PEER REVIEW HISTORY

ARTICLE DETAILS

TITLE (PROVISIONAL)	
AUTHORS	

VERSION 1 - REVIEW

REVIEWER	Dr. E.J. Veen, MD, PhD Amphia Hospital Breda, The Netherlands Surgeon
REVIEW RETURNED	14/02/2012

THE STUDY	The article puts focus on the quality of registering complications in a university hospital and discusses the value / influence and outcome of different resources used for this process. This is an interesting issue as outcome is strongly depending on the methods used for registration. page 2: 13- should we use more or other resources for this purpose? What do the authors mean for this purpose? (for documenting complication eg) In general the terms complication / adverse event are used throughout the manuscript. please try to use one term. (eg page 4 / background) The background is long and i suggest to put the part from line 36 (part of the explanation ...) to line 55 (and a better quality of care) in the discussion section. Methods: page 5 46: How was the randomisation done? 46: The group is small with only 5,5 % of the total population. 48: How is ensured that at least half of the patients had suffered one postoperative adverse event? 48: Why only include patients who underwent a surgical procedure. Studies have been described with almost 10 % complication sin non-operated patients. 55: The fact that patients whose resources could not be retrieved were excluded is a flaw of the study, as this group concerns 45 patients (25 %) In general, how is the registration process organized? Who diagnoses the complication? The complication is discussed during the morning session by hands out? This seams to be a pitfall as much is depending on the reliability and memory of surgeons and residents. Who will enter the complication in the LHCR database?

	How are complications classified? Page 7: The benchmark used in the study is the combination of all resources, which seems appropriate. How were the nursing files screened, by checking the charts or only the textual information? 34: discrepancies were resolved by discussion? Was the inter-observer reliabilty measured (by kappa). This should be given. 41: Table 4: pain is no complication but the result of an an complication / intervention. (however one could imagine that dislocation or wrong placement of epidural analgesia is documented as complication). Pneumonia / cellulitis / phlebitis should be categorised under the heading infection. How is over-infusion defined? Hemodynamic instabillity and shock seems to be the same. What is meant with wound leakage? wrong-k-wire ? change increased dislocation into secondary dislocation. Hernia ? (what kind) . Shunt occlusion should be documented under vascular as thrombosis.
RESULTS & CONCLUSIONS	Results: page 9: 5: Results are presented as the patients with complications. (98 out 0f 135). However we are not informed about the type of documented events missing expect that they were all mild according to the system of clavien. The number and incidence of missing complications per group is more interesting. Is there a significant difference between the analysed resources. 27. How are medical management events defined? The question rises what are mild events? (pain eg? i do not agree that this is a complication) I the discussion on quality improvement / outcome measurement these mild events are of limited value. The events classified 2-4 were also underreported. Especially in the class 3-4 it would be interesting to know which complications are not recorded? The list of complications documents less than 50 % to the reference is broad and has no additional value. Rather describe in each group which complications were most frequently missed. For instance were all anastomotic leakage found? Discussion: Underreporting of complications in the LHCR seems logic if this is done after they have been presented in the morning team session. (which also shows under reporting) page 11: 5: all likely resources should be incorporated for an optimum registration of adverse events. I disagree with this statement, as this will result in a much broader dataset with many events without severe effects for the patient. Rather try to focus on documenting one event accurately which has severe impact for the patient and can be used for quality measurement / improvement. (this has been mentioned / discussed further in the discussion, eg postponed surgical procedure)

	page 12: 29: serious busines (change, eg is a serious aspect of our daily routine)

REVIEWER	Job Kievit Prof of Clinical Decision Analysis, Assoc prof of Surgery Leiden University Medical Centre the Netherlands
REVIEW RETURNED	20/02/2012

