PEER REVIEW HISTORY

BMJ Open publishes all reviews undertaken for accepted manuscripts. Reviewers are asked to complete a checklist review form (http://bmjopen.bmj.com/site/about/resources/checklist.pdf) and are provided with free text boxes to elaborate on their assessment. These free text comments are reproduced below.

ARTICLE DETAILS

TITLE (PROVISIONAL)	"Organisation of delivery of care in operating suite recovery rooms
	within 48 hours postoperatively and patient outcomes after adult
	non-cardiac surgery: a systematic review."
AUTHORS	Lloyd, Courtney Ellen; Ludbrook, Guy; Story, David; Maddern, Guy

VERSION 1 – REVIEW

REVIEWER	Walter Lehmacher, Prof. em. University of Cologne Institute of Medical Statistics, Informatics and Epidemiolgy
REVIEW RETURNED	Germany 23-Nov-2018

GENERAL COMMENTS	You cited several times "EndNote 8 (Clarivate Analytics, Boston,
	USA)".
	The words in the brackets can be deleted after the first citation.

REVIEWER	ANTONELLA ZAMBON
	Department of Statistics and Quantitative Methods - University of
	Milan-Bicocca
REVIEW RETURNED	10-Dec-2018

GENERAL COMMENTS	This is an interesting paper but I suggest to the authors the
GENERAL COMMENTO	
	following issues.
	 In the methods (Information sources and search strategy) they wrote that "Logic grids were used as a tool, to replicate the search throughout the three databases". Which databases? In the paragraph "Synthesis of results" they wrote "there was no increase in mortality rates identified in any of the four studies
	investigating non-ICU pathways for post-operative patients
	[5,7,9,10]. The reference 9 is Fraser's paper. In tables 3 is
	reported that mortality was not investigated (third column) in
	Fraser's paper.
	In the paragraph "Synthesis of results" no recall to the risk of
	bias is done
	4) In the flow-chart are lacking the number of papers excluded for each exclusion criteria

REVIEWER	Art Wallace
REVIEWER	
	University of California San Francisco, United States of America
REVIEW RETURNED	03-Mar-2019
GENERAL COMMENTS	Lloyd et. al. in "What health services initiatives undertaken within
	operating suite recovery rooms have been shown to improve
	patient outcomes after adult non-cardiac surgery: a systematic
	review" attempt to do a metaanalysis of care initiative in the post-

operative setting. They identified 3288 unique studies, select 14 for full text review, and include 8 in their final analysis. While they explain their inclusion criteria they provide no explanation of the 99.75% of the article they identified but did not analyze. Their analysis is essentially of 8 articles (0.24%) that have some relationship to post-operative care. These studies are so homogeneous that they are unable to do a meta-analysis. Without reviewing the 3288 studies they identified, this decision is hard to validate. It would be very helpful to have some description of the 3,280 studies they did not review. Were they all case studies? Did they not have outcome variables? Why were they rejected. It might also have simplified their analysis if they had picked some aspect of post-operative recovery room care such as the use of ICU versus step-down unit for a class of cases such as major vascular or cardiac cases, or use of prolonged post-operative recovery room to avoid admission for ambulatory come and go surgery. They end up analyzing 8 studies that were very homogenous and only one randomized trial. The next problem with the manuscript is it is essentially a large number of very large tables with summaries of the articles. The reader is left to search through tables to understand the validity of the conclusions. For example, because there is so much discussion of the selection of studies and approach to bias there is no discussion of the individual studies. The reader must find a table entitled "Participants additional table:" to find the size of the studies. Studies range greatly in size (152 vs 26), (3345 vs 3030), (119), (26118 vs 24972), (485 vs 448), (694 vs 723), (331 vs 569), (30 vs 30). An analysis of results from a study of 50,000 patients has more value than a study of 60 patients. The reader is forced to identify these differences in the tables, then go back to the manuscript to see what conclusions are made with each article. The format of this manuscript makes it difficult for the reader to make meaningful or valuable conclusions. If the authors had simply written a standard review article, summarizing the results of what was known about different interventions, including references, and assessing the quality of the references in the text of the article, the reader would get a vastly better understanding of what interventions were worthwhile and which were not in postoperative recovery. The reader is left to do much of this analysis themselves by sorting through results in tables. Most of the conclusions the manuscript are supported by single studies that are of "poor" quality, "with significant selection and allocation bias". The conclusions are not well supported by the format of the manuscript. A standard review article addressing a question such as: is managing postoperative patients outside the ICU associated with worse outcomes? The problem with approach is most of the conclusions are supported by single studies. The article is attempting to do a metaanalysis of these questions, presents the results as if they are a metaanalysis, when in reality is it a simple review of the literature with a limited number of references, that are not of high quality, for each conclusion. Assessing whether a study truly decreases mortality requires analysis of the sample size and study quality. The format of the manuscript forces the reader to do this analysis from data provides in extensive tables. This information would be easier to understand, interpret, and establish the value and validity of if the manuscript were a standard review article where the literature supporting each conclusion was analyzed for the reader.

