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Evaluation of the organization and effectiveness of internal audits to govern patient safety in hospitals: A mixed-method study

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ABSTRACT

Objectives

Hospital boards are legally responsible for safe healthcare. They need tools to assist them in their task of governing patient safety. Almost every Dutch hospital performs internal audits, but the effectiveness of these audits for hospital governance has never been evaluated. The aim of this study is to evaluate the organization of internal audits and their effectiveness for hospitals boards to govern patient safety.

Design and setting

A mixed-methods study consisting of a questionnaire regarding the organization of internal audits amongst all Dutch hospitals (n = 89) and interviews with stakeholders regarding the audit process and experienced effectiveness of audits within six hospitals.

Results

Response rate of the questionnaire was 76% and 43 interviews were held. In every responding hospital, the internal audits followed the plan-do-check-act cycle. Every hospital used interviews, document analysis and site visits as input for the internal audit. Boards stated that effective aspects of internal audits were their multidisciplinary scope, their structured and in-depth approach, the usability to monitor improvement activities and to change hospital policy, and the fact that results were used in meetings with staff and boards of supervisors. The qualitative methods (interviews and site visits) used in internal audits enables the identification of soft signals such as unsafe culture or communication and collaboration problems. Reported disadvantages were the low frequency of internal audits and the absence of soft signals in the actual audit reports.

Conclusion

This study shows that internal audits are regarded as effective for patient safety governance, as they help boards to identify patient safety problems, proactively steer patient safety and inform boards of supervisors on the status of patient safety. The description of the Dutch internal audits makes these audits replicable to other healthcare organizations in different settings, enabling hospital boards to complement their systems to govern patient safety.

ARTICLE SUMMARY

Strengths and limitations of this study

- This is the first study that evaluates the organization and the effectiveness of internal audits to govern patient safety in hospitals.
- We performed a mixed-methods study consisting of a questionnaire sent to all Dutch hospitals and interviews with stakeholders in the governance and audit process of six Dutch hospitals.
- The use of qualitative data collection enabled us to gain insight into the experiences of boards with internal audits.
- As we studied internal audits in Dutch hospitals, generalization to other countries or healthcare settings might be limited.

INTRODUCTION

Patient safety should be the top priority of every hospital board [1–3]. Hospital boards are legally accountable for the quality and safety of the delivered care in their hospitals [4,5]. However, while the need for board [4,5]safety oversight has been growing [6,7], healthcare is still often unsafe and boards experience difficulties in overseeing safety risks [8–11]. In order to fulfil their governance role, hospitals boards need methods and tools that provide monitoring information to mitigate or prevent adverse events [12–14].

There are several sources for gathering information that helps boards with the governance of patient safety, and information from internal audits might be one of them. The internal audit is an 'objective assurance and consulting system for detecting patients' risks of adverse events early', which 'should encourage the continuous improvement of patient safety' [15]. It is a systematic evaluation of the quality system of a hospital which aims to improve patient safety by measuring performance of healthcare providers and preconditions for safe care, and comparing these outcomes to (national) standards and guidelines. The measurements are performed by an audit team existing of internal peers (i.e., employees of a hospital who audit colleagues of other departments). The method was implemented in the 1990s to measure whether organizational preconditions for safe care are in place and to induce improvements when safety problems are detected. Internal audits are initiated by hospital boards and implemented top-down.

The reason that almost all Dutch hospitals use internal audits for governance purposes is a combination of the 1996 Care Institutions Quality Act and the constitution of the Netherlands Institute for Accreditation in Healthcare (NIAZ). Hospitals are obliged by the Care Institutions Quality Act to have a quality management system in place, including the assurance that quality activities are undertaken [16]. Since the 1990s, many hospitals are using the quality assurance standards of NIAZ [16]. In order to be accredited by this institute and to give the assurance of safe care to third parties (e.g., healthcare consumers and healthcare insurers), an internal audit system should be in place [17,18]. External accreditation parties such as NIAZ have their own audits (i.e., external audits that they perform to see whether a hospital is ready for external accreditation). This study does not focus on these external audits, but on the *internal* audits that are performed by employees from a hospital itself.

Our study focuses on governance within a hospital from a board of directors' point of view: the need to oversee and to steer patient safety (deriving information from the work floor) and the need to account for patient safety (sending information towards the board of supervisors). We are interested in whether the internal audit assists the board of directors of hospitals in this task. Figure 1 shows examples of tools to govern patient safety, the stakeholders in Dutch hospital governance and the position of internal audits in it (see figure 1).

Almost every hospital in the Netherlands uses internal audits. However, research regarding the effectiveness of internal audits for boards to govern patient safety is lacking. As internal audits are widely used in hospitals, we wondered whether and how the information coming from internal audits is effective for the governance of patient safety (i.e., has a place in hospital governance). Our study has two aims. First, to describe the internal audits in Dutch hospitals, so that, if regarded as being effective, this audit system is replicable to other countries or different healthcare organizations. Second, to describe the views of hospital boards regarding the effectiveness of internal audits to assist them in their task of governing patient safety. We aimed to answer the following questions:

1. How are internal audits organized in Dutch hospitals?

2. Are internal audits regarded as effective for the governance of patient safety by hospital boards?

METHODS

Study design and setting

We performed a mixed methods study on the organization of and experiences with the effectiveness of internal audits in the Netherlands, consisting of a questionnaire survey and individual interviews.

The questionnaire was sent to all Dutch hospitals (n = 89) and interviews took place in six hospitals, which were selected amongst the 89 hospitals. Selection was based on various criteria (see appendix 1). The six hospitals represented both the different types of hospitals in the Netherlands and the different aspects of internal audits. The participating hospitals were located across the country and ranged in size from 536 beds up to 1003 beds. All six hospitals were accredited or were in the process of being accredited, for example, by the Netherlands Institute for Accreditation in Healthcare (NIAZ) or the Joint Commission International (JCI).

By 'hospital boards', we mean a board of directors. Hospital boards across all participating hospitals (questionnaire and interviews) were structured according to the Care-wide Governance Code [19]. In the Netherlands, a board of directors and a board of supervisors represent two independent bodies; a board of directors is responsible for patient safety governance and a board of supervisors supervises a board of directors. A board of directors is accountable for the quality and safety of care to a board of supervisors and external parties such as the Dutch Healthcare Inspectorate (which promotes public health and is a part of government oversight of public health) [20]. The pressure to have a patient safety governance structure in place comes from the Ministry of Health (see figure 1) [21,22].

Participants

The questionnaire was sent to the chairmen of the boards of directors of every Dutch hospital (n = 89), with the option to forward the questionnaire to a person responsible for internal audits at operational level.

The targeted number of interview partners was six members of boards of directors, six members of the boards of supervisors, six quality and safety directors, 12 quality officers (including auditors) and 12 heads of departments or clinical managers (auditees). Participants for the interviews were selected based on purposive sampling to ensure diversity (e.g., experience with audits, auditing, and type of job) and convenience sampling (for availability purposes) [23].

Data collection

Questionnaire

The questionnaire to study the organization and content of internal audits was sent in 2012 by email. The email included the purpose of the study and a statement that anonymous and confidential handling of data was ensured. Informed consent was implied by completing and sending in the questionnaire. A reminder was sent after two weeks. The questionnaire consisted of multiple-choice questions; six general questions and eight questions regarding content and organization of the audit (see appendix 2). The questionnaire was developed based on meetings with experts on auditing (n = 3) and brainstorming sessions (n = 4) with the research team. The questionnaire was pilot-tested by experts on auditing (n = 3) and adapted accordingly.

Interviews

Interviews took place between May of 2012 and November of 2014. All interviews were audio-recorded with the participants' consent and transcribed verbatim according to a standardized format. Data

collection and analyses of interviews were performed according to the 'Consolidated criteria for reporting qualitative studies' (COREQ) [24] (appendix 3) and based on thematic analysis. Interviews were in-depth, face-to-face interviews. All interviews were conducted by experienced interviewers (SvG and GH) and were guided by a topic guide. The topic guide was developed based on brainstorming sessions with the research team and was adapted after each interview. Topics for guiding the interviews included the following themes (see appendix 4):

- Organization and content of internal audit.
- Effectiveness of internal audit information for boards:
    - Use of internal audit for identification of safety risks
    - Use of audit information to steer patient safety
    - Use of internal audit to account for patient safety towards the board of supervisors.

Questions regarding the content and organization of the internal audits were addressed to all interviewees. Questions regarding the regarded effectiveness of internal audits for hospital boards to govern patient safety were addressed to the boards of directors, boards of supervisors, quality and safety directors, and heads of department or clinical managers.

Data analysis

The questionnaire data were analysed using IBM SPSS Statistics version 20. Transcripts of the interviews were coded using Atlas.ti software version 7.0 (ATLAS.ti Scientific Software Development Company, GmbH, Berlin, Germany). The transcriptions of the interviews were analysed using thematic analysis [25]. 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. Codes that related to the same phenomenon were grouped into categories and, finally, themes were identified. Differences were resolved by consensus.

RESULTS

Response and characteristics of respondents

Of the 89 questionnaires sent, 69 were returned (76%). In one hospital, no internal audits were carried out. One questionnaire was filled in by a chairman of the board of directors. The other questionnaires were filled in by employees related to the quality departments. The response rate varied per type of hospital: 88% for university hospitals (n = 7/8), 82% for tertiary teaching hospitals (n = 23/28) and 70% for general hospitals (n = 38/54).

In total, 43 interviews within six hospitals were performed. In two cases the requests for interviews were not granted because of time constraints. Five members of boards of directors were interviewed, as were five members of boards of supervisors, seven quality and safety directors, 14 quality officers (including auditors) and 12 medical specialists or clinical managers (auditees) (see table 1).

Table 1 Interview participants and their characteristics (n = 43)

	n	%
Hospital type		
University hospital	16	37
Tertiary medical teaching hospital	15	35
General hospital	12	28
Function title		
Member of the board of directors	5	12
Member of the board of supervisors	5	12
Quality and safety directors	7	16
Quality officers	14	32
Head of department or clinical manager (auditees)	12	28
Gender		
Female	24	56
Male	19	44
Work experience in current function (years)		
1-5	26	60
6-10	12	28
11-15	5	12

Description of the organization of internal audits in Dutch hospitals

Internal audit cycle and responsibilities of stakeholders

In all six hospitals the internal audits were performed according to the plan-do-check-act cycle. Figure 2 shows the cycle of the internal audits. In all studied hospitals (n = 6), the boards of directors initiated the internal audits and delegated the execution to committees or departments. These departments or committees were responsible for the entire organization of the internal audit cycles, including the appointment of the audit teams. The audit teams performed the internal audits and were recruited amongst employees from the organizations. In some hospitals these auditors were volunteers, while in other hospitals being an auditor was (part of) an employee's job and they were paid for it.

Internal audits investigated individual departments, healthcare processes/pathways or patient safety themes. An audit team prepared the audit, which included the analysis of policy documents, medical record reviews, and a self-evaluation forms filled in by the departments. Preparations also

involved, for example, looking at outcomes of earlier performed audits (see table in appendix 5). In audit team meetings, the outcomes of the preparations were discussed and the focus of the audit (e.g., which specific safety risks would receive extra attention and which topics were included in the audit) were determined. Audit topics ranged from the existence of soap dispensers to interrelation topics such as department culture, communication and cooperation. During an audit day, the audit team visited the departments, or involved departments in cases of auditing healthcare processes/pathways or patient safety themes. Subsequently, the audit team wrote a report in which the impressions of the departments were reflected. With this report, the audit teams provided feedback regarding improvements that must or could be made to increase patient safety (recommendations). Audit results were fed back to the boards of directors for governance purposes, and fed back to the audited departments. Department heads were obligated to make improvement plans. Follow-up of the audit results and recommendations was the responsibility of department heads and was monitored by the boards of directors, or delegated to committees. This audit cycle was repeated periodically.

Organization and content of internal audit

Internal audits were performed once every four years in 66% of the hospitals, once every three years in 13% of the hospitals, once every two years in 10% of the hospitals and once every year in 9% of the hospitals (see appendix 5). The time frame of an internal audit ranged from one month (9%) to seven months (2%), with a time frame of 2 months being most common (27%). Members of the audit teams were nurses (present in audit teams in 96% of the hospitals), management employees (present in audit teams in 84% of the hospitals), allied healthcare professionals (present in audit teams in 75% of the hospitals) and medical specialists (present in audit teams in 68% of the hospitals). One hospital (1%) had 5-10 auditors in total, while 65% of the hospitals had more than 20 auditors in total. In 81% of the hospitals auditors received training, and in 74% of the hospitals auditors were evaluated. Of the 68 hospitals, six did not train nor evaluate their auditors (9%). Hospitals used standards of accreditation institutes (97%), standards set by law (66%), the hospital itself (32%) and the profession (27%) for auditing. As inputs for the internal audit outcomes, the following were used: document analysis by audit team (100% of the hospitals), interviews by audit team (100% of the hospitals), site-visits by audit team (100% of hospitals), self-evaluation by audited department (59% of the hospitals), ad-hoc measures by audit team (34%) and other measures (37%). These other measures were:

- Outcomes of other audits when present, such as audits by external experts, external audits for accreditation and audits initiated by the professional association of medical specialties (visitations);
- Outcomes of surveys amongst employees of partner departments (such as a surveys amongst an orthopaedic department when a radiology department is being audited);
- Outcomes of medical record reviews.

Feedback of audit results

The ways in which audit results were fed back to the boards of directors differed per hospital. Three options have been found:

1. The board of directors receives a report on the headlines deriving from internal audits (aggregated results; found in 50% of the hospitals).

2. The board of directors receives letter with recommendations based on audit results and has the option to ask audited department for the entire audit report (found in 17% of the hospitals).
3. The board of directors receives entire audit report (found in 50% of the hospitals).

In one hospital, multiple options have been found. In that hospital, the board received a report on the headlines deriving from all internal audits and the entire report of the executed audits on supportive departments.

In interviews, members of the boards of directors of all hospitals stated that it is the responsibility of the departments to implement improvement actions, except in the following situations: 1) when patient safety is immediately threatened—in this case, a board of directors uses the internal audit as a 'forced improvement'-instrument; and 2) when improvements cannot be made without support from a board of directors, for example when equipment is out-of-date and cannot be replaced without consent of a board of directors.

Experiences with effectiveness of internal audits

Use of internal audits for identification of safety problems

Board members perceived internal audits as effective for the identification of safety problems for three reasons: 1) broad, multidisciplinary scope; 2) soft signals; and 3) in-depth approach (see table 2 for illustrative quotes).

Interviewees stressed that with internal audits every department of a hospital, including supportive departments, is evaluated periodically. Furthermore, an internal audit has a multidisciplinary focus (e.g., involving the opinions of other departments regarding the audited department and not only focusing on clinicians or nurses, but all employees both in an audit team and as auditees). Board members noted that this broad scope of an internal audit provided a complete overview of the performance of all departments in an entire organization.

According to board members, the use of qualitative methods of gathering information (e.g., interviews and observations) makes an internal audit a suitable instrument not just to establish that things are going wrong, but most of all reveal why these things happen. Board members stated that as a result, an internal audit was able to provide information regarding the soft side of an organization, such as cooperation and communication problems. Nonetheless, they noted these soft signals are not easily translated into facts that can be reported in an audit report.

