

PEER REVIEW HISTORY

BMJ Open publishes all reviews undertaken for accepted manuscripts. Reviewers are asked to complete a checklist review form ([see an example](#)) and are provided with free text boxes to elaborate on their assessment. These free text comments are reproduced below. Some articles will have been accepted based in part or entirely on reviews undertaken for other BMJ Group journals. These will be reproduced where possible.

ARTICLE DETAILS

TITLE (PROVISIONAL)	NATIONAL TRENDS IN HOSPITAL-ACQUIRED PREVENTABLE ADVERSE EVENTS AFTER MAJOR CANCER SURGERY IN THE UNITED STATES
AUTHORS	Roghmann, Florian; Sukumar, Shyam; Trinh, Vincent; Sammon, Jesse; Gervais, Mai-Kim; Tan, Hung-Jui; Ravi, Praful; Kim, Simon; Hu, Jim; Karakiewicz, Pierre; Noldus, Joachim; Sun, Maxine; Menon, Mani; Trinh, Quoc-Dien

VERSION 1 - REVIEW

REVIEWER	Marco Bianchi, MD San Raffaele hospital, Department of Urology; Urological Research Institute; Milan; Italy
REVIEW RETURNED	24-Mar-2013

GENERAL COMMENTS	<p>In the current manuscript Sukumar et al. undertook a national assessment of the quality of major surgical oncology care within a standardized framework of preventable adverse events to examine trends in patient safety within the United States. The authors also evaluated the hypothesis explaining the volume-complication-mortality relationship, which states that higher mortality rates for patients undergoing surgery at lowvolume hospitals is preferentially explained by higher failure-to-rescue rates. The results of the current analyses demonstrates there has been a substantial increase in the national frequency of potentially avoidable adverse-events after major cancer surgery, while there was a concomitant reduction in failure-to-rescue rates and overall-mortality rates. These observations seem to be related with hospital volume.</p> <p>The authors should be applauded for their effort to systematically analyze the outcomes of 8 major cancer surgeries within the United States. Overall the manuscript is well written, the methodology appropriate, and the results clearly explained. However, it would be of interest to the reviewer to better understand why the rate of adverse outcomes is increasing through years. With the improvements of surgical techniques, one would expect a decrease of post-operative complications. Accordingly, an hypothesis for this apparent "paradox" should be stated in the discussion section.</p>
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REVIEWER	Keith Kowalczyk, MD Instructor of Surgery Department of Urology Lombardi Comprehensive Cancer Center
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	Georgetown University Hospital Washington, DC, USA
REVIEW RETURNED	08-Apr-2013

GENERAL COMMENTS	<p>This is an excellent study that I honestly do not have much to add. It is extremely well written and comprehensive analysis of trends in preventable events following cancer surgery. It provides enlightening statistics that lead one to ponder who to improve care for our patients. Additionally, it does pose questions regarding CMS' potential policy of penalizing institutions for increased mortality/complication rate when realistically a higher failure-to-rescue rate seems more appropriate.</p> <p>My one comment would be to see if the authors could add surgeon volume to the analysis. I understand that this may be beyond the scope of an already comprehensive work, however I wonder if they would explore this in the future of if they already have.</p>
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REVIEWER	John Morton, MD, MPH Associate Professor Stanford University
	no competing interests
REVIEW RETURNED	22-Apr-2013

GENERAL COMMENTS	<p>Paper is well done and essentially replicates the following study confining it to oncologic surgery- clearly needs to be cited. Downey JR, Hernandez-Boussard T, Banka G, Morton JM. "Is patient safety improving? National trends in patient safety indicators: 1998-2007," Health Serv Res, 47 (1 Pt 2): 414-30, 2012</p> <p>The graphs are difficult to read and need a different scale or format to be clearer. Can authors comment on the impact of cancer center accreditation, hospital volume of surgery and present on admission diagnoses. Otherwise, paper is well written and conclusions sound.</p>
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REVIEWER	Jesús M ^a Aranaz Andrés
	Servicio de Medicina Preventiva y Calidad Asistencial
	Hospital Universitari Sant Joan d'Alacant.
	Dpto. Salud Pública, Historia de la Ciencia y Ginecología Universidad Miguel Hernández.
REVIEW RETURNED	23-Apr-2013

GENERAL COMMENTS	<p>The paper is a retrospective cross-sectional. The objective of the paper is to estimate Hospital-acquired-adverse events after major cancer surgery.</p> <p>The introduction is good and talks about the fact of multiple studies have demonstrated that significant variation exists in cancer incidence rates and in access to quality cancer care, but variations in the actual quality of surgical oncology care remain unclear.</p>
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	<p>About methodology, the variables are correct defined. The statistical analysis is the suitable one. The statistical meaning of the results is defined. The information of the results answers to the aims of the study and reflects the findings more relevant. The presentation is clear and suitable.</p> <p>It seems to me a good manuscript, correctly developed and with a suitable methodology, and that it supposes an interesting contribution to the knowledge of the health quality improvement.</p>
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VERSION 1 – AUTHOR RESPONSE