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	Conclusions: The strength of evidence supporting the conclusions is modest at best. The biggest conclusion of the manuscript, "There is a striking paucity of literature on this topic, with very few high-quality studies; and further research is required to evaluate and improve the care of post-operative patients in the recovery room setting" would be more convincing if some discussion of the 99.75% of studies identified on the topic but not analyzed were included, otherwise this manuscript is a review article of 8 studies without much detailed analysis of the studies included.
	Specific Comments:
	P4 line 48 "grey literature" what does this mean?
	P12 Line 33 "Four studies investigated non-ICU pathways for care of post-operative patients, and these pathways were not associated with increased mortality rates." This is an important finding. The problem with it is that it is not interpretable as written. The absence of a difference in rates is only significant if the power of the studies is significant enough to actually detect a difference. 30-Day Mortality rates for major inpatient surgery in the VA are in the 0.5% range. The sample size to have an 80% power to see a 50% reduction in mortality would be 9441 patients per group. The sample size to have an 80% power to see a 10% reduction in mortality would be 298770 patients per group or 600,000 patients for a comparison. One of the studies has a sample size of approximately 25,000 patients per group which would be large enough to see a 30% reduction in mortality rates. A standard review of the literature would allow the authors to discuss these fine points and give more background to any conclusion. The four studies mentioned have (152 vs 26), (119), (26,118 vs 24,972), (485 vs 448). The only study that could actually have the power to show a difference in mortality with this intervention is Kastrup et al, so the conclusion appears to be based on four studies and in reality is only based on one (Kastrup) and the details of this study are not presented to the reader. On the question of the addition of an intensivist to the PACU one study showed an increase in PACU stay, the other showed a decrease in total length of stay, some more discussion of this point would be better handled in a standard review of the literature.
	P14 Line 40 Even the conclusion "There were no long-term positive effects were investigated for the use of incentive spirometry" (fix the grammar) but this conclusion is supported by a single study. Prior to making such a conclusion it would be fairer to review the literature for this specific point, find all the studies of incentive spirometry, analyze the results and make a conclusion. Doing a search on PACU studies that have health services interventions, finding 8 studies, and then finding one that finds no outcome for incentive spirometry, limits the sources for an analysis of spirometry efficacy to those in the initial search criteria, and then finds no result. A review of the efficacy of incentive spirometry finds at least 10 randomized trials, and while the results are mixed, there is some efficacy in some situations. This sentence does not reflect a summary of the medical literature on this topic secondary to the search criteria for inclusion of the studies.

VERSION 1 – AUTHOR RESPONSE

Thank you for taking the time to review our manuscript titled "What health service initiatives undertaken within operating suite recovery rooms within 48 hours post-operatively have been shown to improve patient outcomes after adult non-cardiac surgery: a systematic review." All editorial requests and formatting amendments have been completed.

In response to reviewer 1, we have reformatted our citation of EndNote 8. In response to reviewer 2, we have listed the databases used for our literature search (PubMed, Embase and CINAHL) (page 5 line 8). We have also adjusted our conclusion in synthesis of results, to reflect that Fraser et al did not investigate mortality as an outcome measure (page 11 line 6, page 13 line 5). We have also recalled the risk of bias assessment in our synthesis of results (page 13 line 18), highlighting that reliable conclusions cannot be drawn from single studies with small data sets. The flow diagram has been altered to reflect the reasons for exclusions of articles at each stage of the review (Figure 1 REVISED).