Board members indicated that an internal audit is an instrument with a very structured and in-depth approach. The quality and safety of an entire department is being evaluated, from cleaning to medical treatment and from medical chart reviews and policy documents to interviews with employees, after thorough preparations of both an audit team and an audited department. Board members stated that this reveals patient safety problems in a structured way, and because of the fact that improvement actions are suggested, audits help boards prioritize what should be done to improve patient safety. Board members indicated that an internal audit is especially suited for generating patient safety information in a planned and prepared manner, but mentioned that because of the low frequency of internal audits (because of the time-consuming, in-depth approach) there is a lack of real-time information.

Use of audit information to steer quality and safety

Two categories emerged within this theme: 1) monitoring; and 2) incentive for change.

Board members mentioned that embedding internal audit results in a planning and control cycle gives them the opportunity to have a dialogue regarding the status of quality improvements made by departments. They noted that monitoring and frequently discussing audit results and improvement plans contributes to the feeling of being in control. A caveat mentioned by one board member regarding being in control with the internal audit is that, as with every instrument, critical incidents can still happen.

Board members mentioned that audit results can be an incentive for them to adjust hospital policy and culture. Different interviewees stated that internal audit results were a reason for them to make changes happen as soon as possible, whether these were adjustments needed to be made by the board itself, or by departments. Boards used internal audits to start a conversation with staff and as an incentive to visit departments themselves.

Table 2. Themes, categories and quotes relating to effectiveness of internal audit

Theme	Category	Quotes
Use of the internal audit for identification of safety risks	Broad, multidisciplinary scope	*"Well, an internal audit is department-wide and multidisciplinary, you talk with professionals of that department, but also with its customers. Like, if there's an audit at radiology, you talk to specialists of other departments that use the services of radiology as well. With tracers, you don't have that complete overview."* *"And the internal audit contributes to an overall view of a department, of a group of people who are active within a certain discipline: clinicians, nurses, allied healthcare professionals… and yes, you get insight into the department on an aggregated level."*
	Soft signals	*"[With the internal audit] you can get a global impression regarding the actual performance, so to say, and cooperation as well (…). The question could be: 'how is everything going,' and they would say: 'perfect, we are doing the best we can'. Well, show me!"* *"Well, I think that the soft signals… Partially they derive from the internal audit (…) but it is just very complicated, you know. I think an internal audit should begin with the question: 'Why do you like working here?' That is not something you can write down in three sentences in the audit report. It is as soft as you can get, but it is very significant for how people are feeling in their job."*
	In-depth approach	*"So it shows where the need for improvements lie and what you should prioritize… It prioritizes in the way, like, what is going right and what is going wrong?"* *"Especially when auditors don't just score, but ask questions, you get more information, like 'why is it going wrong?'"* *"Maybe it's even more important to be open and susceptible to signals from within the organization. We talk to chairmen of staff and divisions very often. You cannot wait for the internal audit to take place in a few years to feel safe regarding the functioning of a department."*
Use of audit information to steer patient safety.	Monitoring	*"And in our quarterly report, in our four-times-a-year cycle, we ask every unit to report on the audits that have been performed; what were the results, what did you encounter and which actions did you think of, and these actions, are they implemented and are they leading towards results (…)."*

		"For us, as board of directors, it's about knowing what the conclusion regarding the department is, in the context of general functioning, leadership and yes, quality and safety. And that is one of the sources we need to, so to say, feel secure in how the organization is doing."
	Incentive for change	*"Something in which we intervened immediately was the double check on medication. That was a moment in which we said: this is unacceptable. These answers are unacceptable. So I went there, and the medical directors as well, and we said, this is out of the question. This has to change by tomorrow."* *"We've also looked at what is the reason that that happens; don't we need to alter the procedure? So it is about steering, saying: 'this is unacceptable', but it is also a moment of thinking: 'did we organize it correctly?'"*
Use of audit information to account for patient safety	Use of internal audit information in regular meetings with the board of supervisors	*"Yes, to inform. By the way, our board of supervisors is very on top of it, they will ask: what did you do about it? So you need to have that answer as well."*
	Use of audit information to inform the board of supervisors regarding critical incidents	*"And if we say: 'This is critical, these people have to be informed before the report is finished', then I will call them and they will come over."* *"It's not good for internal monitoring because that will cause a mix-up between the responsibilities of the board of directors and the board of supervisors. Negative results of an audit should be solved in the management line of the hospital. Having said that, the existence of an internal audit system, that they are performed accurately, that there are reports on the results and the system as a whole, helps us to trust the board of directors."*

Use of internal audits to account for patient safety

Two categories derived from this theme: 1) use of internal audit information in regular meetings with boards of supervisors; and 2) use of audit information to inform boards of supervisors regarding critical incidents.

Board members stated that an internal audit is one of the information sources used to inform a board of supervisors about the status of patient safety. It is used on a regular base, as part of the regular meetings between boards of directors and boards of supervisors, on an aggregated level. Interviewees stressed the latter: an internal audit is not discussed in detail, as it is not the job of a board of supervisors to monitor departments in detail. Members of boards of directors stated that instead, they use the headlines of the performed audits to show boards of supervisors whether a hospital is able to learn and improve.

There is an exception when discussing an internal audit on an aggregated level. Members of different boards mentioned that when critical incidents derived from internal audits, boards of supervisors are informed of these incidents.

DISCUSSION

The aim of this study was to describe the organization of internal audits in Dutch hospitals and to evaluate the effectiveness of these audits for boards to govern patient safety. Our quantitative and qualitative findings revealed that there were great similarities in how internal audits were organized in the hospitals. The audit cycle, following the plan-do-check-act cycle, the methods used to gather information (e.g., interviews, site visits, and document analysis) and the responsibilities of the boards of directors and the committees responsible for audits were in general the same in all hospitals throughout the Netherlands. Aspects that differed amongst hospitals were related to feasibility, and included the number of auditors and disciplines such as medical specialists present in an audit team, the duration of an internal audit and the amount of methods used to get insight into the quality and safety of departments.

Interviewed hospital board members stated that internal audits help them to identify safety problems and to steer patient safety. Internal audits provide a complete overview of departments, prioritize safety problems, are an incentive to adjust policy and are used to monitor safety improvements. A study regarding governance activities of Australian hospital boards showed four tools that are similar to the effective aspects of an internal audit, namely 'shaping culture', 'measuring progress', 'setting priorities' and 'ensuring accountability' [26]. The use of qualitative methods (e.g., interviews and observations) makes an internal audit unique compared to quantitative instruments (e.g., quality indicators) that boards have for governance. However, since internal audits are highly structured and standardized, their frequency is low which results in limited real-time information. Another disadvantage of an internal audit's formal character is that soft signals deriving from the qualitative methods are difficult to include in the audit report—even though board members mentioned that these outcomes especially say a lot about the quality and safety of care. These outcomes give insight into in problems regarding patient safety culture, communication and collaboration.

The attention to effective board oversight and tools to assist boards in this task is ever growing [2,6,11,26-28]. This study contributes to research in this field by evaluating an instrument that is already used in almost every hospital in the Netherlands. Internal audits in Dutch hospitals has existed since the 1990s and are initiated by hospital boards. However, to our knowledge, the Dutch internal auditing process has never been evaluated before and there is little-to-no literature on the evaluation of the effectiveness of internal audits for hospital governance [16,29,30]. Our study indicates that an internal audit might be a promising instrument for hospital boards. Internal audits provide a complete, multidisciplinary and periodic overview of quality and safety problems, their underlying causes and needed improvement actions. Research regarding dashboards or scorecards using measurements such as the Hospital Standardized Mortality Ratio (HSMR) or complications and lengths of stay, showed that a disadvantage of these measurements is that they do not always provide relevant information regarding the underlying problem(s) or causes related to how to *improve* quality and safety [11,31-34]. Indicators such as HSMR do not go further than revealing that there is a problem, while an internal audit is able to reveal why there is a problem because of the use of qualitative methods [35,36]. Our finding that the soft signals deriving from these qualitative methods are important to gaining insight into the underlying causes of quality and safety problems has been found in other studies regarding board oversight as well [31,37,38].

A strength of this study is that we used a mixed-method approach. The questionnaire enabled us to get a complete overview of the organization of internal audits in all Dutch hospitals and the qualitative measures provided us with in-depth information on the experiences of boards regarded to

the effectiveness of internal audits to govern patient safety. Another strength of this study is the high response rate to both the questionnaire and the interviews; there were only two interviewees who did not grant the request for an interview, resulting in a high internal validity of the results. Moreover, we interviewed every stakeholder in the audit process, including members of boards of directors and boards of supervisors, even though this a group that is not easy to involve (in research).

A limitation of our study is that we studied internal audits only in Dutch hospitals. Therefore, generalization to other countries or healthcare settings might be limited. We know that internal audits exist in hospitals in other countries, however, we have not found literature in which the use of internal audits in these countries has been described or evaluated [16,29] and therefore we could not make comparisons between Dutch internal audits and internal audits in other countries. Another limitation is the number of members of boards of directors that we interviewed for information on their experiences with internal audits. Most of the information on the regarded effectiveness of internal audits came from the interviews with members of boards of directors. Because of time constraints and the time-consuming qualitative methods we used, we could only perform an in-depth study in six hospitals. However, we have reached saturation and found substantial consistency in experiences of boards with internal audits. This led us to believe that their experiences are representative for other hospital boards. Moreover, we were able to use the interviews with quality and safety directors and heads of departments or clinical managers to validate the boards' experiences.

Conclusion

This is the first study in which the organization and the perceived effectiveness of internal audits to govern patient safety in hospitals is evaluated. Our findings showed that internal audits were regarded as effective for the governance of patient safety, as they help boards to identify patient safety problems, steer patient safety and account for patient safety. Internal audits provide boards with structured, standardized, formal and periodic overviews of quality and safety problems and underlying causes in all departments in a hospital, helping boards prioritize improvement actions and giving them a sense of being in control. Furthermore, the use of qualitative methods to identify soft signals makes an internal audit a unique instrument in the entire spectrum of governance strategies for boards. Hospital boards can use the description of Dutch internal audits given in this paper to complement their systems to govern patient safety.

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COMPETING INTERESTS

The authors declare that there are no competing interests. The funding bodies had no involvement in the design and conduct of the study, nor in the writing and submission of this manuscript.

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ETHICAL APPROVAL

The study protocol has been presented to the Medical Ethical Committee of the Radboud University Nijmegen Medical Centre (registration number: 2011/332). The committee declared ethical approval was not required under Dutch National Law.

AUTHORS' CONTRIBUTIONS

SvG carried out the research and drafted the manuscript. MZ conceived the study, contributed to the design and coordination of the study, drafted the manuscript and helped to carry out the research. HW contributed to the design and coordination of the study. HW, GW, PR and WB revised the manuscript critically. All authors read and approved the final manuscript.

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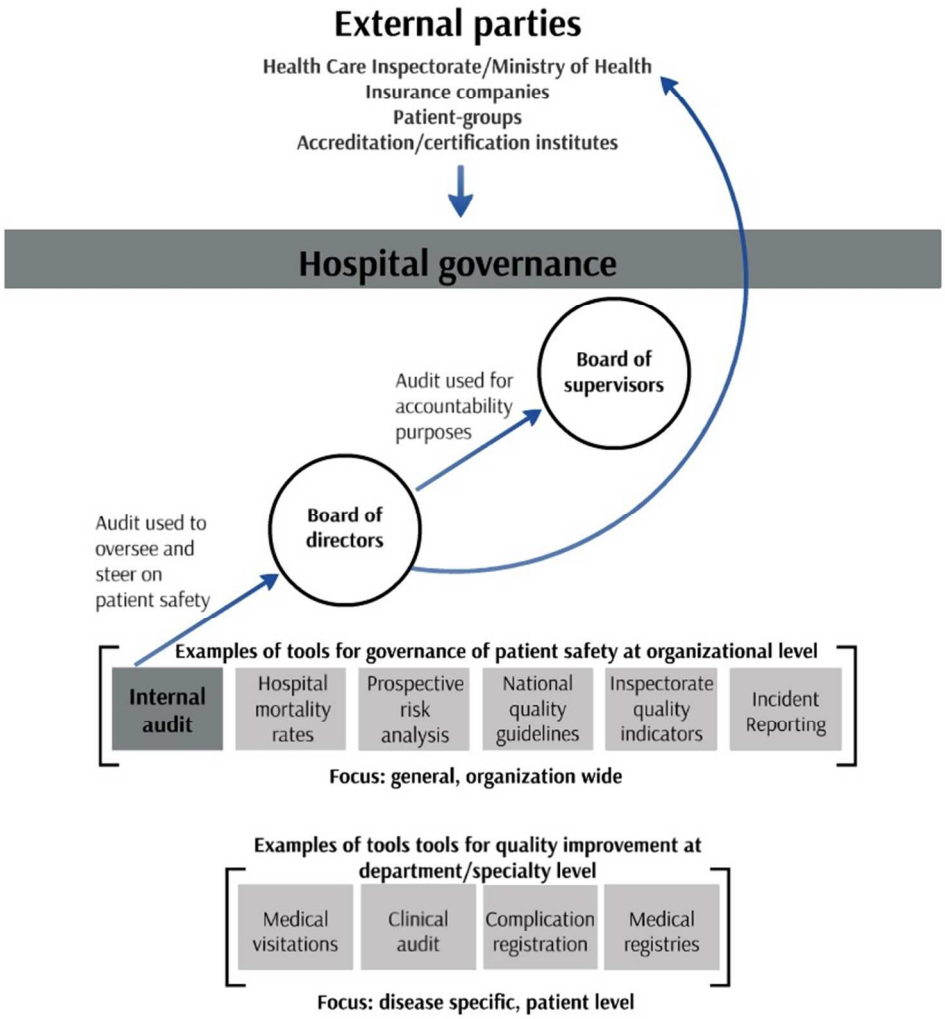

Figure 1. Positioning of internal audit in governance of Dutch hospitals. Framework is based on two studies: the 'Deepening our Understanding of Quality Improvement in Europe' (DUQuE) project [19] and the 'Quality and Safety in Europe by Research' (QUASER) study [20].

229x238mm (96 x 96 DPI)

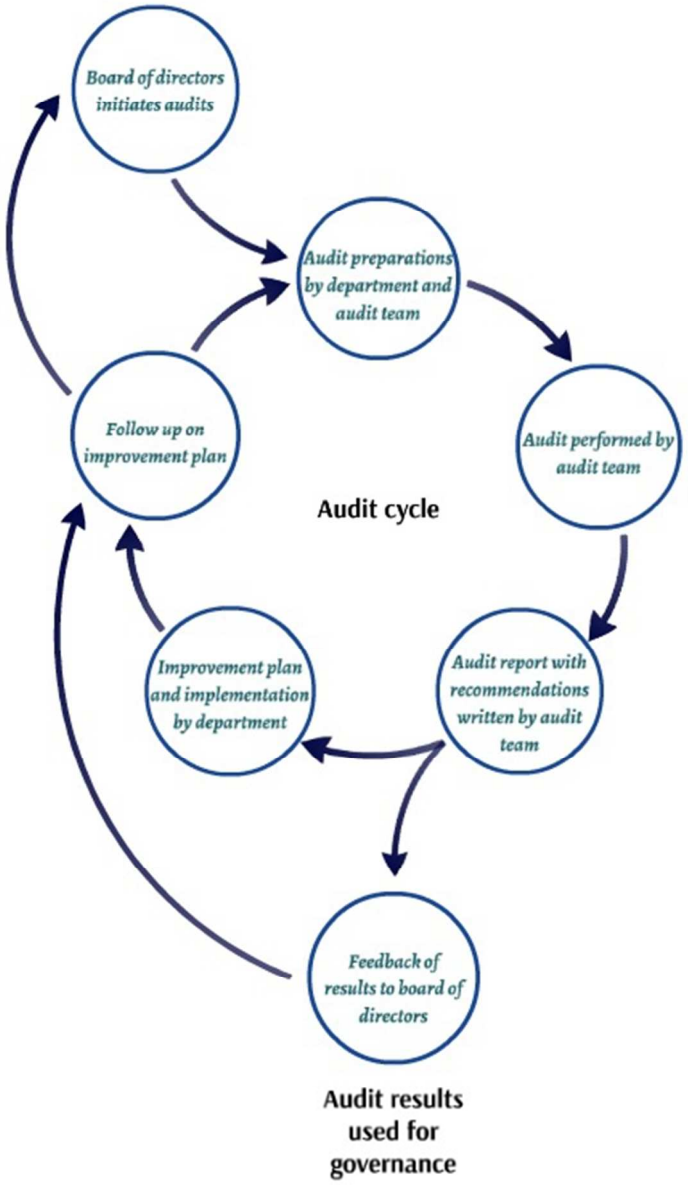

Figure 2. Internal audit cycle for governance purposes.

