PEER REVIEW HISTORY

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ARTICLE DETAILS

TITLE (PROVISIONAL)	Protocol for implementation of the "AusPROM" recommendations for elective surgery patients: A mixed-methods cohort study
AUTHORS	Morris, Meg; Brusco, Natasha; Wood, Jeffrey; Myles, Paul; Hodge, Anita; Jones, Cathy; Lloyd, Damien; Rovtar, Vincent; Clifford, Amanda; Atkinson, Victoria

VERSION 1 – REVIEW

REVIEWER	Mou, Danny Brigham and Women's Hospital, Surgery
REVIEW RETURNED	07-Apr-2021

GENERAL COMMENTS	This is a well thought out, national PROMs implementation initiative that addresses a significant unmet need: a validated, standardized PROM implemented at a national scale to enable meaningful comparisons across institutions. That said, a number of issues warrant addressing. 1. Other nation-wide PROM initiatives have been executed with only variable success (e.g., NHS and ortho-related PROMs). A compelling review of their work is warranted and the authors should indicate how this project will be different / more effective. 2. I really like that this project takes into account the patients' perspective of PROMs. Too many studies focus on clinician's perspective and miss this critical angle. 3. The authors indicate that this system will be designed so that there is minimal hospital staff involvement. Is this realistic? My sense that there will inevitably be required hospital staff support and that the compliance rate will heavily depend on hospital staff (e.g., front desk staff, medical assistants, RNs, MDs) to encourage patients to fill out the PROMs 4. The QOR-15 sounds reasonable, but has this ever been used in any large scale studies comparing performances of various institutions/surgeons? As a surgeon with strong interest in PROMs, I have never heard of this tool. 5. Your focus groups include RNs and MDs, but a lot of PROM implementation is dependent on the front desk staff / office staff / non-clinicians. In fact, our experience in the U.S. is that the non-clinicians are the primary driver for compliance rates. Depending on how this will ultimately be operationalized, you should strongly consider including some non-clinical hospital staff in the focus groups. 6. Your time points for PROM collection may be problematic. Elective knee replacements often don't confer their full benefit until many months after surgery (our incentivized pre/post HOOS/KOOS PROMs are timed at 9 months postop) whereas elective hernia repairs heal in weeks. Though I understand the

	extra complexity involved with tailoring time points to different surgeries, generalizing "all elective surgeries" is quite a leap. This needs to be addressed in some way or acknowledged as a significant limitation.

REVIEWER	Montroni, Isacco Ospedale degli Infermi di Faenza
REVIEW RETURNED	02-May-2021

GENERAL COMMENTS	The authors reported about an absolutely essential activity that is crucial for every surgical practice (AKA evaluating outcomes that matter to patients). The only shame is that not practicing in Australia I wouldn't be able to participate, otherwise, I'd like to congratulate the authors for the study design and looking forward to reading about their experience/results as soon as possible Only few minor annotations: -What is the main difference authors are trying to achieve creating their own Aus-PROM instead of using other instruments that were already validated in that geographical setting, in brief, what is the peculiarity of the Aus-PRO? -Please make sure to define (or look for) the minimal clinically important difference when working with PROM and scores as establishing these thresholds in advance will help the researchers Sagberg LM, Jakola AS, Solheim O. Quality of life assessed with EQ-5D in patients undergoing glioma surgery: what is the responsiveness and minimal clinically important difference? Qual Life Res. 2014 Jun;23(5):1427-34. doi: 10.1007/s11136-013-0593-4. Epub 2013 Dec 7. PMID: 24318084. -Would highly recommend, in designing their own Aus-PROM tool, to keep it as simple as possible (40 items it's way too long to be applied to a broad population). When receiving feedback from phase I these should aim at simplifying the tool rather than adding more variables -Please consider extending (at least for pts undergoing major surgery) the study time to 3 and 6 months as many major surgeries will have an impact at 1 month that needs to be investigated if present later in the followup -please consider matching PROMs (again at least for subgroups) with some of more 'objective' data that could be obtained from patients (example could be TUG, ADL, IADL other examples like Wexner Incontinence Score, etc) in order to understand if poor/good QoL can be translated into poor/good functional outcomes. This could also help later on understanding correlations in case of missing data

VERSION 1 – AUTHOR RESPONSE

Reviewer: 1

This is a well thought out, national PROMs implementation initiative that addresses a significant unmet need: a validated, standardized PROM implemented at a national scale to enable meaningful comparisons across institutions. That said, a number of issues warrant addressing.

1. Other nation-wide PROM initiatives have been executed with only variable success (e.g., NHS and

ortho-related PROMs). A review of their work is warranted and the authors should indicate how this project will be different / more effective.