THE STUDY	Page 6 refers to the WHO reporting guidelines, while those guidelines use the term adverse event for “An injury related to medical management, in contrast to complications of disease”. Given the fact that the definition used in the study does not exclude “complications of disease”, adverse outcome would be a more appropriate term. The sampling method is not entirely clear, apart from the fact that patients with adverse events were oversampled. Thus, page 5 states “random … while ensuring that at least half …” (how?), while page 9 reports “98 out of 135 patients had suffered …”, which is 72%. This makes it less easy to interpret the sample-data in relation to the whole dataset.
RESULTS & CONCLUSIONS	The conclusion that "hospitals and clinicians should be willing to put effort in a structural and reliable means to register not only the beneficial, but also the harmful effects of their professional activities ..." is true, but does not directly follow from the data. First, data on beneficial effects of treatment are event less available than those on harmful. Second, the data are coming from an institution that apparently puts considerable effort in such registration. Finally, the issues of definition and sampling somewhat undermine the strength of the conclusions on the registration "harmful effects of their professional activities". The fact that in this final sentence causality seems to reappear (while it was so clearly excluded on page 6), is again somewhat confusing.
REPORTING & ETHICS	The present study analyses the completeness of quality information in one university medical centre, and concludes that the use and usefulness data on adverse outcomes is dependent upon the completeness and validity of the underlying information. However relevant as an illustration of the ubiquitous data-quality problem, neither the methodology nor the outcomes of the study provide new insight in comparison to what we know from previous studies.

VERSION 1 – AUTHOR RESPONSE

Comments to reviewer 1 (dr. Veen)
The article puts focus on the quality of registering complications in a university hospital and discusses the value / influence and outcome of different resources used for this process. This is an interesting issue as outcome is strongly depending on the methods used for registration.

page 2:
13- should we use more or other resources for this purpose? What do the authors mean for this

purpose? (for documenting complication eg)
We have added "… to achieve a more complete complication registry".

In general the terms complication / adverse event are used throughout the manuscript. please try to use one term. (eg page 4 / background)
We agree with the reviewer this may be confusing. We used the term "complication" to indicate adverse effects of surgical treatment, while "adverse events" could also comprise those due to organisational or managerial errors. We have now used the aggregate term "adverse outcome".

The background is long and i suggest to put the part from line 36 (part of the explanation ...) to line 55 (and a better quality of care) in the discussion section.
We have adopted the reviewer's suggestion and moved this section to the discussion on page 11.

Methods:
page 5
46: How was the randomisation done?
By means of a random number generator. This has now been added in the text.

46: The group is small with only 5,5 % of the total population.
This may seem a relatively small number, but we found no reason to believe this was not a representative sample of patients. Second, the retrieval and screening of all relevant sources for possible adverse outcomes among this number of patients was a huge effort. Third, this percentage is comparable to other related studies, for example by Marang et al. (2005), who included 5.0%.

48: How is ensured that at least half of the patients had suffered one postoperative adverse event?
Half of the patients were randomly selected from the LHCR database after selecting patients with at least one complication recorded.

48: Why only include patients who underwent a surgical procedure. Studies have been described with almost 10 % complication sin non-operated patients.
We agree. The reviewer has pointed us to an error in the patient description, which should be "post-admission" rather than "postoperative". We have corrected this in the text. As a matter of fact, 30% of the included patients did not undergo surgery (see Table 2).

55: The fact that patients whose resources could not be retrieved were excluded is a flaw of the study, as this group concerns 45 patients (25 %)
We do not agree with the reviewer at this point. In case some resources could not be retrieved, we could not check whether any complications had been incorrectly or under-reported in the LHCR. These patients would therefore not be useful to include for the purpose of our study. Furthermore, it is unlikely that excluded patients would represent those with a higher or lower number of incorrect or under-reported adverse outcomes.

In general, how is the registration process organized? Who diagnoses the complication? The complication is discussed during the morning session by hands out?
This seams to be a pitfall as much is depending on the reliability and memory of surgeons and residents. Who will enter the complication in the LHCR database?
We summarized the process of registering complications on the bottom of page 6, under Resources. Adverse outcomes are diagnosed and reported during the daily hand-offs by the treating surgeons and/or residents and recorded by the head of the department, who has a listing of recently discharged patients. These recordings are checked by dedicated administrative personnel and compared with discharge letters. Quarterly, the complications recorded are discussed by the staff and residents to look for possible improvement actions to avoid such complications in the future by adjusting the

policy.

How are complications classified?
Classification of complications in the LHCR is performed via a three-tiered matrix-like classification system based on: 1) type of pathology (e.g., infection, bleeding); 2) location, divided in region (e.g., thorax, abdomen), organ (e.g., lung, liver), or tissue; and 3) determinants and other information (e.g., medication). This is defined in more detail in refs. 5, 7 and 8.

Page 7:
The benchmark used in the study is the combination of all resources, which seems appropriate.
How were the nursing files screened, by checking the charts or only the textual information?
The nursing dossiers, which are separate from the medical dossiers, of all patients were retrieved. These contain both the charts and the texts of the nursing handovers. So, these were both screened.