154x197mm (96 x 96 DPI)

APPENDICES

Appendix 1. Hospital sampling criteria for interviews

Selection criterion	Description
Variation in hospital type	University hospitals, tertiary teaching hospitals[1] and general hospitals .
Variation in standards and regulations for designing internal audit system	Different standards for the design of internal audit systems (e.g. NIAZ, JCI, VMS).
>5 years of experience with internal auditing	Only hospitals with more than five years' experience with internal audits were included, because this assured that one internal audit cycle would have been completed.
Variation in data sources used for internal audit	A distribution of hospitals with different sources of input for their internal audit; such as interviews, observations, surveys amongst employees and patients, and self-evaluation.
Medical specialist in audit team	A distribution of hospitals with, and without medical specialists in their audit team.
Hours spent per internal audit	Hospitals that spent less than 100, between 100-250 and more than 250 hours per audit.
Geographical spread/location	Two different provinces per type of hospital.

[1] Tertiary teaching hospitals in the Netherlands provide highly specialised care and train doctors in collaboration with university hospitals.

Appendix 2. Questionnaire 2012

Content

1. Which standards are used by your hospital for the internal audit (multiple responses possible)?
   - Standards of accreditation institutes
   - Standards set by law
   - Standards set by profession
   - Standards set by hospital itself
   - Other, namely:
2. What is used as input for the internal audit in your hospital (multiple responses possible)?
   - Outcomes of self-evaluation by department
   - Outcomes of document analysis by audit team
   - Outcomes of interviews by audit team
   - Outcomes of site-visits by audit team
   - Outcomes of ad hoc measures by audit team
   - Other, namely:

Organization

3. Who are the members of the audit team in your hospital (multiple responses possible)?
   - Medical specialists
   - Allied healthcare professionals
   - Nurses
   - Management
4. What is the total number of auditors in your hospital?
   - < 5
   - 5-10
   - 10-20
   - >20
5. Do auditors receive training and/or are they structurally evaluated (multiple responses possible)?
   - Training
   - Evaluation
   - No training, no evaluation
6. What is the time frame of one internal audit (from the first preparations to feedback of results to audited department)?
   …… months
7. What is the frequency of the internal audit?
   Once every … year(s)

Appendix 3. COREQ guidelines table

No. Item	Guide questions/description	
Domain 1: Research team and reflexivity		
Personal Characteristics		
1. Inter viewer/facilitator	Which author/s conducted the interview or focus group?	SvG and MZ
2. Credentials	What were the researcher's credentials? E.g. PhD, MD	1 MA, 1 PhD
3. Occupation	What was their occupation at the time of the study?	Research Fellows
4. Gender	Was the researcher male or female?	Both female
5. Experience and training	What experience or training did the researcher have?	Two researchers received training in interviewing. Both followed courses on qualitative research
Relationship with participants		
6. Relationship established	Was a relationship established prior to study commencement?	Yes, to one of them. However, we made sure to act the same as in all other interviews (sending the topic guide prior to the interview, introducing ourselves, no small talk during the interview) so that this did not affect the data.
7. Participant knowledge of the interviewer	What did the participants know about the researcher? e.g. personal goals, reasons for doing the research	Broad outlines given
8. Interviewer characteristics	What characteristics were reported about the inter viewer/facilitator? e.g. Bias, assumptions, reasons and interests in the research topic	Reasons for research
Domain 2: study design		
Theoretical framework		
9. Methodological orientation and Theory	What methodological orientation was stated to underpin the study? e.g. grounded theory, discourse analysis, ethnography, phenomenology, content analysis	Thematic analysis
Participant selection		
10. Sampling	How were participants selected? e.g. purposive, convenience, consecutive, snowball	Purposively sampled
11. Method of approach	How were participants approached? e.g. face-to-face, telephone, mail, email	Face-to-face, telephone and email
12. Sample size	How many participants were in the study?	43
13. Non-participation	How many people refused to participate or dropped out? Reasons?	Two not interviewed for lack of time
Setting		
14. Setting of data collection	Where was the data collected? e.g. home, clinic, workplace	Clinic and workplace
15. Presence of non-participants	Was anyone else present besides the participants and researchers?	No
16. Description of sample	What are the important characteristics of the sample? e.g. demographic data, date	Boards of Directors (n=5), Boards of

		Supervisors (n=5), Quality and safety directors (n=7), Quality officers (n=14), Head of department or clinical manager (auditees) (n=12). Of the interviewees, 56% was female, and 40% had six or more years of experience in their current function.
Data collection		
17. Interview guide	Were questions, prompts, guides provided by the authors? Was it pilot tested?	Interview guides were sent to interviewees prior to the interview. The topic guides were pilot tested.
18. Repeat interviews	Were repeat interviews carried out? If yes, how many?	No
19. Audio/visual recording	Did the research use audio or visual recording to collect the data?	Audiotaped
20. Field notes	Were field notes made during and/or after the interview or focus group?	Yes, after some interviews
21. Duration	What was the duration of the inter views or focus group?	30–60 minutes
22. Data saturation	Was data saturation discussed?	Yes and reached
23. Transcripts returned	Were transcripts returned to participants for comment and/or correction?	If desired; no adjustments were made by interviewees
Domain 3: analysis and findings		
Data analysis		
24. Number of data coders	How many data coders coded the data?	3
25. Description of the coding tree	Did authors provide a description of the coding tree?	Yes
26. Derivation of themes	Were themes identified in advance or derived from the data?	Identified in advanced and derived from the data
27. Software	What software, if applicable, was used to manage the data?	Atlas.ti software version 7.0
28. Participant checking	Did participants provide feedback on the findings?	No
Reporting		
29. Quotations presented	Were participant quotations presented to illustrate the themes/findings? Was each quotation identified? e.g. participant number	Yes, but not with a participant number
30. Data and findings consistent	Was there consistency between the data presented and the findings?	Yes
31. Clarity of major themes	Were major themes clearly presented in the findings?	Yes
32. Clarity of minor themes	Is there a description of diverse cases or discussion of minor themes?	Yes

Appendix 4. Topics for guiding interviews with stakeholders in the audit and governance process

1. How are internal audits set up in your hospital?
2. Is the focus of the audit determined beforehand?
3. Which framework do you use for the internal audit and why?
4. What methods do you use to gather information and why?
5. What kind of information do you get from audits and how do you use it?
6. What does an audit result say about the actual state of a department?
7. To what extent do you use the internal audit to oversee patient safety?
8. To what extent do you use the internal audit to steer patient safety?
9. To what extent are internal audit results discussed with the board of supervisors?
10. To what extent does the internal audit contribute to the feeling of being 'in control'?
11. What were the advantages or disadvantages of the internal audit for your hospital?
12. How do you oversee the quality and safety in your hospital?

Appendix 5. Organization and content of internal audit

Organization and content of the internal audit in Dutch hospitals (n = 68)

	n	%
Frequency of audit§		
Every year	6	9
Every 2 years	7	10
Every 3 years	9	13
Every 4 years	45	66
Time frame of one internal audit		
1 month	6	9
2 months	18	27
3 months	17	25
4 months	6	9
5 months	2	3
6 months	6	9
7 months	2	3
Members of the audit team		
Medical specialists	46	68
Allied healthcare professionals	51	75
Nurses	65	96
Management	57	84
Total number of auditors in hospital		
5–10	1	1
10–20	23	34
>20	44	65
Structural training and/or evaluation of auditors?		
Training	55	81
Evaluation	50	74
No training, no evaluation	6	9
Framework for audit		
Standards of accreditation institutes	66	97
Standards set by law	45	66
Standards set by profession	18	27
Standards set by hospital itself	22	32
Other†	25	37
Input for audit		
Outcomes of self-evaluation by department	40	59
Outcomes of document analysis by audit team	68	100
Outcomes of interviews by audit team	68	100
Outcomes of site-visits by audit team	68	100
Outcomes of ad hoc measures by audit team	23	34
Other¥	14	21

§ When responding to the questions regarding 'Frequency of audit', 'Time frame of audit' and 'Number of auditors', respondents could only choose one option, whereas when responding to the other questions, respondents could choose multiple options.

†ISO, VMS, HKZ, CCL, NEN, NTA, JACIE, MediRisk

¥Outcomes of other audits when present, such as audits by external experts and audits initiated by medical specialties; outcomes of satisfaction questionnaires amongst partner departments (such as an orthopedic department when the radiology department is being audited); outcomes of tracers; outcomes of chart reviews; outcomes of team climate inventory.

Research checklist
COREQ guidelines table

No. Item	Guide questions/description	
Domain 1: Research team and reflexivity		
Personal Characteristics		
1. Inter viewer/facilitator	Which author/s conducted the interview or focus group?	SvG and MZ
2. Credentials	What were the researcher's credentials? E.g. PhD, MD	1 MA, 1 PhD
3. Occupation	What was their occupation at the time of the study?	Research Fellows
4. Gender	Was the researcher male or female?	Both female
5. Experience and training	What experience or training did the researcher have?	Two researchers received training in interviewing. Both followed courses on qualitative research
Relationship with participants		
6. Relationship established	Was a relationship established prior to study commencement?	Yes, to one of them. However, we made sure to act the same as in all other interviews (sending the topic guide prior to the interview, introducing ourselves, no small talk during the interview) so that this did not affect the data.
7. Participant knowledge of the interviewer	What did the participants know about the researcher? e.g. personal goals, reasons for doing the research	Broad outlines given
8. Interviewer characteristics	What characteristics were reported about the inter viewer/facilitator? e.g. Bias, assumptions, reasons and interests in the research topic	Reasons for research
Domain 2: study design		
Theoretical framework		
9. Methodological orientation and Theory	What methodological orientation was stated to underpin the study? e.g. grounded theory, discourse analysis, ethnography, phenomenology, content analysis	Thematic analysis
Participant selection		
10. Sampling	How were participants selected? e.g. purposive, convenience, consecutive, snowball	Purposively sampled
11. Method of approach	How were participants approached? e.g. face-to-face, telephone, mail, email	Face-to-face, telephone and email
12. Sample size	How many participants were in the study?	43
13. Non-participation	How many people refused to participate or dropped out? Reasons?	Two not interviewed for lack of time
Setting		
14. Setting of data collection	Where was the data collected? e.g. home, clinic, workplace	Clinic and workplace
15. Presence of non-participants	Was anyone else present besides the participants and researchers?	No
16. Description of sample	What are the important characteristics of the sample?	Boards of Directors

	e.g. demographic data, date	(n=5), Boards of Supervisors (n=5), Quality and safety directors (n=7), Quality officers (n=14), Head of department or clinical manager (auditees) (n=12). Of the interviewees, 56% was female, and 40% had six or more years of experience in their current function.
Data collection		
17. Interview guide	Were questions, prompts, guides provided by the authors? Was it pilot tested?	Interview guides were sent to interviewees prior to the interview. The topic guides were pilot tested.
18. Repeat interviews	Were repeat interviews carried out? If yes, how many?	No
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25. Description of the coding tree	Did authors provide a description of the coding tree?	Yes
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27. Software	What software, if applicable, was used to manage the data?	Atlas.ti software version 7.0
28. Participant checking	Did participants provide feedback on the findings?	No
Reporting		
29. Quotations presented	Were participant quotations presented to illustrate the themes/findings? Was each quotation identified? e.g. participant number	Yes, but not with a participant number
30. Data and findings consistent	Was there consistency between the data presented and the findings?	Yes
31. Clarity of major themes	Were major themes clearly presented in the findings?	Yes
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No. Item	**Guide questions/description**	
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Personal Characteristics		
1. Inter viewer/facilitator	Which author/s conducted the interview or focus group?	SvG, GH and MZ

2. Credentials	What were the researcher's credentials? E.g. PhD, MD	1 MA, 2 PhD
3. Occupation	What was their occupation at the time of the study?	Research Fellows
4. Gender	Was the researcher male or female?	2 female, 1 male
5. Experience and training	What experience or training did the researcher have?	Two researchers received training in interviewing. Both followed courses on qualitative research
Relationship with participants		
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Domain 2: study design		
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15. Presence of non-participants	Was anyone else present besides the participants and researchers?	No
16. Description of sample	What are the important characteristics of the sample? e.g. demographic data, date	Boards of Directors (n=5), Boards of Supervisors (n=5), Clinical managers (n=12), Quality Officers (n=21) (see table 2). Of the interviewees, 56% was female, and 40% had six or more years of experience in their current function.
Data collection		

17. Interview guide	Were questions, prompts, guides provided by the authors? Was it pilot tested?	Interview guides were sent to interviewees prior to the interview. The topic guides were pilot tested.
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Reporting		
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Evaluation of the organization and effectiveness of internal audits to govern patient safety in hospitals: A mixed-method study

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ABSTRACT

Objectives

Hospital boards are legally responsible for safe healthcare. They need tools to assist them in their task of governing patient safety. Almost every Dutch hospital performs internal audits, but the effectiveness of these audits for hospital governance has never been evaluated. The aim of this study is to evaluate the organization of internal audits and their effectiveness for hospitals boards to govern patient safety.

Design and setting

A mixed-methods study consisting of a questionnaire regarding the organization of internal audits amongst all Dutch hospitals (n = 89) and interviews with stakeholders regarding the audit process and experienced effectiveness of audits within six hospitals.

Results

Response rate of the questionnaire was 76% and 43 interviews were held. In every responding hospital, the internal audits followed the plan-do-check-act cycle. Every hospital used interviews, document analysis and site visits as input for the internal audit. Boards stated that effective aspects of internal audits were their multidisciplinary scope, their structured and in-depth approach, the usability to monitor improvement activities and to change hospital policy, and the fact that results were used in meetings with staff and boards of supervisors. The qualitative methods (interviews and site visits) used in internal audits enables the identification of soft signals such as unsafe culture or communication and collaboration problems. Reported disadvantages were the low frequency of internal audits and the absence of soft signals in the actual audit reports.

Conclusion

This study shows that internal audits are regarded as effective for patient safety governance, as they help boards to identify patient safety problems, proactively steer patient safety and inform boards of supervisors on the status of patient safety. The description of the Dutch internal audits makes these audits replicable to other healthcare organizations in different settings, enabling hospital boards to complement their systems to govern patient safety.

