PEER REVIEW HISTORY

ARTICLE DETAILS

TITLE (PROVISIONAL)	IMPLEMENTATION OF CONSENSUS-BASED PERIOPERATIVE CARE PATHWAYS TO REDUCE CLINICAL VARIATION FOR ELECTIVE SURGERY IN AN AUSTRALIAN PRIVATE HOSPITAL: A MIXED METHODS PRE-POST STUDY PROTOCOL
AUTHORS	Pagano, Lisa; Hemmert, Cameron; Hirschhorn, Andrew; Francis-Auton, Emilie; Arnolda, Gaston; Long, Janet; Braithwaite, Jeffrey; Gumley, Graham; Hibbert, Peter; Churruca, Kate; Hutchinson, Karen; Partington, Andrew; Hughes, Clifford; Gillatt, David; Ellis, Louise A.; Testa, Luke; Patel, Romika; Sarkies, Mitchell N

VERSION 1 – REVIEW

REVIEWER	Rove, Kyle Children's Hospital Colorado, Department of Pediatric Urology
REVIEW RETURNED	09-Jun-2023

GENERAL COMMENTS	The authors propose a hybrid effectiveness-implementation pre-post study that uses the EPIS framework to implement consensus-driven protocols for five common operations. Semi structured interviews will be used to assess implementation barriers and facilitators. This will occur in a single, private hospital. A key outcome sought by the authors is reduction of clinical variation. 1. The authors state they plan to use administrative data from prostatectomy patients to conduct a process evaluation and patient outcomes. Can the authors clarify this? I have concerns about using administrative data outside limited situations because it is well known to have 30-40% error. 2. I appreciate the involvement of patient stakeholders in stage 2, preparation. 3. One of the challenges with standardized perioperative care protocols (like Enhanced Recovery After Surgery), is auditing. You are only as good as what you are doing and you can only know what you are doing by measuring. Measuing is often forgotten or under-resourced. What is your plan to collect important process measure outcomes in stages 3 and 4? How detailed will it be? 4. ERAS is a well-accepted framework for standardized, perioperative care that reduces clinical variation and cost. Why not adapt its principles here? It feels like the authors have gone out of the way NOT to mention enhanced recovery after surgery.

	5. LOS is well known to be an imperfect outcome because there are instances where it is impacted by non-clinical circumstances. Patient experience, patient return to baseline function, complications are more objective measures that can inform standardized care pathways. This is not to say not to report it, but ensure it is not so heavily relied upon as an outcome measure. 6. For the pre-post comparisons of quantitative data, it would be helpful to expand on the planned statistical analysis. Will you propensity match historical controls to standardized pathway patients to account for unmeasured bias? If not, how do you plan to minimize bias in the comparisons? What is your statistical significance threshold? 7. There is no overt hypothesis statement in the manuscript. Please include one. 8. I did not see a checklist (SPIRIT may be appropriate for this work). Apologies if it was done and not sent to me. These are very helpful to ensure a complete manuscript. Overall, this proposed study employs a wide range of methodologies to assess implementation and effectiveness of standardized care pathways for patients undergoing common surgeries.

REVIEWER	Wadhwa, Anupama The University of Texas Southwestern Medical Center, anesthesiology
REVIEW RETURNED	13-Jun-2023

GENERAL COMMENTS	Well written paper on a difficult to address topic. Provides a nice guideline to approach care pathways.

VERSION 1 – AUTHOR RESPONSE

Reviewer 1 comments

1. The authors state they plan to use administrative data from prostatectomy patients to conduct a process evaluation and patient outcomes. Can the authors clarify this? I have concerns about using administrative data outside limited situations because it is well known to have 30-40% error.
Author response: We thank the reviewer for their important query. Administrative data will be used to evaluate all of the surgical cohorts. We have added a sentence in the Quantitative Clinical Outcomes Data section and referenced a study by Sarkies et al that has demonstrated data from routine administrative databases has high levels of agreement with the medical record for both length of stay (93.4%) and discharge destination (91%) data: Sarkies MN, Bowles KA, Skinner EH, Mitchell D, Haas R, Ho M, Salter K, May K, Markham D, O'Brien L, Plumb S, Haines TP. Data collection methods in health services research: hospital length of stay and discharge destination. Appl Clin Inform. 2015 Feb 18;6(1):96-109. doi: 10.4338/ACI-2014-10-RA-0097. No other modifications have been made. Page 17.

