex, date of birth and Medicare number) with reported accuracy exceeding 99%.[26 27]