In response to reviewer three's specific comments; 'grey literature' refers to research that is either unpublished or has been published in non-commercial forms. Examples of grey literature include; government reports, policy statements and conference proceedings. In response to the conclusions that have been discussed regarding mortality for patients managed outside of the ICU; we agree that the lack of powered studies confounds this conclusion. We have discussed this point in the results and discussion section (page 13 line 18, page 14 line 21). We have also included the numbers of participants in each intervention group in the Characteristics of Included Studies Summary Table (page 7), to allow readers to easily identify this issue. In response to the conclusion we have found regarding the use of incentive spirometry in PACU, we have clarified in-text that the more accurate conclusion is "there were no long-term positive effects investigated, or identified, for the use of incentive spirometry in PACU post-operatively" (page 13 line 17). The authors agree that in other studies, incentive spirometry has shown some positive results in other settings, however these could unfortunately not be included, as they did not focus on an intervention undertaken in the PACU specifically.

We would also like to reiterate that this paper is a systematic review, and not a meta-analysis. We were unable to do a meta-analysis due to the heterogeneous nature of the included studies, with varying study designs, and varying outcome measures. This is also discussed in the main article. We chose to complete a systematic review, not a standard review article, as this is the current standard preferred by the NHMRC (National Health and Medical Research Council) in Australia when applying for research funding.

In terms of the small number of studies included in the review, this was due to our specific inclusion and exclusion criteria, as published on our PROSPERO protocol, which is in-line with the PRISMA statement for conduction of systematic reviews. The number of included studies is a reflection of the sparse body of knowledge on PACU, and the need for further research. Many papers that were excluded did not focus on PACU specific interventions, or were not focussed on the correct population group, we hope that the updated flow diagram will better illustrate these reasons for exclusion. In terms of focussing our attention to ICU vs HDU/ step-down units; a recent systematic review of surgical HDUS/ special care units has already been done by Mendis et al [1]. Their systematic review investigated the effect of a 3-level model of care; ie surgical special care unit, (also referred to as a high dependency unit,

intermediate care unit or surgical step-down unit), along with intensive care and ward level care, compared to a 2-level model of care (ie, ward and intensive care unit). Their review provided mixed results, with no indication that implementation of 3-level care improved overall hospital post-operative mortality [1]. As there were few significant positive outcomes identified in this review, we have decided to turn our attention to Recovery Rooms/ PACUs as an alternative health service delivery model. The authors of this systematic review also encountered similar issues while reviewing literature in this area; including heterogeneous study designs and patient outcomes preventing full meta-analysis, non-powered studies with small sample sizes, and significant risk of bias of included studies. It is also important to note, that ICU is not an aspect of a recovery room/ PACU, it is a separate, significantly more expensive, location to deliver care. While there are other studies that investigate ICU versus ward-care, or ICU versus step-down, none of these studies included PACU as an alternative location for care delivery.

Thank you for your time and valuable feedback. If you have any further questions or comments regarding the review, please feel free to contact us.

1. Mendis, N., et al., A Systematic Review of the Impact of Surgical Special Care Units on Patient Outcomes and Health Care Resource Utilization. Anesth Analg, 2019. **128**(3): p. 533-542.

VERSION 2 – REVIEW

REVIEWER	Antonella Zambon
	University of Milano-Bicocca, Italy
REVIEW RETURNED	07-Aug-2019
GENERAL COMMENTS	Only one suggestion. In the last paragraph of Synthesis of Results you specify "It must be noted that the risk of bias of the included studies confounds results" I suggest to substitute "confounds" with "modifies"
REVIEWER	Arthur Wallace, M.D., Ph.D.
	University of California San Francisco Department of
	Anesthesiology and Perioperative Care and San Francisco
	Veterans Administration Hospital
REVIEW RETURNED	23-Sep-2019
GENERAL COMMENTS	Lloyd et al. in "What health service initiatives undertaken within operating suite recovery rooms within 48 hours post-operatively have been shown to improve patient outcomes after adult non- cardiac surgery: a systematic review." State that they have reviewed all English language literature on health service undertaken within operating suite recovery rooms within 48 hours post-operatively that have been shown to improve patient outcomes after adult non-cardiac surgery. There is a fundamental problem with this title and claim. There are numerous programs that have been implemented to reduce risk in patients after surgery including perioperative beta blockade, perioperative antiemetic therapy, perioperative analgesia, ERAS protocols, FastTracking, regional anesthesia, medication choice, reversal of non-depolarizing muscle relaxant choice, pain scoring systems, etc., etc. etc. The claim that they have reviewed the world literature and found the eight references that summarize all "health