34: discrepancies were resolved by discussion? Was the inter-observer reliabilty measured (by kappa). This should be given.
The two investigators who extracted the data verified this by investigating each other's first 10 patients and found their agreement was nearly perfect. Subsequently, they consulted each other or their supervisors in case of uncertainties interpreting the texts of the resources. We adapted this in the text for more clarity. We did not calculate an inter-observer kappa value.

41: Table 4: pain is no complication but the result of a complication / intervention. (however one could imagine that dislocation or wrong placement of epidural analgesia is documented as complication).
Problems with epidural analgesia have indeed been recorded as complications. Besides, according to the definition used for complications, pain can be considered as an outcome, unwanted by the patient, following medical or surgical intervention that requires further treatment.

Pneumonia / cellulitis / phlebitis should be categorised under the heading infection.
We agree these diagnoses could be categorized as infectious disorders. However, the LHCR also distinguishes the location in its matrix, thereby separating, for example, vascular-related infections from pulmonary ones.

How is over-infusion defined?
This was defined as a higher that required intravenous fluid suppletion, which was reported as complication if detected as such by the nurse or physician, diagnosed on a thoracic X-ray or central arterial monitoring system, and requiring diuretics.

Hemodynamic instabillity and shock seems to be the same.
You are right; we have now transposed this to Shock.

What is meant with wound leakage?
Any unexpected leakage from a postoperative, traumatic or secondary healing wound requiring specific additional treatment.

wrong-k-wire ?
In retrospect, in one case another K-wire should have been removed.

change increased dislocation into secondary dislocation.
We have done so.

Hernia ? (what kind) . Shunt occlusion should be documented under vascular as thrombosis.
It was one patient who had a hernia of the trocar site. We agree the shunt occlusion is a form of

vascular occlusion and have now transposed this item for more clarity, although the LHCR codes these two separately.

Results:

page 9:
5: Results are presented as the patients with complications. (98 out 0f 135).
However we are not informed about the type of documented events missing except that they were all mild according to the system of clavien. The number and incidence of missing complications per group is more interesting.
We had stated the missed “mild” complications on page 9. We have now also added the (few) class 2 and 3 complications the LHCR missed.

Is there a significant difference between the analysed resources.
In this study, all data of all selected patients were available. Hence, there is no sample of complications from each resource taken, which could cause any imprecision about the percentages complications found or missed. Therefore no statistics are required to this end. The results show the absolute differences in complications retrieved from the various resources.

27. How are medical management events defined?
These events were defined as being due to hospital organizational or managerial errors, like cancelled surgical procedures, rather than events due to the care given for the disease.

The question rises what are mild events? (pain eg? i do not agree that this is a complication)
In the discussion on quality improvement / outcome measurement these mild events are of limited value.
We considered mild events to be class-1 adverse outcomes, i.e. those leading to temporary health disadvantage and recovering without (re)operation. This is defined at the bottom of page 7 and page 9, line 19. Events may be “mild” in the eyes of the surgeon, but can be perceived by patients as important and undesirable, particularly when undergoing elective surgical interventions.

The events classified 2-4 were also underreported. Especially in the class 3-4 it would be interesting to know which complications are not recorded?
As indicated in Table 4, The LHCR had missed only one class-3 complication as compared to the reference standard (i.e. a pressure ulcer; now mentioned on page 9). Other sources had missed more complications, as mentioned on page 10, second paragraph.

The list of complications documents less than 50 % to the reference is broad and has no additional value. Rather describe in each group which complications were most frequently missed. For instance were all anastomotic leakage found?
We have now mentioned the complications missed by the LHCR on page 9. Fortunately, no anastomotic leakages were found missing in the LHCR. Because of the long list of complications observed, we preferred to mention them separately only in some comparisons of the various resources. We did mention the most underreported complications at the bottom of page 10.

Discussion:
Underreporting of complications in the LHCR seems logic if this is done after they have been presented in the morning team session. (which also shows under reporting)
This is exactly our point. Hence, we suggest turning to complementary resources if a more complete recording of all adverse outcomes is desired to be able to take measures to reduce or avoid them in the future.

page 11:
5: all likely resources should be incorporated for an optimum registration of adverse events.
I disagree with this statement, as this will result in a much broader dataset with many events without severe effects for the patient.
Rather try to focus on documenting one event accurately which has severe impact for the patient and can be used for quality measurement / improvement. (this has been mentioned / discussed further in the discussion, eg postponed surgical procedure)
We partly agree with the reviewer and have addressed in the discussion section on pages 11-12 that there is a choice between two options, both with their pros and cons: On the one hand complete registration of also the minor complications, to be able to reduce or avoid such complications that may be mild, but at the same time important and undesirable to patients. Alternatively, a “light” version of complication registration would be easier to achieve, but would omit these mild complications, some of which are being used as quality indicators (e.g. pressure ulcers, wound infections).

page 12:
29: serious busines (change, eg is a serious aspect of our daily routine)
We have adapted this sentence accordingly.

