PEER REVIEW HISTORY

ARTICLE DETAILS

TITLE (PROVISIONAL)	Evaluation of the organization and effectiveness of internal audits to govern patient safety in hospitals: A mixed-method study
AUTHORS	van Gelderen, Saskia; Zegers, Marieke; Boeijen, Wilma; Westert, Gert; Robben, Paul; Wollersheim, Hub

VERSION 1 - REVIEW

REVIEWER	Sue Hignett Loughborough University, UK
REVIEW RETURNED	23-Dec-2016

GENERAL COMMENTS	This is an interesting topic but needs attention to provide a wider context for readers outside Netherlands. For example there is research to discuss different approaches for corporate (organisational processes, finance, contracts etc.) and clinical (treatment, medical equipment etc.) audits. I suspect that there are many clinical audits taking place which influence decision-making relevant to patient safety - were these included? The paper will benefits from taking a critical stance to the role of quality management for safety issues. I suggest considering whether the quality system of the hospital (performance and preconditions) is the appropriate paradigm to give a true reflection about safety. There have been recent papers discussing the limitations of following a quality paradigm rather than a safety science paradigm to address patient safety. It was unclear whether the questionnaire and interview were both focussed on the same research questions (how was audit carried out and was it effective), or whether the issues from the questionnaire results were then used to inform the interview schedule? Was the questionnaire distributed as online survey or as attachment to email? For the pilot, did you also check if the target participants would be able to complete it rather than just piloting with experts? Suggest that Table 2 is embedded in the text rather than in tabular format.

REVIEWER	Kees Ahaus University of Groningen, Faculty of Economics and Business, The Netherlands
REVIEW RETURNED	04-Jan-2017

GENERAL COMMENTS	Thank you for giving me the opportunity to review this interesting paper on the organization and perceived effectiveness of internal audits in hospitals. The research is very relevant as hospitals (in the Netherlands) spend a lot of efforts of time and effort to conduct these audits, and there has not been a study yet to systematically evaluate the effectiveness of this quality improvement instrument. The authors report in their well-written paper the results of a mixed-method study, which consists of a combination of a questionnaire (n=89, high response of 69) and in-depth interviews (43 interviews in six hospitals with board members, members of the board of supervisors, quality and safety directors, quality officers and clinicians/clinical managers). Both questionnaire and interviews (e.g. use of COREQ checklist) are well-designed. The questionnaire provides relevant basic descriptive information about the use of audits, the qualitative research is more interesting as it gives in-depth information which is analysed with an inductive approach. The result is a study which is predominantly descriptive, but gives useful insights into the way internal audits are deployed. Overall, I am positive about this paper, but a few issues might need more clarification: - Regarding the concept and scope of internal audits, it seems that the authors want to focus on audits as an instrument to assure patient safety (page 4, line 48: ….'research regarding the effectiveness of internal audits for boards to govern patient safety is lacking'). However, why they limit to patient safety is not clear, and even not logical, as the data refer to the use of internal audits in complying to standards like for example NIAZ-accreditation, which have a broader scope of quality improvement. - The descriptive data shows that the audits have a rather different focus (page 8, line 55): departments, healthcare processes/pathways, patient safety themes. This could have influenced the perceived effectiveness as some audit initiatives have a more top down approach without real involvement of clinicians, while other initiatives such as clinical audits might have a more bottom-up approach with much involvement of clinicians. - Audits assess compliance to standards. It's clear for the reader that this refers to standards of accreditation institutes, but what kind of standards are provided by law, by the hospital itself and by the profession (page 9, line 35) is not completely clear. I suggest to give a few examples. - The authors indicate that they have used an inductive approach in coding and category-building (page 7, line 32). The categories are presented in table 2 in three themes (use of audits for risk identification, for steering patient safety and for accounting for patient safety). Was this interesting distinction also inductively derived from the data, or was it taken as a starting point? - I suggest to leave out the word 'great' in 'great similarities' in the discussion page 13, line 7, as I experience from the data that audits are quite diverse in how they are deployed (different topics, low/higher frequency, standards used, reporting). - The data are perceptions of effectiveness, this could be mentioned as a limitation as the study does not provide evidence of the actual effectiveness (how applying audits and feedback might affect health outcomes). - I miss the Cochrane review on audit and feedback of Ivers, Jamtvedt et al. in the list of references.

VERSION 1 – AUTHOR RESPONSE

Reviewer 1
N.B. the line numbers refer to the numbers directly on the left side of the text, not the numbers on the left side of the page.