2. I appreciate the involvement of patient stakeholders in stage 2, preparation.
Author response: Thank you for your endorsement and we agree that the involvement of patient stakeholders is a useful and important part of research design. Page 3

3. One of the challenges with standardized perioperative care protocols (like Enhanced Recovery After Surgery), is auditing. You are only as good as what you are doing and you can only know what you are doing by measuring. Measuring is often forgotten or under-resourced. What is your plan to collect important process measure outcomes in stages 3 and 4? How detailed will it be?
Author response: Thank you for your comment and we agree that auditing is an essential component of evaluating the successful implementation of a perioperative pathway. The planned procedures for auditing will involve the extraction of data from a hospital database relating to compliance with components of the implemented pathways. This will occur at regular intervals throughout the study period and the information will be presented to clinicians at scheduled meetings, for example, at monthly discipline meetings. Further description of the auditing process has been added to the manuscript. Page 11.

4. ERAS is a well-accepted framework for standardized, perioperative care that reduces clinical variation and cost. Why not adapt its principles here? It feels like the authors have gone out of the way NOT to mention enhanced recovery after surgery.
Author response: The reviewer has raised an important point. ERAS pathways are indeed an accepted framework but are not universally implemented in Australia. There are many ways to describe our intervention across the literature, for example ERAS, models of care, pathways, and protocols, to name a few. The hospital we're working with has chosen to use the term "consensus-based perioperative pathways" to refer to the intervention being implemented. A key criterion of our pathways was that it was evidence-based, and this is where it overlaps with ERAS. Whilst all of these protocols are evidence-based, local conditions often require them to be adapted. We have added text to the introduction to make reference to this broader nomenclature. We also refer to some literature on ERAS protocols in the discussion section of the manuscript (pp 20-21). Page 5.

5. LOS is well known to be an imperfect outcome because there are instances where it is impacted by non-clinical circumstances. Patient experience, patient return to baseline function, complications are more objective measures that can inform standardized care pathways. This is not to say not to report it, but ensure it is not so heavily relied upon as an outcome measure.
Author response: We fully agree that there are some limitations to using LOS as an outcome measure and we explicitly acknowledge this in the manuscript (i.e., "… the research team does not view LOS as the most important clinical outcome for these four cohorts …"). As described in the manuscript, other clinical and implementation outcomes will also be analysed pre and post-intervention to examine the effectiveness of the pathways. For example, hospital acquired complications and hospital readmission will be assessed in all cohorts, and PREMS and PROM will be examined in the prostatectomy cohort.

6. For the pre-post comparisons of quantitative data, it would be helpful to expand on the planned statistical analysis. Will you propensity match historical controls to standardized pathway patients to account for unmeasured bias? If not, how do you plan to minimize bias in the comparisons? What is your statistical significance threshold?
Author response: Thank you for this suggestion. Due to the limited quantity of data available in the pre- and post-intervention periods, we do not plan to use propensity score matching in our analysis of the quantitative secondary outcomes. We anticipate a temporal trend in outcomes such as LOS and thus plan to use available data to control for this important source of bias. We will of course report changes in patient characteristics over time to inform the reader of the potential for bias. If no temporal trends are found, a post hoc analysis will be considered to address confounding through changes in patient spectrum, before and after intervention.
The estimated between-group difference and the 95% confidence intervals (95% CI) will be reported and for significant testing, p values <0.05 will be considered statistically significant. This information has been added to the manuscript to further expand on the planned statistical analysis. Page 19.

7. There is no overt hypothesis statement in the manuscript. Please include one.
Author response: Thank you for identifying this point and we have included a hypothesis statement in the 'Objectives' section of the manuscript. Page 6.

8. I did not see a checklist (SPIRIT may be appropriate for this work). Apologies if it was done and not sent to me. These are very helpful to ensure a complete manuscript.
Author response: Thank you, we have now added the SPIRIT checklist as a supplementary file (Supplementary File 4).

Overall, this proposed study employs a wide range of methodologies to assess implementation and effectiveness of standardized care pathways for patients undergoing common surgeries.
Author response: We thank the reviewer for their close reading of our manuscript and for their positive summary of our paper.

Reviewer 2 comments:
Well written paper on a difficult to address topic. Provides a nice guideline to approach care pathways.
Author response: We thank the reviewer for their reading of our manuscript and for the positive comments on our paper.

VERSION 2 – REVIEW

REVIEWER	Rove, Kyle Children's Hospital Colorado, Department of Pediatric Urology
REVIEW RETURNED	08-Jul-2023

GENERAL COMMENTS	The authors have satisfactorily modified their submission and answered my original queries.

VERSION 2 – AUTHOR RESPONSE

REVIEWER 1 COMMENTS	
The authors have satisfactorily modified their submission and answered my original queries.	We thank the reviewer for their reading of our revised manuscript.