ARTICLE SUMMARY

Strengths and limitations of this study

- This is the first study that evaluates the organization and the effectiveness of internal audits to govern patient safety in hospitals.
- We performed a mixed-methods study consisting of a questionnaire sent to all Dutch hospitals and interviews with stakeholders in the governance and audit process of six Dutch hospitals.
- The use of qualitative data collection enabled us to gain insight into the experiences of boards with internal audits.
- As we studied internal audits in Dutch hospitals, generalization to other countries or healthcare settings might be limited.

INTRODUCTION

Patient safety should be the top priority of every hospital board [1–3]. Hospital boards are legally accountable for the quality and safety of the delivered care in their hospitals [4,5]. However, while the need for board safety oversight has been growing [6–8], healthcare is still often unsafe and boards experience difficulties in overseeing safety risks [9–12]. In order to fulfil their governance role, hospitals boards need methods and tools that provide monitoring information to mitigate or prevent adverse events [13–15].

There are several sources for gathering information that helps boards with the governance of patient safety, and information from internal audits might be one of them. The internal audit is an 'objective assurance and consulting system for detecting patients' risks of adverse events early', which 'should encourage the continuous improvement of patient safety' [16]. It is a systematic evaluation of the quality system of a hospital which aims to improve patient safety by measuring performance of healthcare providers and preconditions for safe care, and comparing these outcomes to (national) standards and guidelines. The measurements are performed by an audit team existing of internal peers (i.e., employees of a hospital who audit colleagues of other departments). The method was implemented in the 1990s to measure whether organizational preconditions for safe care are in place and to induce improvements when safety problems are detected. Internal audits are initiated by hospital boards and implemented top-down.

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.

The reason that almost all Dutch hospitals use internal audits for governance purposes is a combination of the 1996 Care Institutions Quality Act and the constitution of the Netherlands Institute for Accreditation in Healthcare (NIAZ). Hospitals are obliged by the Care Institutions Quality Act to have a quality management system in place, including the assurance that quality activities are undertaken [19]. Since the 1990s, many hospitals are using the quality assurance standards of NIAZ [19]. In order to be accredited by this institute and to give the assurance of safe care to third parties (e.g., healthcare consumers and healthcare insurers), an internal audit system should be in place [20,21]. External accreditation parties such as NIAZ have their own audits (i.e., external audits that they perform to see whether a hospital is ready for external accreditation). This study does not focus on these external audits, but on the *internal* audits that are performed by employees from a hospital itself.

Our study focuses on governance within a hospital from a board of directors' point of view: the need to oversee and to steer patient safety (deriving information from the work floor) and the need to account for patient safety (sending information towards the board of supervisors). We are interested in whether the internal audit assists the board of directors of hospitals in this task. Figure 1 shows examples of tools to govern patient safety, the stakeholders in Dutch hospital governance and the position of internal audits in it (see figure 1).

Almost every hospital in the Netherlands uses internal audits. However, research regarding the effectiveness of internal audits for boards to govern patient safety is lacking. As internal audits are widely used in hospitals, we wondered whether and how the information coming from internal audits is effective for the governance of patient safety (i.e., has a place in hospital governance). Our study has two aims. First, to describe the internal audits in Dutch hospitals, so that, if regarded as being

effective, this audit system is replicable to other countries or different healthcare organizations. Second, to describe the views of hospital boards regarding the effectiveness of internal audits to assist them in their task of governing patient safety. We aimed to answer the following questions:

1. How are internal audits organized in Dutch hospitals?
2. Are internal audits regarded as effective for the governance of patient safety by hospital boards?

METHODS

Study design and setting

We performed a mixed methods study on the organization of and experiences with the effectiveness of internal audits in the Netherlands, consisting of a questionnaire survey and individual interviews.

The questionnaire was sent to all Dutch hospitals (n = 89) and interviews took place in six hospitals, which were selected amongst the 89 hospitals. Selection was based on various criteria (see appendix 1). The six hospitals represented both the different types of hospitals in the Netherlands and the different aspects of internal audits. The participating hospitals were located across the country and ranged in size from 536 beds up to 1003 beds. All six hospitals were accredited or were in the process of being accredited, for example, by the Netherlands Institute for Accreditation in Healthcare (NIAZ) or the Joint Commission International (JCI).

By 'hospital boards', we mean a board of directors. Hospital boards across all participating hospitals (questionnaire and interviews) were structured according to the Care-wide Governance Code [22]. In the Netherlands, a board of directors and a board of supervisors represent two independent bodies; a board of directors is responsible for patient safety governance and a board of supervisors supervises a board of directors. A board of directors is accountable for the quality and safety of care to a board of supervisors and external parties such as the Dutch Healthcare Inspectorate (which promotes public health and is a part of government oversight of public health) [23]. The pressure to have a patient safety governance structure in place comes from the Ministry of Health (see figure 1) [24,25].

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).

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.

Participants

The questionnaire was sent to the chairmen of the boards of directors of every Dutch hospital (n = 89), with the option to forward the questionnaire to a person responsible for internal audits at operational level.

The targeted number of interview partners was six members of boards of directors, six members of the boards of supervisors, six quality and safety directors, 12 quality officers (including auditors) and 12 heads of departments or clinical managers (auditees). Participants for the interviews were selected based on purposive sampling to ensure diversity (e.g., experience with audits, auditing, and type of job) and convenience sampling (for availability purposes) [28].

Data collection

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.

Questionnaire

An invitation to participate in the questionnaire to study the organization and content of internal audits was sent in 2012 by email. The email included the link to the online survey, the purpose of the study and a statement that anonymous and confidential handling of data was ensured. Informed consent was implied by completing and sending in the questionnaire. A reminder was sent after two weeks. The questionnaire consisted of multiple-choice questions; six general questions and eight questions regarding content and organization of the audit (see appendix 2). The questionnaire was developed based on meetings with experts on auditing (n = 3) and brainstorming sessions (n = 4) with the research team. The questionnaire was pilot-tested by target participants (n = 3) and adapted accordingly.

Interviews

Interviews took place between May of 2012 and November of 2014. All interviews were audio-recorded with the participants' consent and transcribed verbatim according to a standardized format. Data collection and analyses of interviews were performed according to the 'Consolidated criteria for reporting qualitative studies' (COREQ) [29] (appendix 3) and based on thematic analysis. Interviews were in-depth, face-to-face interviews. All interviews were conducted by experienced interviewers (SvG and GH) and were guided by a topic guide. The topic guide was developed based on results from the questionnaire (regarding the organization and content of internal audit only) and brainstorming sessions with the research team, and was adapted after each interview. Topics for guiding the interviews included the following themes (see appendix 4):

- Organization and content of internal audit.
- Effectiveness of internal audit information for boards:
    - Use of internal audit for identification of safety risks
    - Use of audit information to steer patient safety
    - Use of internal audit to account for patient safety towards the board of supervisors.

Questions regarding the content and organization of the internal audits were addressed to all interviewees. Questions regarding the regarded effectiveness of internal audits for hospital boards to govern patient safety were addressed to the boards of directors, boards of supervisors, quality and safety directors, and heads of department or clinical managers. On each hospital site, interviews were held until saturation was reached [30].

Data analysis

The questionnaire data were analysed using IBM SPSS Statistics version 20. Transcripts of the interviews were coded using Atlas.ti software version 7.0 (ATLAS.ti Scientific Software Development Company, GmbH, Berlin, Germany). The transcriptions of the interviews were analysed using thematic analysis [30]. 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. Codes that related to the same phenomenon were grouped into categories and, finally, themes were identified. Differences were resolved by consensus.

RESULTS

Response and characteristics of respondents

Of the 89 questionnaires sent, 69 were returned (76%). In one hospital, no internal audits were carried out. One questionnaire was filled in by a chairman of the board of directors. The other questionnaires were filled in by employees related to the quality departments. The response rate varied per type of hospital: 88% for university hospitals (n = 7/8), 82% for tertiary teaching hospitals (n = 23/28) and 70% for general hospitals (n = 38/54).

In total, 43 interviews within six hospitals were performed. In two cases the requests for interviews were not granted because of time constraints. Five members of boards of directors were interviewed, as were five members of boards of supervisors, seven quality and safety directors, 14 quality officers (including auditors) and 12 medical specialists or clinical managers (auditees) (see table 1).

Table 1 Interview participants and their characteristics (n = 43)

	n	**%**
Hospital type		
University hospital	16	37
Tertiary medical teaching hospital	15	35
General hospital	12	28
Function title		
Member of the board of directors	5	12
Member of the board of supervisors	5	12
Quality and safety directors	7	16
Quality officers	14	32
Head of department or clinical manager (auditees)	12	28
Gender		
Female	24	56
Male	19	44
Work experience in current function (years)		
1-5	26	60
6-10	12	28
11-15	5	12

Description of the organization of internal audits in Dutch hospitals

Internal audit cycle and responsibilities of stakeholders

In all six hospitals the internal audits were performed according to the plan-do-check-act cycle. Figure 2 shows the cycle of the internal audits (see figure 2). In all studied hospitals (n = 6), the boards of directors initiated the internal audits and delegated the execution to committees or departments. These departments or committees were responsible for the entire organization of the internal audit cycles, including the appointment of the audit teams. The audit teams performed the internal audits and were recruited amongst employees from the organizations. In some hospitals these auditors were volunteers, while in other hospitals being an auditor was (part of) an employee's job and they were paid for it.

Internal audits focussed on hospital departments and in some cases *also* on healthcare pathways and/or patient safety themes. An audit team prepared the audit, which included the analysis

of policy documents, medical record reviews, and a self-evaluation forms filled in by the departments. Preparations also involved, for example, looking at outcomes of earlier performed audits (see table in appendix 5). In audit team meetings, the outcomes of the preparations were discussed and the focus of the audit (e.g., which specific safety risks would receive extra attention and which topics were included in the audit) were determined. Audit topics ranged from the existence of soap dispensers to interrelation topics such as department culture, communication and cooperation. During an audit day, the audit team visited the departments, or involved departments in cases of auditing healthcare processes/pathways or patient safety themes. Subsequently, the audit team wrote a report in which the impressions of the departments were reflected. With this report, the audit teams provided feedback regarding improvements that must or could be made to increase patient safety (recommendations). Audit results were fed back to the boards of directors for governance purposes, and fed back to the audited departments. Department heads were obligated to make improvement plans. Follow-up of the audit results and recommendations was the responsibility of department heads and was monitored by the boards of directors, or delegated to committees. This audit cycle was repeated periodically.

Organization and content of internal audit

Internal audits were performed once every four years in 66% of the hospitals, once every three years in 13% of the hospitals, once every two years in 10% of the hospitals and once every year in 9% of the hospitals (see appendix 5). The time frame of an internal audit ranged from one month (9%) to seven months (2%), with a time frame of 2 months being most common (27%). Members of the audit teams were nurses (present in audit teams in 96% of the hospitals), management employees (present in audit teams in 84% of the hospitals), allied healthcare professionals (present in audit teams in 75% of the hospitals) and medical specialists (present in audit teams in 68% of the hospitals). One hospital (1%) had 5-10 auditors in total, while 65% of the hospitals had more than 20 auditors in total. In 81% of the hospitals auditors received training, and in 74% of the hospitals auditors were evaluated. Of the 68 hospitals, six did not train nor evaluate their auditors (9%). 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. As inputs for the internal audit outcomes, the following were used: document analysis by audit team (100% of the hospitals), interviews by audit team (100% of the hospitals), site-visits by audit team (100% of hospitals), self-evaluation by audited department (59% of the hospitals), ad-hoc measures by audit team (34%) and other measures (37%). These other measures were:

- Outcomes of other audits when present, such as audits by external experts, external audits for accreditation and audits initiated by the professional association of medical specialties (visitations);
- Outcomes of surveys amongst employees of partner departments (such as a surveys amongst an orthopaedic department when a radiology department is being audited);
- Outcomes of medical record reviews.

Feedback of audit results

The ways in which audit results were fed back to the boards of directors differed per hospital. Three options have been found:

1. The board of directors receives a report on the headlines deriving from internal audits (aggregated results; found in 50% of the hospitals).
2. The board of directors receives letter with recommendations based on audit results and has the option to ask audited department for the entire audit report (found in 17% of the hospitals).
3. The board of directors receives entire audit report (found in 50% of the hospitals).

In one hospital, multiple options have been found. In that hospital, the board received a report on the headlines deriving from all internal audits and the entire report of the executed audits on supportive departments.

In interviews, members of the boards of directors of all hospitals stated that it is the responsibility of the departments to implement improvement actions, except in the following situations: 1) when patient safety is immediately threatened—in this case, a board of directors uses the internal audit as a 'forced improvement'-instrument; and 2) when improvements cannot be made without support from a board of directors, for example when equipment is out-of-date and cannot be replaced without consent of a board of directors.

Experiences with effectiveness of internal audits

Use of internal audits for identification of safety problems

Board members perceived internal audits as effective for the identification of safety problems for three reasons: 1) broad, multidisciplinary scope; 2) soft signals; and 3) in-depth approach (see table 2 for illustrative quotes).

Interviewees stressed that with internal audits every department of a hospital, including supportive departments, is evaluated periodically. Furthermore, an internal audit has a multidisciplinary focus (e.g., involving the opinions of other departments regarding the audited department and not only focusing on clinicians or nurses, but all employees both in an audit team and as auditees). Board members noted that this broad scope of an internal audit provided a complete overview of the performance of all departments in an entire organization.

According to board members, the use of qualitative methods of gathering information (e.g., interviews and observations) makes an internal audit a suitable instrument not just to establish that things are going wrong, but most of all reveal why these things happen. Board members stated that as a result, an internal audit was able to provide information regarding the soft side of an organization, such as cooperation and communication problems. Nonetheless, they noted these soft signals are not easily translated into facts that can be reported in an audit report.

Board members indicated that an internal audit is an instrument with a very structured and in-depth approach. The quality and safety of an entire department is being evaluated, from cleaning to medical treatment and from medical chart reviews and policy documents to interviews with employees, after thorough preparations of both an audit team and an audited department. Board members stated that this reveals patient safety problems in a structured way, and because of the fact that improvement actions are suggested, audits help boards prioritize what should be done to improve patient safety. Board members indicated that an internal audit is especially suited for generating patient safety information in a planned and prepared manner, but mentioned that because of the low frequency of internal audits (because of the time-consuming, in-depth approach) there is a lack of real-time information.

Use of audit information to steer quality and safety

Two categories emerged within this theme: 1) monitoring; and 2) incentive for change.

Board members mentioned that embedding internal audit results in a planning and control cycle gives them the opportunity to have a dialogue regarding the status of quality improvements made by departments. They noted that monitoring and frequently discussing audit results and improvement plans contributes to the feeling of being in control. A caveat mentioned by one board member regarding being in control with the internal audit is that, as with every instrument, critical incidents can still happen.

Board members mentioned that audit results can be an incentive for them to adjust hospital policy and culture. Different interviewees stated that internal audit results were a reason for them to make changes happen as soon as possible, whether these were adjustments needed to be made by the board itself, or by departments. Boards used internal audits to start a conversation with staff and as an incentive to visit departments themselves.