1. This is an interesting topic but needs attention to provide a wider context for readers outside Netherlands. For example there is research to discuss different approaches for corporate (organisational processes, finance, contracts etc.) and clinical (treatment, medical equipment etc.) audits. I suspect that there are many clinical audits taking place which influence decision-making relevant to patient safety - were these included?
Response: We would like to start by thanking you for your valuable feedback on our manuscript. We understand that it is important to provide a wider context for international readers, as this is a huge issue throughout our entire research; the fact that internal audits are a very specific type of audit and are not performed in every country. Clinical audits and corporate audits are indeed also performed in the Netherlands. However, they are not the focus of our research. Clinical audits are professional driven, mainly focussed on professional performance and are thoroughly evaluated (Ivers et al. 2012); corporate audits are mainly focussed on financial aspects of an organisation. Boards of Dutch hospitals initiated internal audits, besides clinical and corporate audits, to get a better overview of the level of patient safety at hospital and department level. Internal audits are 'audits organised at hospital level and directed at several levels of patient care, including policy, patient safety culture, guideline adherence of professionals, and outcomes at the patient level (Hanskamp-Sebregts et al. 2013)'. We added the following sentences:
Page 6, line 22:
Our study focussed on internal audits; 'audits organised at hospital level and directed at several levels of patient care, including policy, patient safety culture, guideline adherence of professionals, and outcomes at the patient level [16]', looking at every department of a hospital, initiated by the board of directors and implemented top-down. We did not focus on corporate audits (mainly focussed on financial aspects) or clinical audits (initiated by health care professionals and implemented bottom-up).

2. The paper will benefits from taking a critical stance to the role of quality management for safety issues. I suggest considering whether the quality system of the hospital (performance and preconditions) is the appropriate paradigm to give a true reflection about safety. There have been recent papers discussing the limitations of following a quality paradigm rather than a safety science paradigm to address patient safety.
Response: We agree that performance and preconditions alone might not be enough to secure patient safety. When internal audits were implemented in the 1990s, the focus was on the performance of quality systems and even though internal audits were performed, incidents still occurred. Following this, internal audits were optimized to account for more than just these preconditions. We added the following sentences to the discussion section:
Page 13, line 41:
Research regarding patient safety is focusing more and more on whether quality management systems (preconditions and performance) are able to give true insight into patient safety [40]. In this light, we feel it is important to keep developing internal audits to include cooperation, culture and communication so that this instrument is not just a tick box activity that looks at preconditions only.

3. It was unclear whether the questionnaire and interview were both focussed on the same research questions (how was audit carried out and was it effective), or whether the issues from the questionnaire results were then used to inform the interview schedule?
Response: The research question regarding the organisation of the internal audit (how the internal audit was carried out) was studied with both the questionnaire and the interviews. Issues from the questionnaire were indeed used as input for the interviews in order to gain in-depth information on this

subject. The research question regarding the effectiveness of the internal audit was studied with interviews only. We added the following sentences to the methods section to make this more clear.
Page 7, line 2:
The research question regarding the organization of the internal audit was studied with both the questionnaire and the interviews. Issues from the questionnaire were used as input for the interviews in order to gain in-depth information on this subject. The research question regarding the effectiveness of the internal audit was studied with interviews only.
Page 7, line 23:
…results from the questionnaire (regarding the organization and content of internal audit only) and…

4. Was the questionnaire distributed as online survey or as attachment to email? For the pilot, did you also check if the target participants would be able to complete it rather than just piloting with experts?
Response: The questionnaire was an online survey. For the pilot, the 'experts on auditing' were in fact the target participants. We adjusted this in the method section:
Page 7, line 7:
An invitation to participate in
Page 7, line 8:
the link to the online survey
Page 7, line 14:
target participants

5. Suggest that Table 2 is embedded in the text rather than in tabular format.
Response: Thank you for your suggestion. We feel that table 2 gives a structured overview of themes and categories, however, we would like to leave this decision with the editor.

Reviewer 2
N.B. the line numbers refer to the numbers directly on the left side of the text, not the numbers on the left side of the page.