service initiatives undertaken within operating suite recovery rooms within 48 hours post-operatively have been shown to improve patient outcomes after adult non-cardiac surgery" is simply not accurate. They reviewed eight manuscripts that studied various postoperative programs and summarized the disparate studies. They looked at studies that reported on discharge criteria tools, pathways, the effect of an intensivist in the post operative recovery room, (Post Anesthesia Care Unit) PACU rehabilitations, and one that looked at incentive spirometry effect on oxygen saturation. It is very clear that the literature in this field is inadequate as they only found one prospective clinical trial and only one trial with sufficient power to detect mortality rates. The manuscript found that the literature is lacking and was not able to conclude much. It is unclear what the value of this review really is other than to stimulate research into the safety and effectiveness of PACU practices. Even the conclusions of the manuscript are profoundly limited secondary to the methodology and limitations of the study. "Managing selected post-operative patients in a recovery room, or PACU, instead of ICU, does not appear to be associated with worse patient outcomes, however due to the high risk of bias within studies, the strength of evidence is moderate at best." The study does not present the criteria for patients who would be appropriate for a PACU instead of ICU recovery, so the finding is not valuable to guide care. There are patient who can clearly be recovered in the PACU others that clearly need ICU and this manuscript does not clarify how to make that decision rendering the finding of little value.
Page 3 Line 55 "This is the first systematic review to provide a summary of all health services interventions" You did not review ALL health services interventions you reviewed a few. What about perioperative beta blockade, perioperative antiemetic therapy, perioperative analgesia, ERAS protocols, FastTracking, regional anesthesia, medication choice, reversal of non-depolarizing muscle relaxant choice, etc., etc. etc. You reviewed 8 papers on a variety of topics and concluded little. It would be more convincing to actually do a review of one topic such as protocols, or ERAS, or discharge criteria, or criteria to decide on placement. You did not review ALL health services interventions in the PACU and you didn't really conclude anything definitive about any of the ones you looked at: protocols, intensivists, incentive spirometry, discharge criteria tools. It would be a vastly better study if you reviewed the literature on a single topic like ERAS, or discharge tools, or utilization management rules and then could make some definitive decision on something.
Page 4 Line 6. " ANY health services initiatives." You reviewed a couple. You did not review all of them.
Page 4 line 37. 38.2 what? Percentage? Total numbers? What are the units of the term 38.2?
Page 4 line 42post operative complications are now at pandemic levels Really? In 1950 the mortality from general anesthesia with a muscle relaxant was 1:200, now it is between 1:20,000 and 1:200,000. 30-day mortality for inpatient surgical procedures is 0.5% and 0.1% for outpatient surgery. How does that make a statement of NOW AT PANDEMIC LEVELS? I understand you are quoting a reference that used this term but

there is not suddenly worse rates of post operative complications, the rates are significantly less than 20 years ago.
Page 13 Line 48 "There were no long-term positive benefits investigated." Yes, but there were short term effects. You did not emphasize the results they reported.
Page 15 Line 25 I did a PubMed Search on PACU AND Metaanalysis and found 22 metaanalysis studies on factors that affect patients in the PACU. Is this really the first systematic review to investigate the health service initiatives undertaken in recovery rooms, and their impact on outcomes after PACU discharge? I found 22 other metaanalysis on different approaches to improving care in the PACU? How can you make this statement?

VERSION 2 – AUTHOR RESPONSE

<u>Reviewer 2</u>

Reviewer 2 suggested that we modify the last paragraph of Synthesis or Results, substituting "confounds results" with "modifies results".

In response to reviewer 2, we have changed this sentence to read "It must be noted that the risk of bias of the included studies modifies results" (page 14 line 6).