Table 2. Themes, categories and quotes relating to effectiveness of internal audit

Theme	Category	Quotes
Use of the internal audit for identification of safety risks	Broad, multidisciplinary scope	*"Well, an internal audit is department-wide and multidisciplinary, you talk with professionals of that department, but also with its customers. Like, if there's an audit at radiology, you talk to specialists of other departments that use the services of radiology as well. With tracers, you don't have that complete overview."* *"And the internal audit contributes to an overall view of a department, of a group of people who are active within a certain discipline: clinicians, nurses, allied healthcare professionals… and yes, you get insight into the department on an aggregated level."*
	Soft signals	*"[With the internal audit] you can get a global impression regarding the actual performance, so to say, and cooperation as well (…). The question could be: 'how is everything going,' and they would say: 'perfect, we are doing the best we can'. Well, show me!"* *"Well, I think that the soft signals… Partially they derive from the internal audit (…) but it is just very complicated, you know. I think an internal audit should begin with the question: 'Why do you like working here?' That is not something you can write down in three sentences in the audit report. It is as soft as you can get, but it is very significant for how people are feeling in their job."*
	In-depth approach	*"So it shows where the need for improvements lie and what you should prioritize… It prioritizes in the way, like, what is going right and what is going wrong?"* *"Especially when auditors don't just score, but ask questions, you get more information, like 'why is it going wrong?'"* *"Maybe it's even more important to be open and susceptible to signals from within the organization. We talk to chairmen of staff and divisions very often. You cannot wait for the internal audit to take place in a few years to feel safe regarding the functioning of a department."*

Use of audit information to steer patient safety.	Monitoring	*"And in our quarterly report, in our four-times-a-year cycle, we ask every unit to report on the audits that have been performed; what were the results, what did you encounter and which actions did you think of, and these actions, are they implemented and are they leading towards results (…)."* *"For us, as board of directors, it's about knowing what the conclusion regarding the department is, in the context of general functioning, leadership and yes, quality and safety. And that is one of the sources we need to, so to say, feel secure in how the organization is doing."*
	Incentive for change	*"Something in which we intervened immediately was the double check on medication. That was a moment in which we said: this is unacceptable. These answers are unacceptable. So I went there, and the medical directors as well, and we said, this is out of the question. This has to change by tomorrow."* *"We've also looked at what is the reason that that happens; don't we need to alter the procedure? So it is about steering, saying: 'this is unacceptable', but it is also a moment of thinking: 'did we organize it correctly?'"*
Use of audit information to account for patient safety	Use of internal audit information in regular meetings with the board of supervisors	*"Yes, to inform. By the way, our board of supervisors is very on top of it, they will ask: what did you do about it? So you need to have that answer as well."*
	Use of audit information to inform the board of supervisors regarding critical incidents	*"And if we say: 'This is critical, these people have to be informed before the report is finished', then I will call them and they will come over."* *"It's not good for internal monitoring because that will cause a mix-up between the responsibilities of the board of directors and the board of supervisors. Negative results of an audit should be solved in the management line of the hospital. Having said that, the existence of an internal audit system, that they are performed accurately, that there are reports on the results and the system as a whole, helps us to trust the board of directors."*

Use of internal audits to account for patient safety

Two categories derived from this theme: 1) use of internal audit information in regular meetings with boards of supervisors; and 2) use of audit information to inform boards of supervisors regarding critical incidents.

Board members stated that an internal audit is one of the information sources used to inform a board of supervisors about the status of patient safety. It is used on a regular base, as part of the regular meetings between boards of directors and boards of supervisors, on an aggregated level. Interviewees stressed the latter: an internal audit is not discussed in detail, as it is not the job of a board of supervisors to monitor departments in detail. Members of boards of directors stated that instead, they use the headlines of the performed audits to show boards of supervisors whether a hospital is able to learn and improve.

There is an exception when discussing an internal audit on an aggregated level. Members of different boards mentioned that when critical incidents derived from internal audits, boards of supervisors are informed of these incidents.

DISCUSSION

The aim of this study was to describe the organization of internal audits in Dutch hospitals and to evaluate the effectiveness of these audits for boards to govern patient safety. Our quantitative and qualitative findings revealed that there were similarities in how internal audits were organized in the hospitals. The audit cycle, following the plan-do-check-act cycle, the methods used to gather information (e.g., interviews, site visits, and document analysis) and the responsibilities of the boards of directors and the committees responsible for audits were in general the same in all hospitals throughout the Netherlands. Aspects that differed amongst hospitals were related to feasibility, and included the number of auditors and disciplines such as medical specialists present in an audit team, the duration of an internal audit and the amount of methods used to get insight into the quality and safety of departments.

Interviewed hospital board members stated that internal audits help them to identify safety problems and to steer patient safety. Internal audits provide a complete overview of departments, prioritize safety problems, are an incentive to adjust policy and are used to monitor safety improvements. A study regarding governance activities of Australian hospital boards showed four tools that are similar to the effective aspects of an internal audit, namely 'shaping culture', 'measuring progress', 'setting priorities' and 'ensuring accountability' [31]. The use of qualitative methods (e.g., interviews and observations) makes an internal audit unique compared to quantitative instruments (e.g., quality indicators) that boards have for governance. However, since internal audits are highly structured and standardized, their frequency is low which results in limited real-time information. Another disadvantage of an internal audit's formal character is that soft signals deriving from the qualitative methods are difficult to include in the audit report—even though board members mentioned that these outcomes especially say a lot about the quality and safety of care. These outcomes give insight into in problems regarding patient safety culture, communication and collaboration.

The attention to effective board oversight and tools to assist boards in this task is ever growing [2,6,12,31-33]. This study contributes to research in this field by evaluating an instrument that is already used in almost every hospital in the Netherlands. Internal audits in Dutch hospitals has existed since the 1990s and are initiated by hospital boards. However, to our knowledge, the Dutch internal auditing process has never been evaluated before and there is little-to-no literature on the evaluation of the effectiveness of internal audits for hospital governance [19,34,35]. Our study indicates that an internal audit might be a promising instrument for hospital boards. Internal audits provide a complete, multidisciplinary and periodic overview of quality and safety problems, their underlying causes and needed improvement actions. Research regarding dashboards or scorecards using measurements such as the Hospital Standardized Mortality Ratio (HSMR) or complications and lengths of stay, showed that a disadvantage of these measurements is that they do not always provide relevant information regarding the underlying problem(s) or causes related to how to *improve* quality and safety [12,36-39]. Indicators such as HSMR do not go further than revealing that there is a problem, while an internal audit is able to reveal why there is a problem because of the use of qualitative methods [40,41]. Our finding that the soft signals deriving from these qualitative methods are important to gaining insight into the underlying causes of quality and safety problems has been found in other studies regarding board oversight as well [36,42,43]. 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 [44]. 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.

A strength of this study is that we used a mixed-method approach. The questionnaire enabled us to get a complete overview of the organization of internal audits in all Dutch hospitals and the qualitative measures provided us with in-depth information on the experiences of boards regarded to the effectiveness of internal audits to govern patient safety. Another strength of this study is the high response rate to both the questionnaire and the interviews; there were only two interviewees who did not grant the request for an interview, resulting in a high internal validity of the results. Moreover, we interviewed every stakeholder in the audit process, including members of boards of directors and boards of supervisors, even though this a group that is not easy to involve (in research).

A limitation of our study is that we studied internal audits only in Dutch hospitals. Therefore, generalization to other countries or healthcare settings might be limited. We know that internal audits exist in hospitals in other countries, however, we have not found literature in which the use of internal audits in these countries has been described or evaluated [19,34] and therefore we could not make comparisons between Dutch internal audits and internal audits in other countries. Another limitation is the number of members of boards of directors that we interviewed for information on their experiences with internal audits. Most of the information on the regarded effectiveness of internal audits came from the interviews with members of boards of directors. Because of time constraints and the time-consuming qualitative methods we used, we could only perform an in-depth study in six hospitals. However, we have reached saturation and found substantial consistency in experiences of boards with internal audits. This led us to believe that their experiences are representative for other hospital boards. Moreover, we were able to use the interviews with quality and safety directors and heads of departments or clinical managers to validate the boards' experiences. 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]).

Conclusion

This is the first study in which the organization and the perceived effectiveness of internal audits to govern patient safety in hospitals is evaluated. Our findings showed that internal audits were regarded as effective for the governance of patient safety, as they help boards to identify patient safety problems, steer patient safety and account for patient safety. Internal audits provide boards with structured, standardized, formal and periodic overviews of quality and safety problems and underlying causes in all departments in a hospital, helping boards prioritize improvement actions and giving them a sense of being in control. Furthermore, the use of qualitative methods to identify soft signals makes an internal audit a unique instrument in the entire spectrum of governance strategies for boards. Hospital boards can use the description of Dutch internal audits given in this paper to complement their systems to govern patient safety.

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COMPETING INTERESTS

The authors declare that there are no competing interests. The funding bodies had no involvement in the design and conduct of the study, nor in the writing and submission of this manuscript.

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ETHICAL APPROVAL

The study protocol has been presented to the Medical Ethical Committee of the Radboud University Nijmegen Medical Centre (registration number: 2011/332). The committee declared ethical approval was not required under Dutch National Law.

AUTHORS' CONTRIBUTIONS

SvG carried out the research and drafted the manuscript. MZ conceived the study, contributed to the design and coordination of the study, drafted the manuscript and helped to carry out the research. HW contributed to the design and coordination of the study. HW, GW, PR and WB revised the manuscript critically. All authors read and approved the final manuscript.

FIGURE LEGENDS

Figure 1.

Positioning of internal audit in governance of Dutch hospitals. Framework is based on two studies: the 'Deepening our Understanding of Quality Improvement in Europe' (DUQuE) project [24] and the 'Quality and Safety in Europe by Research' (QUASER) study [25].

Figure 2.

Internal audit cycle for governance purposes.

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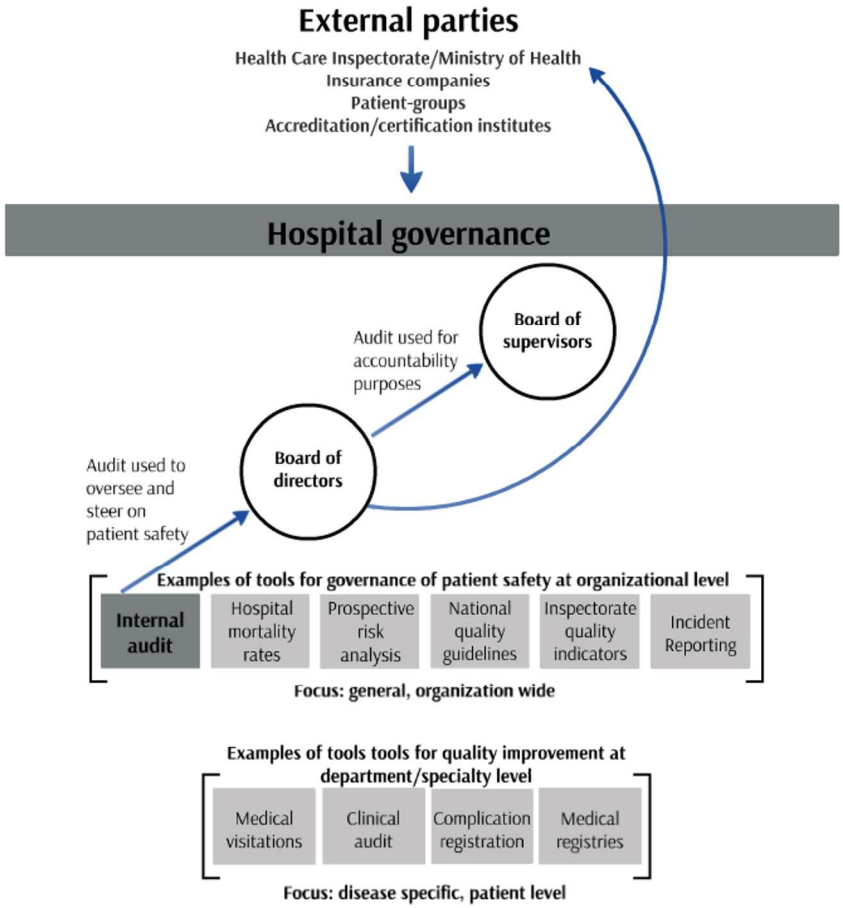

Figure 2. Positioning of internal audit in governance of Dutch hospitals. Framework is based on two studies: the 'Deepening our Understanding of Quality Improvement in Europe' (DUQuE) project [24] and the 'Quality and Safety in Europe by Research' (QUASER) study [25].

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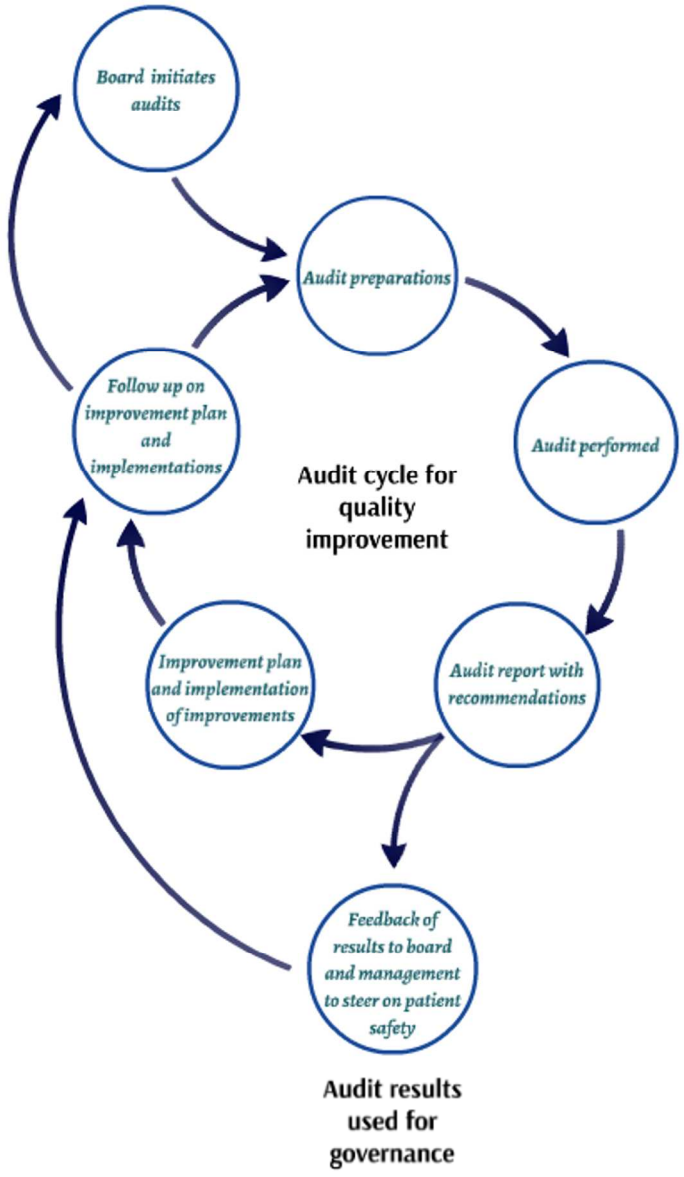

Figure 2. Internal audit cycle for governance purposes.