1. Regarding the concept and scope of internal audits, it seems that the authors want to focus on audits as an instrument to assure patient safety (page 4, line 48: ….'research regarding the effectiveness of internal audits for boards to govern patient safety is lacking'). However, why they limit to patient safety is not clear, and even not logical, as the data refer to the use of internal audits in complying to standards like for example NIAZ-accreditation, which have a broader scope of quality improvement.
Response: First of all, thank you so much for your valuable feedback on our manuscript. Indeed, internal audits have a broader scope than patient safety alone. Information coming from audits is used for various purposes: 1) for continuous quality improvement; 2) to control, adjust and secure quality improvement processes; and 3) to account for the quality and safety of provided care (Gerritsen et al. 2000). Our research focuses on patient safety, as safety of care is one of the domains of quality of care alongside effectiveness, timeliness, efficiency, patient-centeredness, and equal distribution of care. Safety of care, no patient harm, is by far the most important domain of quality of care (Institute of Medicine (US) Committee on Quality of Health Care in America 2000). The shift from critical incidents as a private mishap to public disasters have led to the need for board safety oversight (Behr et al. 2015). However, little is known about the use of internal audits for patient safety governance. As internal audits are already used in every Dutch hospital, we wanted to know whether they could be used for this purpose as well. We added the following sentences.
Page 6, line 26:
Internal audits have a broader scope than patient safety alone. Information coming from audits is used for various purposes: 1) for continuous quality improvement; 2) to control, adjust and secure

quality improvement processes; and 3) to account for the quality and safety of provided care [26]. Our research focuses on patient safety. Safety of care, no patient harm, is one of the most important domain of quality of care [27]. Hospital boards in the Netherlands are legally responsible for safe healthcare and over the past few years, (critical) incidents have become 'public events' for which boards are held accountable [8]. This led to the necessity for board safety oversight and, sub sequentially, the focus of our research.

2. The descriptive data shows that the audits have a rather different focus (page 8, line 55): departments, healthcare processes/pathways, patient safety themes. This could have influenced the perceived effectiveness as some audit initiatives have a more top down approach without real involvement of clinicians, while other initiatives such as clinical audits might have a more bottom-up approach with much involvement of clinicians.
Response: We have looked at the same type of audit, i.e. internal audits; all with a top-down approach and initiated by the boards of directors. Internal audits focussed on hospital departments and in some cases also on healthcare pathways and patient safety themes. We changed the text to make it more clear.
Page 9, line 25:
Internal audits focussed on hospital departments and in some cases also on healthcare pathways and/or patient safety themes.

3. Audits assess compliance to standards. It's clear for the reader that this refers to standards of accreditation institutes, but what kind of standards are provided by law, by the hospital itself and by the profession (page 9, line 35) is not completely clear. I suggest to give a few examples.
Response: Thank you for your suggestion. We added some examples.
Page 10, line 26:
Hospitals used standards of accreditation institutes (97%), standards set by law (e.g., national safety themes, including adherence to sepsis bundles, protocols for medication reconciliation at hospital admission and hospital discharge) (66%), the hospital itself (e.g., Team Climate Inventory to measure the improvement climate of teams of healthcare providers) (32%), and the profession (e.g., guidelines from medical associations) (27%) for auditing.

4. The authors indicate that they have used an inductive approach in coding and category-building (page 7, line 32). The categories are presented in table 2 in three themes (use of audits for risk identification, for steering patient safety and for accounting for patient safety). Was this interesting distinction also inductively derived from the data, or was it taken as a starting point?
Response: We used thematic analysis. Two researchers (SvG and MZ) independently analysed and discussed the content of the first (n = 3) interviews, which formed the basis of a coding framework. One researcher (SvG) analysed the rest of the interviews by applying the coding framework and modifying it through an inductive and iterative process. All three themes were derived from the data (see method section, page 7, line 39).

5. I suggest to leave out the word 'great' in 'great similarities' in the discussion page 13, line 7, as I experience from the data that audits are quite diverse in how they are deployed (different topics, low/higher frequency, standards used, reporting).
Response: Thank you for your suggestion. We adjusted this.

6. The data are perceptions of effectiveness, this could be mentioned as a limitation as the study does not provide evidence of the actual effectiveness (how applying audits and feedback might affect health outcomes).
Response: Indeed, we added a sentence to the limitations section.
Page 15, line 23:
Finally, effectiveness in this study has not been established in terms of 'hard numbers' like changes in

healthcare outcomes. In this study, we were interested in perceptions of effectiveness to govern patient safety by hospital boards (qualitative research is preferred to explore experiences in-depth [30]).

7. I miss the Cochrane review on audit and feedback of Ivers, Jamtvedt et al. in the list of references.
Response: Thank you for pointing out that we missed this important reference. We refer to this reference in the introduction section and added the following sentences:
Page 4, line 19:
Several studies regarding the effectiveness of clinical audits on professional practice have been performed [17]. The found effects are small and differ per study. This can be partially explained by the differences in study population, form and content of studied audits and used research methods and outcomes [18]. Knowledge regarding the effectiveness of internal audits for internal patient safety governance by hospital boards is, however, scarce and therefore subject of this study.