Reviewer 3

Reviewer 3 has made a number of comments in relation to the review; including the terms of the review, inclusion criteria, adequacy of the literature in this area, criteria for PACU and ICU admission, a review versus a systematic review, the future incidence of postoperative complications, systems versus specific interventions, and the effects of incentive spirometry. These are addressed in individual paragraphs below.

In response to reviewer 3, we would first like to clarify the <u>terms of our review question</u>, and inclusion criteria for the review. Health services research, also known as health systems research (or health policy and systems research), is a multidisciplinary field that examines access to, and the use, cost quality, delivery, organisation, financing and outcomes of health care services[1]. This is used to identify new knowledge about the structure, processes, and effect of health systems for individuals and populations. In this systematic review, we are focussing on the delivery and organisation of models of care and how they relate to patient outcomes. This includes areas such as; location of care delivery, staffing models, multi-disciplinary team involvement, and implementation of care or discharge criteria. We are not focussing on drugs, equipment, or new technologies. Our introduction has been amended to clarify the focus of the review (page 3 line 29). We have also updated our title, to clarify that we are investigating health systems (page 1 line 2). We believe it is critical that outcomes from standard service models are reviewed, tested, and have adaptations tested, in an era of changing population, and a need for high value care, to provide more sustainable healthcare for the future. For example, Mendis et al[2] recently published a systematic review of the surgical high acuity model, and found minimal data, with

little to no impact on patient outcomes. Medical Emergency Response Teams, or Rapid Response Teams (RRT), are also an area where the system of care, not the specific drugs or individual patient therapy have been investigated. Maharaj et al published a systematic review and meta-analysis in 2015 examining the effect of this model of care on patient outcomes[3]. Our review takes the view that similar scrutiny should be placed on the PACU model of care.

To further clarify our <u>inclusion criteria</u> (page 4-5), we would like to highlight that we are focussing on health systems (defined above), and specifically, systems initiatives and interventions undertaken in PACU in the post-operative period. We are not exploring interventions in the pre-operative period, or interventions undertaken in the operating room itself. Studies that explored the relationship between interventions in recovery and mortality, morbidity, hospital length of stay, unplanned ICU admission and return to theatre were our main focus.

In response to the comments that the <u>literature in this field is inadequate</u>, and the conclusion of the manuscript is limited; we agree with this statement. As stated in our conclusion (page 15), there is a striking paucity of literature surrounding this topic, with very few high-quality studies, and we firmly believe that further research is required in this area. With a small number of heterogeneous studies, with different primary endpoints, that were not powered for major outcomes; we cannot draw any further reliable conclusions.

Regarding the comment that this review does not present <u>the criteria for patients who would be</u> <u>appropriate for PACU instead of ICU level care</u>, we have expanded our narrative regarding the results of individual studies (page 11 line 7) to address this. Only two of the included studies stated their admission criteria for PACU, and all had significant selection bias, with admission to PACU often being at the discretion of the attending anaesthetist.

In response to the suggestion that a <u>review of a topic be done instead of a systematic review</u>; we acknowledge that a review of one topic may have yielded interesting results, however, a systematic review is the current standard required by the NHMRC (National Health and Medical Research Council) when applying for further funding for medical research in Australia. Many of the topics listed by the reviewer, also concern interventions that are not undertaken in recovery itself, and are outside of the scope of this review.

Regarding the comment that <u>post-operative complication rates are not increasing</u>; we would like to highlight that it is increasingly recognised that age alone is a major predictor of post-operative complications, and that the incidence is high (20%), in patients over 70, as identified in the REASON study[4]. These complications have a substantial impact on patient-centred outcomes and resource requirements, (including length of stay, and readmission rates), and thus are highly relevant. Based on age projections of most developed countries, we have estimated the impact of this change, and believe it qualifies as pandemic[5].

In response to the search for <u>PACU meta-analyses</u> done by reviewer 3, we would again like to highlight that we have focussed this review on health systems, or service initiatives, not drugs or equipment.

Most of the studies identified are drug trials, and investigate interventions undertaken in the operative room, not in recovery itself.

Regarding the effects of <u>incentive spirometry</u>, we have included the short-term positive effects in the synthesis of results (page 14 line 3), with the caveat that no long-term positive effects were investigated or identified. On page 4, we have also amended the typographic error. The sentence now reads "... an increase of 38.2% compared to 2004..." (page 4 line 18).