Reviewer: Marco Bianchi, MD;
San Raffaele hospital, Department of Urology; Urological Research Institute; Milan; Italy

In the current manuscript Sukumar et al. undertook a national assessment of the quality of major surgical oncology care within a standardized framework of preventable adverse events to examine trends in patient safety within the United States. The authors also evaluated the hypothesis explaining the volume-complication-mortality relationship, which states that higher mortality rates for patients undergoing surgery at low-volume hospitals is preferentially explained by higher failure-to-rescue rates. The results of the current analyses demonstrates there has been a substantial increase in the national frequency of potentially avoidable adverse-events after major cancer surgery, while there was a concomitant reduction in failure-to-rescue rates and overall-mortality rates. These observations seem to be related with hospital volume.

The authors should be applauded for their effort to systematically analyze the outcomes of 8 major cancer surgeries within the United States. Overall the manuscript is well written, the methodology appropriate, and the results clearly explained. However, it would be of interest to the reviewer to better understand why the rate of adverse outcomes is increasing through years. With the improvements of surgical techniques, one would expect a decrease of post-operative complications. Accordingly, an hypothesis for this apparent "paradox" should be stated in the discussion section.

-We thank the reviewer for this helpful comment.

To comply, we added the following to our discussion:

“The increase may be attributed to changes in case-mix, including an aging population. Conversely, the emergence of multi-resistant bacteria may contribute to the recorded trends [...] Nonetheless, alternate explanations include refinements in coding practices, which may have led to better recognition and recording of non-lethal adverse events, thereby resulting in an apparent decrease in mortality rates.”

Reviewer: Keith Kowalczyk, MD
Instructor of Surgery
Department of Urology
Lombardi Comprehensive Cancer Center
Georgetown University Hospital
Washington, DC, USA

This is an excellent study that I honestly do not have much to add. It is extremely well written and comprehensive analysis of trends in preventable events following cancer surgery. It provides enlightening statistics that lead one to ponder who to improve care for our patients. Additionally, it does pose questions regarding CMS' potential policy of penalizing institutions for increased mortality/complication rate when realistically a higher failure-to-rescue rate seems more appropriate.

My one comment would be to see if the authors could add surgeon volume to the analysis. I understand that this may be beyond the scope of an already comprehensive work, however I wonder if they would explore this in the future of if they already have.

-We thank the reviewer for his comment. Unfortunately the Nationwide Inpatient Sample does not provide reliable information on surgeon volume. The information is not provided by many states, and oft miscoded in others: some surgical units are identified with a single ID. Therefore, these analyses cannot be performed in the Nationwide Inpatient Sample. As suggested, our research team will pursue this topic in future projects analyzing datasets that provide this information, such as SEER-Medicare.

Reviewer: John Morton, MD, MPH
Associate Professor
Stanford University

no competing interests

Paper is well done and essentially replicates the following study confining it to oncologic surgery- clearly needs to be cited. Downey JR, Hernandez-Boussard T, Banka G, Morton JM. "Is patient safety improving? National trends in patient safety indicators: 1998-2007," Health Serv Res, 47 (1 Pt 2): 414-30, 2012

This is an important comment.
To comply, we cited the suggested paper.

The graphs are difficult to read and need a different scale or format to be clearer.

-We thank the reviewer for this comment and have reformatted several figures.

Can authors comment on the impact of cancer center accreditation, hospital volume of surgery and present on admission diagnoses. Otherwise, paper is well written and conclusions sound.

-We did not analyze the impact of cancer center accreditation, as hospital attributes to identify those centers is not provided consistently for all states. To perform such an analysis would have required the exclusion of a significant number of states, and therefore would not have allowed us to provide nationally representative figures.
In contrast, hospital volume of surgery is accounted for in all of our multivariable analyses. Diagnoses at admission are adjusted for using the Charlson Comorbidity Index, which is also included in our multivariable analyses.

Reviewer: 4

If you have any further comments for the authors please enter them below.
The paper is a retrospective cross-sectional. The objective of the paper is to estimate Hospital-acquired-adverse events after major cancer surgery.

The introduction is good and talks about the fact of multiple studies have demonstrated that significant variation exists in cancer incidence rates and in access to quality cancer care, but variations in the actual quality of surgical oncology care remain unclear.

About methodology, the variables are correct defined. The statistical analysis is the suitable one. The statistical meaning of the results is defined. The information of the results answers to the aims of the study and reflects the findings more relevant. The presentation is clear and suitable.
It seems to me a good manuscript, correctly developed and with a suitable methodology, and that it supposes an interesting contribution to the knowledge of the health quality improvement.

-We thank the reviewer for his kind assessment of our manuscript. To answer the last question, we cannot directly share our dataset as per NIS data-use agreement. However, any independent research group can assess the raw dataset for a nominal fee and perform subset or alternate examinations on the same topic.