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APPENDICES

Appendix 1. Hospital sampling criteria for interviews

Selection criterion	Description
Variation in hospital type	University hospitals, tertiary teaching hospitals[1] and general hospitals .
Variation in standards and regulations for designing internal audit system	Different standards for the design of internal audit systems (e.g. NIAZ, JCI, VMS).
>5 years of experience with internal auditing	Only hospitals with more than five years' experience with internal audits were included, because this assured that one internal audit cycle would have been completed.
Variation in data sources used for internal audit	A distribution of hospitals with different sources of input for their internal audit; such as interviews, observations, surveys amongst employees and patients, and self-evaluation.
Medical specialist in audit team	A distribution of hospitals with, and without medical specialists in their audit team.
Hours spent per internal audit	Hospitals that spent less than 100, between 100-250 and more than 250 hours per audit.
Geographical spread/location	Two different provinces per type of hospital.

[1] Tertiary teaching hospitals in the Netherlands provide highly specialised care and train doctors in collaboration with university hospitals.

Appendix 2. Questionnaire 2012

Content

1. Which standards are used by your hospital for the internal audit (multiple responses possible)?
   - Standards of accreditation institutes
   - Standards set by law
   - Standards set by profession
   - Standards set by hospital itself
   - Other, namely:
2. What is used as input for the internal audit in your hospital (multiple responses possible)?
   - Outcomes of self-evaluation by department
   - Outcomes of document analysis by audit team
   - Outcomes of interviews by audit team
   - Outcomes of site-visits by audit team
   - Outcomes of ad hoc measures by audit team
   - Other, namely:

Organization

3. Who are the members of the audit team in your hospital (multiple responses possible)?
   - Medical specialists
   - Allied healthcare professionals
   - Nurses
   - Management
4. What is the total number of auditors in your hospital?
   - < 5
   - 5-10
   - 10-20
   - >20
5. Do auditors receive training and/or are they structurally evaluated (multiple responses possible)?
   - Training
   - Evaluation
   - No training, no evaluation
6. What is the time frame of one internal audit (from the first preparations to feedback of results to audited department)?
   …… months
7. What is the frequency of the internal audit?
   Once every … year(s)

Appendix 3. COREQ guidelines table

No. Item	Guide questions/description	
Domain 1: Research team and reflexivity		
Personal Characteristics		
1. Inter viewer/facilitator	Which author/s conducted the interview or focus group?	SvG and MZ
2. Credentials	What were the researcher's credentials? E.g. PhD, MD	1 MA, 1 PhD
3. Occupation	What was their occupation at the time of the study?	Research Fellows
4. Gender	Was the researcher male or female?	Both female
5. Experience and training	What experience or training did the researcher have?	Two researchers received training in interviewing. Both followed courses on qualitative research
Relationship with participants		
6. Relationship established	Was a relationship established prior to study commencement?	Yes, to one of them. However, we made sure to act the same as in all other interviews (sending the topic guide prior to the interview, introducing ourselves, no small talk during the interview) so that this did not affect the data.
7. Participant knowledge of the interviewer	What did the participants know about the researcher? e.g. personal goals, reasons for doing the research	Broad outlines given
8. Interviewer characteristics	What characteristics were reported about the inter viewer/facilitator? e.g. Bias, assumptions, reasons and interests in the research topic	Reasons for research
Domain 2: study design		
Theoretical framework		
9. Methodological orientation and Theory	What methodological orientation was stated to underpin the study? e.g. grounded theory, discourse analysis, ethnography, phenomenology, content analysis	Thematic analysis
Participant selection		
10. Sampling	How were participants selected? e.g. purposive, convenience, consecutive, snowball	Purposively sampled
11. Method of approach	How were participants approached? e.g. face-to-face, telephone, mail, email	Face-to-face, telephone and email
12. Sample size	How many participants were in the study?	43
13. Non-participation	How many people refused to participate or dropped out? Reasons?	Two not interviewed for lack of time
Setting		
14. Setting of data collection	Where was the data collected? e.g. home, clinic, workplace	Clinic and workplace
15. Presence of non-participants	Was anyone else present besides the participants and researchers?	No
16. Description of sample	What are the important characteristics of the sample? e.g. demographic data, date	Boards of Directors (n=5), Boards of

		Supervisors (n=5), Quality and safety directors (n=7), Quality officers (n=14), Head of department or clinical manager (auditees) (n=12). Of the interviewees, 56% was female, and 40% had six or more years of experience in their current function.
Data collection		
17. Interview guide	Were questions, prompts, guides provided by the authors? Was it pilot tested?	Interview guides were sent to interviewees prior to the interview. The topic guides were pilot tested.
18. Repeat interviews	Were repeat interviews carried out? If yes, how many?	No
19. Audio/visual recording	Did the research use audio or visual recording to collect the data?	Audiotaped
20. Field notes	Were field notes made during and/or after the interview or focus group?	Yes, after some interviews
21. Duration	What was the duration of the inter views or focus group?	30–60 minutes
22. Data saturation	Was data saturation discussed?	Yes and reached
23. Transcripts returned	Were transcripts returned to participants for comment and/or correction?	If desired; no adjustments were made by interviewees
Domain 3: analysis and findings		
Data analysis		
24. Number of data coders	How many data coders coded the data?	3
25. Description of the coding tree	Did authors provide a description of the coding tree?	Yes
26. Derivation of themes	Were themes identified in advance or derived from the data?	Identified in advanced and derived from the data
27. Software	What software, if applicable, was used to manage the data?	Atlas.ti software version 7.0
28. Participant checking	Did participants provide feedback on the findings?	No
Reporting		
29. Quotations presented	Were participant quotations presented to illustrate the themes/findings? Was each quotation identified? e.g. participant number	Yes, but not with a participant number
30. Data and findings consistent	Was there consistency between the data presented and the findings?	Yes
31. Clarity of major themes	Were major themes clearly presented in the findings?	Yes
32. Clarity of minor themes	Is there a description of diverse cases or discussion of minor themes?	Yes

Appendix 4. Topics for guiding interviews with stakeholders in the audit and governance process

1. How are internal audits set up in your hospital?
2. Is the focus of the audit determined beforehand?
3. Which framework do you use for the internal audit and why?
4. What methods do you use to gather information and why?
5. What kind of information do you get from audits and how do you use it?
6. What does an audit result say about the actual state of a department?
7. To what extent do you use the internal audit to oversee patient safety?
8. To what extent do you use the internal audit to steer patient safety?
9. To what extent are internal audit results discussed with the board of supervisors?
10. To what extent does the internal audit contribute to the feeling of being 'in control'?
11. What were the advantages or disadvantages of the internal audit for your hospital?
12. How do you oversee the quality and safety in your hospital?

Appendix 5. Organization and content of internal audit

Organization and content of the internal audit in Dutch hospitals (n = 68)

	n	%
Frequency of audit[§]		
Every year	6	9
Every 2 years	7	10
Every 3 years	9	13
Every 4 years	45	66
Time frame of one internal audit		
1 month	6	9
2 months	18	27
3 months	17	25
4 months	6	9
5 months	2	3
6 months	6	9
7 months	2	3
Members of the audit team		
Medical specialists	46	68
Allied healthcare professionals	51	75
Nurses	65	96
Management	57	84
Total number of auditors in hospital		
5–10	1	1
10–20	23	34
>20	44	65
Structural training and/or evaluation of auditors?		
Training	55	81
Evaluation	50	74
No training, no evaluation	6	9
Framework for audit		
Standards of accreditation institutes	66	97
Standards set by law	45	66
Standards set by profession	18	27
Standards set by hospital itself	22	32
Other[†]	25	37
Input for audit		
Outcomes of self-evaluation by department	40	59
Outcomes of document analysis by audit team	68	100
Outcomes of interviews by audit team	68	100
Outcomes of site-visits by audit team	68	100
Outcomes of ad hoc measures by audit team	23	34
Other[¥]	14	21

[§] When responding to the questions regarding 'Frequency of audit', 'Time frame of audit' and 'Number of auditors', respondents could only choose one option, whereas when responding to the other questions, respondents could choose multiple options.

[†]ISO, VMS, HKZ, CCL, NEN, NTA, JACIE, MediRisk

¥Outcomes of other audits when present, such as audits by external experts and audits initiated by medical specialties; outcomes of satisfaction questionnaires amongst partner departments (such as an orthopedic department when the radiology department is being audited); outcomes of tracers; outcomes of chart reviews; outcomes of team climate inventory.

Research checklist
COREQ guidelines table

No. Item	Guide questions/description	
Domain 1: Research team and reflexivity		
Personal Characteristics		
1. Inter viewer/facilitator	Which author/s conducted the interview or focus group?	SvG and MZ
2. Credentials	What were the researcher's credentials? E.g. PhD, MD	1 MA, 1 PhD
3. Occupation	What was their occupation at the time of the study?	Research Fellows
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5. Experience and training	What experience or training did the researcher have?	Two researchers received training in interviewing. Both followed courses on qualitative research
Relationship with participants		
6. Relationship established	Was a relationship established prior to study commencement?	Yes, to one of them. However, we made sure to act the same as in all other interviews (sending the topic guide prior to the interview, introducing ourselves, no small talk during the interview) so that this did not affect the data.
7. Participant knowledge of the interviewer	What did the participants know about the researcher? e.g. personal goals, reasons for doing the research	Broad outlines given
8. Interviewer characteristics	What characteristics were reported about the inter viewer/facilitator? e.g. Bias, assumptions, reasons and interests in the research topic	Reasons for research
Domain 2: study design		
Theoretical framework		
9. Methodological orientation and Theory	What methodological orientation was stated to underpin the study? e.g. grounded theory, discourse analysis, ethnography, phenomenology, content analysis	Thematic analysis
Participant selection		
10. Sampling	How were participants selected? e.g. purposive, convenience, consecutive, snowball	Purposively sampled
11. Method of approach	How were participants approached? e.g. face-to-face, telephone, mail, email	Face-to-face, telephone and email
12. Sample size	How many participants were in the study?	43
13. Non-participation	How many people refused to participate or dropped out? Reasons?	Two not interviewed for lack of time
Setting		
14. Setting of data collection	Where was the data collected? e.g. home, clinic, workplace	Clinic and workplace
15. Presence of non-participants	Was anyone else present besides the participants and researchers?	No
16. Description of sample	What are the important characteristics of the sample?	Boards of Directors

	e.g. demographic data, date	(n=5), Boards of Supervisors (n=5), Quality and safety directors (n=7), Quality officers (n=14), Head of department or clinical manager (auditees) (n=12). Of the interviewees, 56% was female, and 40% had six or more years of experience in their current function.
Data collection		
17. Interview guide	Were questions, prompts, guides provided by the authors? Was it pilot tested?	Interview guides were sent to interviewees prior to the interview. The topic guides were pilot tested.
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Data analysis		
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25. Description of the coding tree	Did authors provide a description of the coding tree?	Yes
26. Derivation of themes	Were themes identified in advance or derived from the data?	Identified in advanced and derived from the data
27. Software	What software, if applicable, was used to manage the data?	Atlas.ti software version 7.0
28. Participant checking	Did participants provide feedback on the findings?	No
Reporting		
29. Quotations presented	Were participant quotations presented to illustrate the themes/findings? Was each quotation identified? e.g. participant number	Yes, but not with a participant number
30. Data and findings consistent	Was there consistency between the data presented and the findings?	Yes
31. Clarity of major themes	Were major themes clearly presented in the findings?	Yes
32. Clarity of minor themes	Is there a description of diverse cases or discussion of minor themes?	Yes
No. Item	**Guide questions/description**	
Domain 1: Research team and reflexivity		
Personal Characteristics		
1. Inter viewer/facilitator	Which author/s conducted the interview or focus group?	SvG, GH and MZ

2. Credentials	What were the researcher's credentials? E.g. PhD, MD	1 MA, 2 PhD
3. Occupation	What was their occupation at the time of the study?	Research Fellows
4. Gender	Was the researcher male or female?	2 female, 1 male
5. Experience and training	What experience or training did the researcher have?	Two researchers received training in interviewing. Both followed courses on qualitative research
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16. Description of sample	What are the important characteristics of the sample? e.g. demographic data, date	Boards of Directors (n=5), Boards of Supervisors (n=5), Clinical managers (n=12), Quality Officers (n=21) (see table 2). Of the interviewees, 56% was female, and 40% had six or more years of experience in their current function.
Data collection		

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Evaluation of the organization and effectiveness of internal audits to govern patient safety in hospitals: A mixed-method study

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ABSTRACT

Objectives

Hospital boards are legally responsible for safe healthcare. They need tools to assist them in their task of governing patient safety. Almost every Dutch hospital performs internal audits, but the effectiveness of these audits for hospital governance has never been evaluated. The aim of this study is to evaluate the organization of internal audits and their effectiveness for hospitals boards to govern patient safety.

Design and setting

A mixed-methods study consisting of a questionnaire regarding the organization of internal audits amongst all Dutch hospitals (n = 89) and interviews with stakeholders regarding the audit process and experienced effectiveness of audits within six hospitals.

Results

Response rate of the questionnaire was 76% and 43 interviews were held. In every responding hospital, the internal audits followed the plan-do-check-act cycle. Every hospital used interviews, document analysis and site visits as input for the internal audit. Boards stated that effective aspects of internal audits were their multidisciplinary scope, their structured and in-depth approach, the usability to monitor improvement activities and to change hospital policy, and the fact that results were used in meetings with staff and boards of supervisors. The qualitative methods (interviews and site visits) used in internal audits enables the identification of soft signals such as unsafe culture or communication and collaboration problems. Reported disadvantages were the low frequency of internal audits and the absence of soft signals in the actual audit reports.

Conclusion

This study shows that internal audits are regarded as effective for patient safety governance, as they help boards to identify patient safety problems, proactively steer patient safety and inform boards of supervisors on the status of patient safety. The description of the Dutch internal audits makes these audits replicable to other healthcare organizations in different settings, enabling hospital boards to complement their systems to govern patient safety.

ARTICLE SUMMARY

Strengths and limitations of this study

- This is the first study that evaluates the organization and the effectiveness of internal audits to govern patient safety in hospitals.
- We performed a mixed-methods study consisting of a questionnaire sent to all Dutch hospitals and interviews with stakeholders in the governance and audit process of six Dutch hospitals.
- The use of qualitative data collection enabled us to gain insight into the experiences of boards with internal audits.
- As we studied internal audits in Dutch hospitals, generalization to other countries or healthcare settings might be limited.

INTRODUCTION

Patient safety should be the top priority of every hospital board [1–3]. Hospital boards are legally accountable for the quality and safety of the delivered care in their hospitals [4,5]. However, while the need for board safety oversight has been growing [6–8], healthcare is still often unsafe and boards experience difficulties in overseeing safety risks [9–12]. In order to fulfil their governance role, hospitals boards need methods and tools that provide monitoring information to mitigate or prevent adverse events [13–15].

There are several sources for gathering information that helps boards with the governance of patient safety, and information from internal audits might be one of them. The internal audit is an 'objective assurance and consulting system for detecting patients' risks of adverse events early', which 'should encourage the continuous improvement of patient safety' [16]. It is a systematic evaluation of the quality system of a hospital which aims to improve patient safety by measuring performance of healthcare providers and preconditions for safe care, and comparing these outcomes to (national) standards and guidelines. The measurements are performed by an audit team existing of internal peers (i.e., employees of a hospital who audit colleagues of other departments). The method was implemented in the 1990s to measure whether organizational preconditions for safe care are in place and to induce improvements when safety problems are detected. Internal audits are initiated by hospital boards and implemented top-down.

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.