Thank you for this helpful comment. Given the restricted word count, we have added a short discussion on this in the revised Discussion:

“The results will be compared and contrasted with previous nation-wide PROM implementation projects. This will be important given the challenges encountered during the implementation of some measures, such as the UK NHS PROM (50) and some orthopaedic-related PROMs (51). The current project will be different and arguably more effective due to strong consumer engagement at all stages of design and implementation, as well as drawing upon the learnings of hundreds of surgical outcome studies of the QoR-15 from across the globe (52,53), including large randomised trials (54-56).”

2. I really like that this project takes into account the patients' perspective of PROMs. Too many studies focus on clinician's perspective and miss this critical angle.

Thankyou – co-design is a central part of our project design and implementation.

3. The authors indicate that this system will be designed so that there is minimal hospital staff involvement. Is this realistic? My sense that there will inevitably be required hospital staff support and that the compliance rate will heavily depend on hospital staff (e.g., front desk staff, medical assistants, RNs, MDs) to encourage patients to fill out the PROMs

The reviewer is correct, hence we have revised the text on page 4 as follows:

“A key goal is to simplify administration, whilst acknowledging that compliance be assisted by hospital staff (e.g., front desk staff, medical assistants, nurses, allied health professionals, medical practitioners, surgeons) encouraging patients to fill out the PROMs”.

4. The QOR-15 sounds reasonable, but has this ever been used in any large scale studies comparing performances of various institutions/surgeons?

Yes, the QoR-15 has been used in hundreds of surgical outcome studies around the world (Myles 2020; Kleif 2018), including in large randomised trials (Myles, Short, Corcoran). A quick Google Scholar search identified >500 publications. For interest, the Perioperative Quality Improvement Program (www.pqip.org.uk) in the UK collects, amongst other process and outcome data, QoR-15 scores as their nominated main PROM after surgery.

We have now added these references to the revised manuscript.

- Myles PS. More than just morbidity and mortality - quality of recovery and long-term functional recovery after surgery. Anaesthesia. 2020;75 Suppl 1:e143-e150.

- Kleif J, Waage J, Christensen KB, Gögenur I. Systematic review of the QoR-15 score, a patient- reported outcome measure measuring quality of recovery after surgery and anaesthesia. Br J Anaesth. 2018;120(1):28-36.
- Myles PS, Bellomo R, Corcoran T, Forbes A, Peyton P, Story D, Christophi C, Leslie K, McGuinness S, Parke R, Serpell J, Chan MTV, Painter T, SA, Minto G, Wallace S, on behalf of the Australian and New Zealand College of Anaesthetists Clinical Trials Network (ANZCA CTN), and the Australian and New Zealand Intensive Care Society Clinical Trials Group (ANZICS CTG). Restrictive versus liberal fluid therapy for major abdominal surgery. N Engl J Med 2018; 378:2263-74.
- Short TG, Campbell D, Frampton C, Chan MTV, Myles PS, Corcoran TB, et al. Anaesthetic depth and complications after major surgery: an international, randomised controlled trial. Lancet 2019;394(10212):1907-14.
- Corcoran T, Myles PS, Forbes AB, Cheng AC, Bach LA, O'Loughlin E, Leslie K, Chan MTV, Story D, Short TG, Martin C, Coutts P, Ho KM, for the Australian and New Zealand College of Anaesthetists Clinical Trials Network (ANZCA CTN), and the Australian Society for Infectious Diseases (ASID) Clinical Research Network. Dexamethasone and surgical site infection. N Engl J Med 2021; 384:1731-41.

5. Your focus groups include RNs and MDs, but a lot of PROM implementation is dependent on the front desk staff / office staff / non-clinicians. In fact, our experience in the U.S. is that the non-clinicians are the primary driver for compliance rates. Depending on how this will ultimately be operationalized, you should strongly consider including some non-clinical hospital staff in the focus groups.

Yes, we agree this is very important and we always planned to include some non-clinical hospital staff in the focus groups. The manuscript has been edited to make this clear on pages 8 & 9 of the revised manuscript:

"…Therefore, there will be two perspectives: (i) from staff implementing it centrally at corporate office; (ii) staff in the hospitals who are encouraging patients to complete the ePROM as well as utilise findings from the ePROM survey. This will include health professionals as well as some non-clinical hospital staff from the front desk and administration teams."

6. Your time points for PROM collection may be problematic. Elective knee replacements often don't confer their full benefit until many months after surgery (our incentivized pre/post HOOS/KOOS PROMs are timed at 9 months postop) whereas elective hernia repairs heal in weeks. Though I understand the extra complexity involved with tailoring time points to different surgeries, generalizing "all elective surgeries" is quite a leap. This needs to be addressed in some way or acknowledged as a significant limitation.