Reviewer 3
N.B. the line numbers refer to the numbers directly on the left side of the text, not the numbers on the left side of the page.

1. However, the fact that it is a descriptive study is its main weakness. The article would be much stronger and more useful if the authors showed evidence of factors that are associated with improved patient safety. For example, the authors could identify some specific improvement efforts developed as a result of internal audits and show how these efforts were effective. Or, the authors could identify some standard patient outcomes and explore whether different attributes (composition, size, training of audit teams; standards used; frequency of audits) are associated with them.
Response: Thank you for taking the time to provide valuable feedback on our manuscript. Indeed, effectiveness in this study has not been established in terms of 'hard numbers' like changes in healthcare outcomes. We were interested in the perceived effectiveness of internal audits to govern patient safety and we believe that qualitative methods are preferred to explore experiences of board of directors in depth. Internal audits are an instrument initiated by hospital boards and the information is used for various purposes 1) for continuous quality improvement; 2) to control, adjust and secure quality improvement processes; and 3) to account for the quality and safety of provided care (Gerritsen et al. 2000; Hanskamp-Sebregts et al. 2013). However; it is unknown what the added value for hospital boards actually is. That is why our study focuses on the question whether internal audits are regarded as effective by hospital boards to govern patient safety. We added the following sentences in the discussion section:
Page 15, line 23:
Finally, effectiveness in this study has not been established in terms of 'hard numbers' like changes in healthcare outcomes. In this study, we were interested in perceptions of effectiveness to govern patient safety by hospital boards (qualitative research is preferred to explore experiences in-depth [30]).

2. In the current, descriptive approach the tables could be improved. Table 1 could have columns for each of the six hospitals showing the number of interviews by function title and work experience. Appendix 5 should be Table 2 and would benefit from having columns for University Hospital, Tertiary medical teaching hospital, and General hospital.
Response: Thank you for your suggestion. We think that Table 1 will not benefit from more detail information. However, we would like to leave this decision with the editor. Regarding appendix 5, we feel that our manuscript benefits from a more narrative approach instead of presenting the table. That is why we choose to include this table as an appendix.

VERSION 2 – REVIEW

REVIEWER	Sue Hignett Loughborough University, UK
REVIEW RETURNED	20-Feb-2017

GENERAL COMMENTS	I am satisfied that the authors have addressed my comments

REVIEWER	Kees Ahaus University of Groningen Faculty of Economics and Business Department of Operations The Netherlands
REVIEW RETURNED	13-Mar-2017

GENERAL COMMENTS	I would like to commend the authors with this revised version of an interesting and well-written paper. All the issues of my previous review were successfully addressed. I have a few very minor comments after reading this version of the paper: • The authors discuss the role of the board of supervisors, which was subject of the studies of Daan Botje as well. I have noticed that he speaks of board of trustees, while referring to this board. I wonder what is the best English word for this board in a typical two-tiered governance model. • Page 10, line 1, please remove 'a' before 'self-evaluation forms ….'. • Page 12, the third quotation could have been grouped in the soft signals category as well. Maybe the authors can reconsider this, and move the quotation to the other category, but they can also decide to keep it as it is. • Page 21, this should be figure 1 instead of 2.

VERSION 2 – AUTHOR RESPONSE

First of all, thank you so much for your positive feedback and helping us to improve our paper!

1. The authors discuss the role of the board of supervisors, which was subject of the studies of Daan Botje as well. I have noticed that he speaks of board of trustees, while referring to this board. I wonder what is the best English word for this board in a typical two-tiered governance model.
Thank you for your reflections on this matter. As a research group, we had some discussions regarding this subject as well. Even though we found that the terms 'board of trustees' and 'board of supervisors' are both used in a two-tier governance model, we choose to use the latter. This choice was based on Eeckloo, Delesie and Vleugels (2007), who use the terms 'trustees' and 'management' in general, but 'board of directors' and 'board of supervisors' specifically for the Dutch two-tier governance model.

2. Page 10, line 1, please remove 'a' before 'self-evaluation forms ….'.
Thank you for pointing this out. We removed this word.

3. Page 12, the third quotation could have been grouped in the soft signals category as well. Maybe the authors can reconsider this, and move the quotation to the other category, but they can also decide to keep it as it is.

Thank you so much for your suggestion. We agree that this quotation has some elements of the soft signals category, but we think that it is best grouped as it is now, and we decided to keep it as it is.

4. Page 21, this should be figure 1 instead of 2
Thank you for pointing this out. We adjusted this.