The reason that almost all Dutch hospitals use internal audits for governance purposes is a combination of the 1996 Care Institutions Quality Act and the constitution of the Netherlands Institute for Accreditation in Healthcare (NIAZ). Hospitals are obliged by the Care Institutions Quality Act to have a quality management system in place, including the assurance that quality activities are undertaken [19]. Since the 1990s, many hospitals are using the quality assurance standards of NIAZ [19]. In order to be accredited by this institute and to give the assurance of safe care to third parties (e.g., healthcare consumers and healthcare insurers), an internal audit system should be in place [20,21]. External accreditation parties such as NIAZ have their own audits (i.e., external audits that they perform to see whether a hospital is ready for external accreditation). This study does not focus on these external audits, but on the *internal* audits that are performed by employees from a hospital itself.

Our study focuses on governance within a hospital from a board of directors' point of view: the need to oversee and to steer patient safety (deriving information from the work floor) and the need to account for patient safety (sending information towards the board of supervisors). We are interested in whether the internal audit assists the board of directors of hospitals in this task. Figure 1 shows examples of tools to govern patient safety, the stakeholders in Dutch hospital governance and the position of internal audits in it (see figure 1).

Almost every hospital in the Netherlands uses internal audits. However, research regarding the effectiveness of internal audits for boards to govern patient safety is lacking. As internal audits are widely used in hospitals, we wondered whether and how the information coming from internal audits is effective for the governance of patient safety (i.e., has a place in hospital governance). Our study has two aims. First, to describe the internal audits in Dutch hospitals, so that, if regarded as being

effective, this audit system is replicable to other countries or different healthcare organizations. Second, to describe the views of hospital boards regarding the effectiveness of internal audits to assist them in their task of governing patient safety. We aimed to answer the following questions:

1. How are internal audits organized in Dutch hospitals?
2. Are internal audits regarded as effective for the governance of patient safety by hospital boards?

METHODS

Study design and setting

We performed a mixed methods study on the organization of and experiences with the effectiveness of internal audits in the Netherlands, consisting of a questionnaire survey and individual interviews.

The questionnaire was sent to all Dutch hospitals (n = 89) and interviews took place in six hospitals, which were selected amongst the 89 hospitals. Selection was based on various criteria (see appendix 1). The six hospitals represented both the different types of hospitals in the Netherlands and the different aspects of internal audits. The participating hospitals were located across the country and ranged in size from 536 beds up to 1003 beds. All six hospitals were accredited or were in the process of being accredited, for example, by the Netherlands Institute for Accreditation in Healthcare (NIAZ) or the Joint Commission International (JCI).

By 'hospital boards', we mean a board of directors. Hospital boards across all participating hospitals (questionnaire and interviews) were structured according to the Care-wide Governance Code [22]. In the Netherlands, a board of directors and a board of supervisors represent two independent bodies; a board of directors is responsible for patient safety governance and a board of supervisors supervises a board of directors. A board of directors is accountable for the quality and safety of care to a board of supervisors and external parties such as the Dutch Healthcare Inspectorate (which promotes public health and is a part of government oversight of public health) [23]. The pressure to have a patient safety governance structure in place comes from the Ministry of Health (see figure 1) [24,25].

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).

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.

Participants

The questionnaire was sent to the chairmen of the boards of directors of every Dutch hospital (n = 89), with the option to forward the questionnaire to a person responsible for internal audits at operational level.

The targeted number of interview partners was six members of boards of directors, six members of the boards of supervisors, six quality and safety directors, 12 quality officers (including auditors) and 12 heads of departments or clinical managers (auditees). Participants for the interviews were selected based on purposive sampling to ensure diversity (e.g., experience with audits, auditing, and type of job) and convenience sampling (for availability purposes) [28].

Data collection

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.

Questionnaire

An invitation to participate in the questionnaire to study the organization and content of internal audits was sent in 2012 by email. The email included the link to the online survey, the purpose of the study and a statement that anonymous and confidential handling of data was ensured. Informed consent was implied by completing and sending in the questionnaire. A reminder was sent after two weeks. The questionnaire consisted of multiple-choice questions; six general questions and eight questions regarding content and organization of the audit (see appendix 2). The questionnaire was developed based on meetings with experts on auditing (n = 3) and brainstorming sessions (n = 4) with the research team. The questionnaire was pilot-tested by target participants (n = 3) and adapted accordingly.

Interviews

Interviews took place between May of 2012 and November of 2014. All interviews were audio-recorded with the participants' consent and transcribed verbatim according to a standardized format. Data collection and analyses of interviews were performed according to the 'Consolidated criteria for reporting qualitative studies' (COREQ) [29] (appendix 3) and based on thematic analysis. Interviews were in-depth, face-to-face interviews. All interviews were conducted by experienced interviewers (SvG and GH) and were guided by a topic guide. The topic guide was developed based on results from the questionnaire (regarding the organization and content of internal audit only) and brainstorming sessions with the research team, and was adapted after each interview. Topics for guiding the interviews included the following themes (see appendix 4):

- Organization and content of internal audit.
- Effectiveness of internal audit information for boards:
    - Use of internal audit for identification of safety risks
    - Use of audit information to steer patient safety
    - Use of internal audit to account for patient safety towards the board of supervisors.

Questions regarding the content and organization of the internal audits were addressed to all interviewees. Questions regarding the regarded effectiveness of internal audits for hospital boards to govern patient safety were addressed to the boards of directors, boards of supervisors, quality and safety directors, and heads of department or clinical managers. On each hospital site, interviews were held until saturation was reached [30].

Data analysis

The questionnaire data were analysed using IBM SPSS Statistics version 20. Transcripts of the interviews were coded using Atlas.ti software version 7.0 (ATLAS.ti Scientific Software Development Company, GmbH, Berlin, Germany). The transcriptions of the interviews were analysed using thematic analysis [30]. 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. Codes that related to the same phenomenon were grouped into categories and, finally, themes were identified. Differences were resolved by consensus.

RESULTS

Response and characteristics of respondents

Of the 89 questionnaires sent, 69 were returned (76%). In one hospital, no internal audits were carried out. One questionnaire was filled in by a chairman of the board of directors. The other questionnaires were filled in by employees related to the quality departments. The response rate varied per type of hospital: 88% for university hospitals (n = 7/8), 82% for tertiary teaching hospitals (n = 23/28) and 70% for general hospitals (n = 38/54).

In total, 43 interviews within six hospitals were performed. In two cases the requests for interviews were not granted because of time constraints. Five members of boards of directors were interviewed, as were five members of boards of supervisors, seven quality and safety directors, 14 quality officers (including auditors) and 12 medical specialists or clinical managers (auditees) (see table 1).

Table 1 Interview participants and their characteristics (n = 43)

	n	%
Hospital type		
University hospital	16	37
Tertiary medical teaching hospital	15	35
General hospital	12	28
Function title		
Member of the board of directors	5	12
Member of the board of supervisors	5	12
Quality and safety directors	7	16
Quality officers	14	32
Head of department or clinical manager (auditees)	12	28
Gender		
Female	24	56
Male	19	44
Work experience in current function (years)		
1-5	26	60
6-10	12	28
11-15	5	12

Description of the organization of internal audits in Dutch hospitals

Internal audit cycle and responsibilities of stakeholders

In all six hospitals the internal audits were performed according to the plan-do-check-act cycle. Figure 2 shows the cycle of the internal audits (see figure 2). In all studied hospitals (n = 6), the boards of directors initiated the internal audits and delegated the execution to committees or departments. These departments or committees were responsible for the entire organization of the internal audit cycles, including the appointment of the audit teams. The audit teams performed the internal audits and were recruited amongst employees from the organizations. In some hospitals these auditors were volunteers, while in other hospitals being an auditor was (part of) an employee's job and they were paid for it.

Internal audits focussed on hospital departments and in some cases *also* on healthcare pathways and/or patient safety themes. An audit team prepared the audit, which included the analysis

of policy documents, medical record reviews, and self-evaluation forms filled in by the departments. Preparations also involved, for example, looking at outcomes of earlier performed audits (see table in appendix 5). In audit team meetings, the outcomes of the preparations were discussed and the focus of the audit (e.g., which specific safety risks would receive extra attention and which topics were included in the audit) were determined. Audit topics ranged from the existence of soap dispensers to interrelation topics such as department culture, communication and cooperation. During an audit day, the audit team visited the departments, or involved departments in cases of auditing healthcare processes/pathways or patient safety themes. Subsequently, the audit team wrote a report in which the impressions of the departments were reflected. With this report, the audit teams provided feedback regarding improvements that must or could be made to increase patient safety (recommendations). Audit results were fed back to the boards of directors for governance purposes, and fed back to the audited departments. Department heads were obligated to make improvement plans. Follow-up of the audit results and recommendations was the responsibility of department heads and was monitored by the boards of directors, or delegated to committees. This audit cycle was repeated periodically.

Organization and content of internal audit

Internal audits were performed once every four years in 66% of the hospitals, once every three years in 13% of the hospitals, once every two years in 10% of the hospitals and once every year in 9% of the hospitals (see appendix 5). The time frame of an internal audit ranged from one month (9%) to seven months (2%), with a time frame of 2 months being most common (27%). Members of the audit teams were nurses (present in audit teams in 96% of the hospitals), management employees (present in audit teams in 84% of the hospitals), allied healthcare professionals (present in audit teams in 75% of the hospitals) and medical specialists (present in audit teams in 68% of the hospitals). One hospital (1%) had 5-10 auditors in total, while 65% of the hospitals had more than 20 auditors in total. In 81% of the hospitals auditors received training, and in 74% of the hospitals auditors were evaluated. Of the 68 hospitals, six did not train nor evaluate their auditors (9%). 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. As inputs for the internal audit outcomes, the following were used: document analysis by audit team (100% of the hospitals), interviews by audit team (100% of the hospitals), site-visits by audit team (100% of hospitals), self-evaluation by audited department (59% of the hospitals), ad-hoc measures by audit team (34%) and other measures (37%). These other measures were:

- Outcomes of other audits when present, such as audits by external experts, external audits for accreditation and audits initiated by the professional association of medical specialties (visitations);
- Outcomes of surveys amongst employees of partner departments (such as a surveys amongst an orthopaedic department when a radiology department is being audited);
- Outcomes of medical record reviews.

Feedback of audit results

The ways in which audit results were fed back to the boards of directors differed per hospital. Three options have been found:

1. The board of directors receives a report on the headlines deriving from internal audits (aggregated results; found in 50% of the hospitals).
2. The board of directors receives letter with recommendations based on audit results and has the option to ask audited department for the entire audit report (found in 17% of the hospitals).
3. The board of directors receives entire audit report (found in 50% of the hospitals).

In one hospital, multiple options have been found. In that hospital, the board received a report on the headlines deriving from all internal audits and the entire report of the executed audits on supportive departments.

In interviews, members of the boards of directors of all hospitals stated that it is the responsibility of the departments to implement improvement actions, except in the following situations: 1) when patient safety is immediately threatened—in this case, a board of directors uses the internal audit as a 'forced improvement'-instrument; and 2) when improvements cannot be made without support from a board of directors, for example when equipment is out-of-date and cannot be replaced without consent of a board of directors.

Experiences with effectiveness of internal audits

Use of internal audits for identification of safety problems

Board members perceived internal audits as effective for the identification of safety problems for three reasons: 1) broad, multidisciplinary scope; 2) soft signals; and 3) in-depth approach (see table 2 for illustrative quotes).

Interviewees stressed that with internal audits every department of a hospital, including supportive departments, is evaluated periodically. Furthermore, an internal audit has a multidisciplinary focus (e.g., involving the opinions of other departments regarding the audited department and not only focusing on clinicians or nurses, but all employees both in an audit team and as auditees). Board members noted that this broad scope of an internal audit provided a complete overview of the performance of all departments in an entire organization.

According to board members, the use of qualitative methods of gathering information (e.g., interviews and observations) makes an internal audit a suitable instrument not just to establish that things are going wrong, but most of all reveal why these things happen. Board members stated that as a result, an internal audit was able to provide information regarding the soft side of an organization, such as cooperation and communication problems. Nonetheless, they noted these soft signals are not easily translated into facts that can be reported in an audit report.

Board members indicated that an internal audit is an instrument with a very structured and in-depth approach. The quality and safety of an entire department is being evaluated, from cleaning to medical treatment and from medical chart reviews and policy documents to interviews with employees, after thorough preparations of both an audit team and an audited department. Board members stated that this reveals patient safety problems in a structured way, and because of the fact that improvement actions are suggested, audits help boards prioritize what should be done to improve patient safety. Board members indicated that an internal audit is especially suited for generating patient safety information in a planned and prepared manner, but mentioned that because of the low frequency of internal audits (because of the time-consuming, in-depth approach) there is a lack of real-time information.

Use of audit information to steer quality and safety

Two categories emerged within this theme: 1) monitoring; and 2) incentive for change.

Board members mentioned that embedding internal audit results in a planning and control cycle gives them the opportunity to have a dialogue regarding the status of quality improvements made by departments. They noted that monitoring and frequently discussing audit results and improvement plans contributes to the feeling of being in control. A caveat mentioned by one board member regarding being in control with the internal audit is that, as with every instrument, critical incidents can still happen.

Board members mentioned that audit results can be an incentive for them to adjust hospital policy and culture. Different interviewees stated that internal audit results were a reason for them to make changes happen as soon as possible, whether these were adjustments needed to be made by the board itself, or by departments. Boards used internal audits to start a conversation with staff and as an incentive to visit departments themselves.

Table 2. Themes, categories and quotes relating to effectiveness of internal audit

Theme	Category	Quotes
Use of the internal audit for identification of safety risks	Broad, multidisciplinary scope	*"Well, an internal audit is department-wide and multidisciplinary, you talk with professionals of that department, but also with its customers. Like, if there's an audit at radiology, you talk to specialists of other departments that use the services of radiology as well. With tracers, you don't have that complete overview."* *"And the internal audit contributes to an overall view of a department, of a group of people who are active within a certain discipline: clinicians, nurses, allied healthcare professionals… and yes, you get insight into the department on an aggregated level."*
	Soft signals	*"[With the internal audit] you can get a global impression regarding the actual performance, so to say, and cooperation as well (…). The question could be: 'how is everything going,' and they would say: 'perfect, we are doing the best we can'. Well, show me!"* *"Well, I think that the soft signals… Partially they derive from the internal audit (…) but it is just very complicated, you know. I think an internal audit should begin with the question: 'Why do you like working here?' That is not something you can write down in three sentences in the audit report. It is as soft as you can get, but it is very significant for how people are feeling in their job."*
	In-depth approach	*"So it shows where the need for improvements lie and what you should prioritize… It prioritizes in the way, like, what is going right and what is going wrong?"* *"Especially when auditors don't just score, but ask questions, you get more information, like 'why is it going wrong?'"* *"Maybe it's even more important to be open and susceptible to signals from within the organization. We talk to chairmen of staff and divisions very often. You cannot wait for the internal audit to take place in a few years to feel safe regarding the functioning of a department."*

Use of audit information to steer patient safety.	Monitoring	*"And in our quarterly report, in our four-times-a-year cycle, we ask every unit to report on the audits that have been performed; what were the results, what did you encounter and which actions did you think of, and these actions, are they implemented and are they leading towards results (…)."* *"For us, as board of directors, it's about knowing what the conclusion regarding the department is, in the context of general functioning, leadership and yes, quality and safety. And that is one of the sources we need to, so to say, feel secure in how the organization is doing."*
	Incentive for change	*"Something in which we intervened immediately was the double check on medication. That was a moment in which we said: this is unacceptable. These answers are unacceptable. So I went there, and the medical directors as well, and we said, this is out of the question. This has to change by tomorrow."* *"We've also looked at what is the reason that that happens; don't we need to alter the procedure? So it is about steering, saying: 'this is unacceptable', but it is also a moment of thinking: 'did we organize it correctly?'"*
Use of audit information to account for patient safety	Use of internal audit information in regular meetings with the board of supervisors	*"Yes, to inform. By the way, our board of supervisors is very on top of it, they will ask: what did you do about it? So you need to have that answer as well."*
	Use of audit information to inform the board of supervisors regarding critical incidents	*"And if we say: 'This is critical, these people have to be informed before the report is finished', then I will call them and they will come over."* *"It's not good for internal monitoring because that will cause a mix-up between the responsibilities of the board of directors and the board of supervisors. Negative results of an audit should be solved in the management line of the hospital. Having said that, the existence of an internal audit system, that they are performed accurately, that there are reports on the results and the system as a whole, helps us to trust the board of directors."*

Use of internal audits to account for patient safety

Two categories derived from this theme: 1) use of internal audit information in regular meetings with boards of supervisors; and 2) use of audit information to inform boards of supervisors regarding critical incidents.