We acknowledge the reviewers insights here – this is an important point and we have added new text in the methods section to clarify that time points for data collections will be investigated through the consumer and staff feedback on acceptability. We have also added on page 10:

"It is acknowledged that optimal time-points for PROM data collection can sometimes vary according to the patients' condition. For example, elective knee replacement patients often don't confer their full benefit until many months after surgery whereas elective hernia repairs recover within weeks. The extra complexity involved with tailoring time points to different surgeries was beyond the scope of the current study, hence we standardised the time-points for PROMs data collection for elective surgeries. The optimal time points for data collection will be further investigated through the consumer and staff feedback on acceptability. ".

Reviewer: 2

The authors reported about an absolutely essential activity that is crucial for every surgical practice (AKA evaluating outcomes that matter to patients). The only shame is that not practicing in Australia I wouldn't be able to participate, otherwise, I'd like to congratulate the authors for the study design and looking forward to reading about their experience/results as soon as possible

Thank you for your kind words!

Only few minor annotations:
-What is the main difference authors are trying to achieve creating their own Aus-PROM instead of using other instruments that were already validated in that geographical setting, in brief, what is the peculiarity of the Aus-PRO?

We wish to clarify that the AusPROM is *not* a new measurement tool, but a set of recommendations for implementation of PROMS (in this case the QoR-15). We have revised the introduction to make this clearer so this is not mis-interpreted. The reviewer is correct that it would not be strategic create yet another PROM. We have therefore added a new sentence in the Discussion to clarify this:

"Of note, the AusPROM is not yet another new PROM. Rather it is a set of recommendations for implementation of PROMS in hospital settings".

Please make sure to define (or look for) the minimal clinically important difference when working with PROM and scores as establishing these thresholds in advance will help the researchers

We agree completely with the reviewer. We have already done this for the QoR-15 scale, which was 4.6 to 8.0 (P Myles et al. Minimal Clinically Important Difference for Three Quality of Recovery Scales. (Anesthesiology 2016; 125).

We have therefore added the following new text on page 15:

"Of note, the minimally clinically important difference for the QoR-15 PROM has already been established by Myles et al (2016) as 4.6 to 8.0 (49). The manuscript by Myles et al. also shows the value of the "patient acceptable symptom state" (PASS) (49). For the QoR-15 it is a score or 118 or better. PASS defines what minimal threshold (score) patients would accept for their own recovery".

Would highly recommend, in designing their own Aus-PROM tool, to keep it as simple as possible. When receiving feedback from phase I these should aim at simplifying the tool rather than adding more variables

We agree and are keeping the AusPROM recommendations as simple and brief as possible and shall monitor this in the feedback from focus groups.

Please consider extending (at least for pts undergoing major surgery) the study time to 3 and 6 months as many major surgeries will have an impact at 1 month that needs to be investigated if present later in the follow up

Thank you for this suggestion. The timepoints are an important point and we have added new text in the methods section to clarify that time points for data collections will be investigated through the consumer and staff feedback on acceptability. Although we cannot extend them at this time, we have added on page 10:

"It is acknowledged that optimal time-points for PROM data collection can sometimes vary according to the patients' condition. For example, elective knee replacement patients often don't confer their full benefit until many months after surgery whereas elective hernia repairs recover within weeks. The extra complexity involved with tailoring time points to different surgeries was beyond the scope of the current study, hence we standardised the time-points for PROMs data collection for elective surgeries. The optimal time points for data collection will be further investigated through the consumer and staff feedback on acceptability.".

Please consider matching PROMs (again at least for subgroups) with some of more 'objective' data that could be obtained from patients (example could be TUG, ADL, IADL other examples like Wexner Incontinence Score, etc) in order to understand if poor/good QoL can be translated into poor/good functional outcomes. This could also help later on understanding correlations in case of missing data

This is a really interesting and insightful suggestion which we may apply in a future extension of the project. It is beyond the scope of this already complex manuscript and project to add further design features at this point in time.

We do note that the third aim of the study is to "establish if the QoR-15 PROM has concurrent validity with the EQ-5D-5L". While the EQ-5D-5L is not an objective scale (as suggested by the reviewer), it does provide some comparison of the QoR-15 with another well validated multi-attribute quality of life tool.

VERSION 2 – REVIEW

REVIEWER	Mou, Danny Brigham and Women's Hospital, Surgery
REVIEW RETURNED	18-Jul-2021

GENERAL COMMENTS	All reviewer comments have been sufficiently addressed. Appropriate for publication.