Thank you for your time and valuable feedback. If you have any further questions or comments regarding the review, please feel free to contact us.

Kind Regards,

Courtney Lloyd, Guy Ludbrook, David Story and Guy Maddern.

- Institute of Medicine Committee on Health Services Research, T. and I. Work Force, in *Health* Services Research: Opportunities for an Expanding Field of Inquiry: An Interim Statement, S. Thaul, K.N. Lohr, and R.E. Tranquada, Editors. 1994, National Academies Press (US): Washington (DC).
- 2. Mendis, N., et al., A Systematic Review of the Impact of Surgical Special Care Units on Patient Outcomes and Health Care Resource Utilization. Anesth Analg, 2019. **128**(3): p. 533-542.
- 3. Maharaj, R., I. Raffaele, and J. Wendon, *Rapid response systems: a systematic review and meta-analysis.* Crit Care, 2015. **19**: p. 254.
- 4. Story, D.A., et al., Complications and mortality in older surgical patients in Australia and New Zealand (the REASON study): a multicentre, prospective, observational study. Anaesthesia, 2010. **65**(10): p. 1022-30.
- 5. Ludbrook, G. and Walsh, R. *The impact of age on the future burden of postoperative complications in Australia.* Anaesth Intensive Care, 2019 (in press).

VERSION 3 – REVIEW

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REVIEWER	Arthur Wallace, M.D., Ph.D.
	University of California, San Francisco and San Francisco
	Veterans Affairs Medical Center
REVIEW RETURNED	22-Nov-2019
GENERAL COMMENTS	The authors have not incorporated any of the suggested improvements or even edits that have been requested. Even simple improvement such as word choice to avoid confusion were not incorporated.
	I will include my comments from the first draft as the authors did not bother to even consider improvements.
	Lloyd et al. in "What health service initiatives undertaken within operating suite recovery rooms within 48 hours post-operatively have been shown to improve patient outcomes after adult non-

cardiac surgery: a systematic review." State that they have
reviewed all English language literature on health service
undertaken within operating suite recovery rooms within 48 hours
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non-depolarizing muscle relaxant choice, pain scoring systems,
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of PACU practices. Even the conclusions of the manuscript are
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VERSION 3 – AUTHOR RESPONSE

Response to Reviewers

C. Lloyd, G. Ludbrook, D. Story, G. Maddern

Dear Editorial Team and Reviewer,

Thank you for taking the time to review our manuscript initially titled "What health system initiatives undertaken within operating suite recovery rooms within 48 hours post-operatively have been shown to improve patient outcomes after adult non-cardiac surgery: a systematic review."

We would like to respond to the specific comments from the associate editor. In regards to the statement that the study does not present the criteria for patients who would be appropriate for a PACU instead of ICU recovery, so the finding is not valuable to guide care. There are patients who can clearly be recovered in the PACU others that clearly need ICU and this manuscript does not clarify how to make that decision rendering the finding of little value. We agree there is not clarity in the literature about decisions on destinations after surgery. There is substantial disparity between the resources and cost of recovery room then ward care, and ICU, making such decisions, and evidence to support those decisions, extremely important if good outcomes and sustainable costs are to be achieved in an ageing increasingly co-morbid population. The aim of this review is to highlight the paucity of data currently available. We have recently published a correspondence letter in BJA which starts to address this issue[1]; through risk identification and stratification to care pathways, showing standard levels of care may be inadequate. We hope this review stimulates more work in this area.

Regarding the suggestion that we consider revising the title to make it abundantly clear that this is about models of delivery of care; thank you for your suggestion, we have amended the title

accordingly. The systematic review is now titled "Organisation of delivery of care in operating suite recovery rooms within 48 hours postoperatively and patient outcomes after adult non-cardiac surgery: a systematic review."

We have also included a results section in the abstract as suggested.

Thank you for your time and valuable feedback. If you have any further questions or comments regarding the review, please feel free to contact us.

Kind Regards,

Courtney Lloyd, Guy Ludbrook, David Story and Guy Maddern.

1. Lloyd, C., et al., *Incidence of early major adverse events after surgery in moderate-risk patients: early postoperative adverse events.* Br J Anaesth, 2019.