Comments to reviewer 2 (Prof. Kievit)

Page 6 refers to the WHO reporting guidelines, while those guidelines use the term adverse event for “An injury related to medical management, in contrast to complications of disease”. Given the fact that the definition used in the study does not exclude “complications of disease”, adverse outcome would be a more appropriate term.
We have now uniformized these terms as much as possible and used “adverse outcome(s)” wherever appropriate.

The sampling method is not entirely clear, apart from the fact that patients with adverse events were oversampled.
Thus, page 5 states “random … while ensuring that at least half …” (how?), while page 9 reports “98 out of 135 patients had suffered …”, which is 72%.
This makes it less easy to interpret the sample-data in relation to the whole dataset.
We have now elaborated on patient selection in the Methods section on page 5. We took a random sample of 90 patients in the LHCR and another random sample of 90 patients after selecting those patients in the LHCR who had at least one complication, totalling an oversampled complication rate of 72.6%.
The reader has to keep in kind that our sample data are not representative of the adverse outcome incidence in the whole data set, as we specifically studied the completeness of the different resources rather than the true incidence of adverse outcomes.

The conclusion that "hospitals and clinicians should be willing to put effort in a structural and reliable means to register not only the beneficial, but also the harmful effects of their professional activities ..." is true, but does not directly follow from the data. First, data on beneficial effects of treatment are event less available than those on harmful. Second, the data are coming from an institution that apparently puts considerable effort in such registration. Finally, the issues of definition and sampling somewhat undermine the strength of the conclusions on the registration "harmful effects of their professional activities". The fact that in this final sentence causality seems to reappear (while it was so clearly excluded on page 6), is again somewhat confusing.
We agree with the reviewer that this statement is an inference based on the conclusion in the preceding sentence, meant as a take-home message for clinical practice.
First, beneficial effects are usually available as numbers of (surgical) interventions performed, which

are meant to be beneficial to our patients. Many intervention studies present such data as primary endpoints, while adverse outcomes are usually defined merely as secondary outcome parameters. Yet, given the increasing attention from governmental institutions, hospitals, and patients on quality and safety of care, a proper complication registration seems a prerequisite, which we indeed pursue in our institution.
We have rephrased the last sentence of the conclusion to cover this issue more appropriately.

The present study analyses the completeness of quality information in one university medical centre, and concludes that the use and usefulness data on adverse outcomes is dependent upon the completeness and validity of the underlying information.
However relevant as an illustration of the ubiquitous data-quality problem, neither the methodology nor the outcomes of the study provide new insight in comparison to what we know from previous studies.
Previous studies by others have indeed addressed various aspects of complication registration, for example the usefulness of prospective, routine reporting of surgical complications, adverse outcomes after discharge, incidence of complications in non-operated surgical patients, or the comparison of complication registration between different hospitals.
We are convinced this paper offers additional insight as it addresses the reliability of a commonly used national complication registration system as compared to other resources and suggests ways how and why this could be improved, by bringing in data from other available clinical resources.
The value of the nursing dossier to complete the complication registration has, to our knowledge, never been shown before.

VERSION 2 – REVIEW

REVIEWER	Eelco Veen MD / PhD Amphia Hospital , The Netherlands Surgeon
REVIEW RETURNED	22/03/2012

GENERAL COMMENTS	Page 4 background Background and purpose of the study are better described and clear 7: and lower hospital morbidity and mortality The purpose of the study is interesting as it discusses the difficulties in registering complications (adverse outcomes). It is clear that when using different resources to document / register complications one will find differences in incidence and type of documented events. The results of the manuscript confirms this statement and discusses the use of it in general practice and quality improvements. I believe that the registry process will become to broad for adequate registration in this way and put more focus on specific outcome en process measures for quality improvement. However the study as done by Ubbink et al could help in finding adverse outcomes usable for quality improvements. The pros and cons of this issue has been discussed.