Board members stated that an internal audit is one of the information sources used to inform a board of supervisors about the status of patient safety. It is used on a regular base, as part of the regular meetings between boards of directors and boards of supervisors, on an aggregated level. Interviewees stressed the latter: an internal audit is not discussed in detail, as it is not the job of a board of supervisors to monitor departments in detail. Members of boards of directors stated that instead, they use the headlines of the performed audits to show boards of supervisors whether a hospital is able to learn and improve.

There is an exception when discussing an internal audit on an aggregated level. Members of different boards mentioned that when critical incidents derived from internal audits, boards of supervisors are informed of these incidents.

DISCUSSION

The aim of this study was to describe the organization of internal audits in Dutch hospitals and to evaluate the effectiveness of these audits for boards to govern patient safety. Our quantitative and qualitative findings revealed that there were similarities in how internal audits were organized in the hospitals. The audit cycle, following the plan-do-check-act cycle, the methods used to gather information (e.g., interviews, site visits, and document analysis) and the responsibilities of the boards of directors and the committees responsible for audits were in general the same in all hospitals throughout the Netherlands. Aspects that differed amongst hospitals were related to feasibility, and included the number of auditors and disciplines such as medical specialists present in an audit team, the duration of an internal audit and the amount of methods used to get insight into the quality and safety of departments.

Interviewed hospital board members stated that internal audits help them to identify safety problems and to steer patient safety. Internal audits provide a complete overview of departments, prioritize safety problems, are an incentive to adjust policy and are used to monitor safety improvements. A study regarding governance activities of Australian hospital boards showed four tools that are similar to the effective aspects of an internal audit, namely 'shaping culture', 'measuring progress', 'setting priorities' and 'ensuring accountability' [31]. The use of qualitative methods (e.g., interviews and observations) makes an internal audit unique compared to quantitative instruments (e.g., quality indicators) that boards have for governance. However, since internal audits are highly structured and standardized, their frequency is low which results in limited real-time information. Another disadvantage of an internal audit's formal character is that soft signals deriving from the qualitative methods are difficult to include in the audit report—even though board members mentioned that these outcomes especially say a lot about the quality and safety of care. These outcomes give insight into in problems regarding patient safety culture, communication and collaboration.

The attention to effective board oversight and tools to assist boards in this task is ever growing [2,6,12,31-33]. This study contributes to research in this field by evaluating an instrument that is already used in almost every hospital in the Netherlands. Internal audits in Dutch hospitals has existed since the 1990s and are initiated by hospital boards. However, to our knowledge, the Dutch internal auditing process has never been evaluated before and there is little-to-no literature on the evaluation of the effectiveness of internal audits for hospital governance [19,34,35]. Our study indicates that an internal audit might be a promising instrument for hospital boards. Internal audits provide a complete, multidisciplinary and periodic overview of quality and safety problems, their underlying causes and needed improvement actions. Research regarding dashboards or scorecards using measurements such as the Hospital Standardized Mortality Ratio (HSMR) or complications and lengths of stay, showed that a disadvantage of these measurements is that they do not always provide relevant information regarding the underlying problem(s) or causes related to how to *improve* quality and safety [12,36-39]. Indicators such as HSMR do not go further than revealing that there is a problem, while an internal audit is able to reveal why there is a problem because of the use of qualitative methods [40,41]. Our finding that the soft signals deriving from these qualitative methods are important to gaining insight into the underlying causes of quality and safety problems has been found in other studies regarding board oversight as well [36,42,43]. 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 [44]. 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.

A strength of this study is that we used a mixed-method approach. The questionnaire enabled us to get a complete overview of the organization of internal audits in all Dutch hospitals and the qualitative measures provided us with in-depth information on the experiences of boards regarded to the effectiveness of internal audits to govern patient safety. Another strength of this study is the high response rate to both the questionnaire and the interviews; there were only two interviewees who did not grant the request for an interview, resulting in a high internal validity of the results. Moreover, we interviewed every stakeholder in the audit process, including members of boards of directors and boards of supervisors, even though this a group that is not easy to involve (in research).

A limitation of our study is that we studied internal audits only in Dutch hospitals. Therefore, generalization to other countries or healthcare settings might be limited. We know that internal audits exist in hospitals in other countries, however, we have not found literature in which the use of internal audits in these countries has been described or evaluated [19,34] and therefore we could not make comparisons between Dutch internal audits and internal audits in other countries. Another limitation is the number of members of boards of directors that we interviewed for information on their experiences with internal audits. Most of the information on the regarded effectiveness of internal audits came from the interviews with members of boards of directors. Because of time constraints and the time-consuming qualitative methods we used, we could only perform an in-depth study in six hospitals. However, we have reached saturation and found substantial consistency in experiences of boards with internal audits. This led us to believe that their experiences are representative for other hospital boards. Moreover, we were able to use the interviews with quality and safety directors and heads of departments or clinical managers to validate the boards' experiences. 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]).

Conclusion

This is the first study in which the organization and the perceived effectiveness of internal audits to govern patient safety in hospitals is evaluated. Our findings showed that internal audits were regarded as effective for the governance of patient safety, as they help boards to identify patient safety problems, steer patient safety and account for patient safety. Internal audits provide boards with structured, standardized, formal and periodic overviews of quality and safety problems and underlying causes in all departments in a hospital, helping boards prioritize improvement actions and giving them a sense of being in control. Furthermore, the use of qualitative methods to identify soft signals makes an internal audit a unique instrument in the entire spectrum of governance strategies for boards. Hospital boards can use the description of Dutch internal audits given in this paper to complement their systems to govern patient safety.

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COMPETING INTERESTS

The authors declare that there are no competing interests. The funding bodies had no involvement in the design and conduct of the study, nor in the writing and submission of this manuscript.

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ETHICAL APPROVAL

The study protocol has been presented to the Medical Ethical Committee of the Radboud University Nijmegen Medical Centre (registration number: 2011/332). The committee declared ethical approval was not required under Dutch National Law.

AUTHORS' CONTRIBUTIONS

SvG carried out the research and drafted the manuscript. MZ conceived the study, contributed to the design and coordination of the study, drafted the manuscript and helped to carry out the research. HW contributed to the design and coordination of the study. HW, GW, PR and WB revised the manuscript critically. All authors read and approved the final manuscript.

DATA SHARING

No additional data

FIGURE LEGENDS

Figure 1.

Positioning of internal audit in governance of Dutch hospitals. Framework is based on two studies: the 'Deepening our Understanding of Quality Improvement in Europe' (DUQuE) project [24] and the 'Quality and Safety in Europe by Research' (QUASER) study [25].

Figure 2.

Internal audit cycle for governance purposes.

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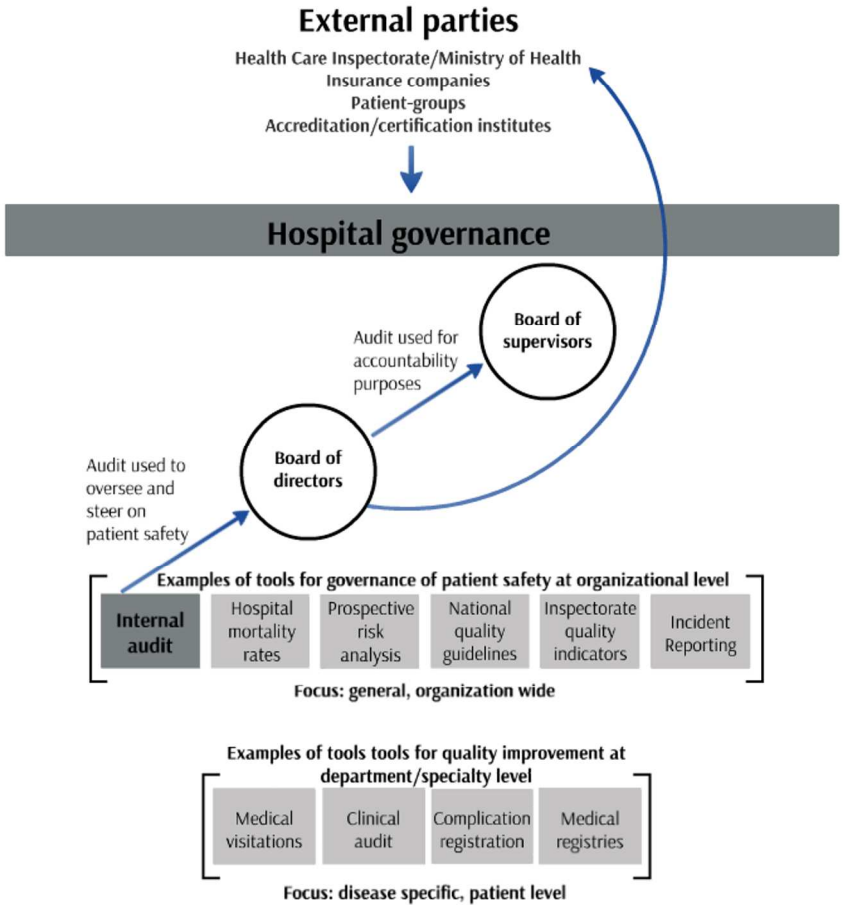

Figure 2. Positioning of internal audit in governance of Dutch hospitals. Framework is based on two studies: the 'Deepening our Understanding of Quality Improvement in Europe' (DUQuE) project [24] and the 'Quality and Safety in Europe by Research' (QUASER) study [25].

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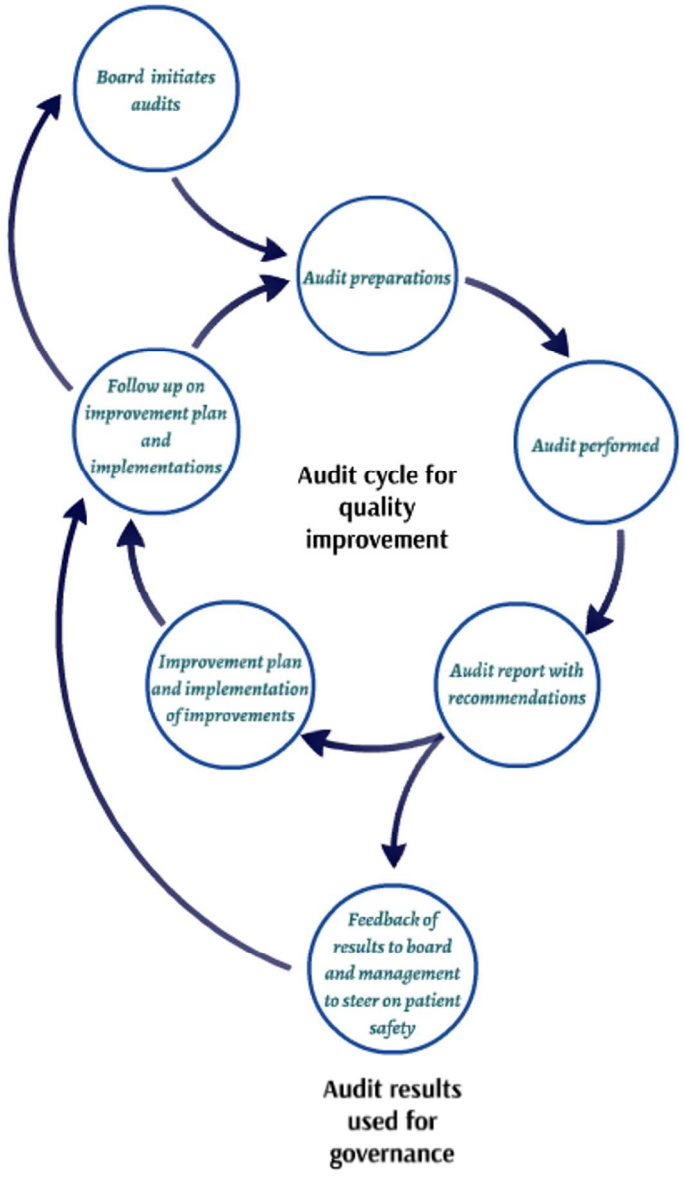

Figure 2. Internal audit cycle for governance purposes.

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APPENDICES

Appendix 1. Hospital sampling criteria for interviews

Selection criterion	Description
Variation in hospital type	University hospitals, tertiary teaching hospitals[1] and general hospitals .
Variation in standards and regulations for designing internal audit system	Different standards for the design of internal audit systems (e.g. NIAZ, JCI, VMS).
>5 years of experience with internal auditing	Only hospitals with more than five years' experience with internal audits were included, because this assured that one internal audit cycle would have been completed.
Variation in data sources used for internal audit	A distribution of hospitals with different sources of input for their internal audit; such as interviews, observations, surveys amongst employees and patients, and self-evaluation.
Medical specialist in audit team	A distribution of hospitals with, and without medical specialists in their audit team.
Hours spent per internal audit	Hospitals that spent less than 100, between 100-250 and more than 250 hours per audit.
Geographical spread/location	Two different provinces per type of hospital.

[1] Tertiary teaching hospitals in the Netherlands provide highly specialised care and train doctors in collaboration with university hospitals.

Appendix 2. Questionnaire 2012

Content

1. Which standards are used by your hospital for the internal audit (multiple responses possible)?
   - Standards of accreditation institutes
   - Standards set by law
   - Standards set by profession
   - Standards set by hospital itself
   - Other, namely:
2. What is used as input for the internal audit in your hospital (multiple responses possible)?
   - Outcomes of self-evaluation by department
   - Outcomes of document analysis by audit team
   - Outcomes of interviews by audit team
   - Outcomes of site-visits by audit team
   - Outcomes of ad hoc measures by audit team
   - Other, namely:

Organization

3. Who are the members of the audit team in your hospital (multiple responses possible)?
   - Medical specialists
   - Allied healthcare professionals
   - Nurses
   - Management
4. What is the total number of auditors in your hospital?
   - < 5
   - 5-10
   - 10-20
   - >20
5. Do auditors receive training and/or are they structurally evaluated (multiple responses possible)?
   - Training
   - Evaluation
   - No training, no evaluation
6. What is the time frame of one internal audit (from the first preparations to feedback of results to audited department)?
   …… months
7. What is the frequency of the internal audit?
   Once every … year(s)

Appendix 3. COREQ guidelines table

No. Item	Guide questions/description	
Domain 1: Research team and reflexivity		
Personal Characteristics		
1. Inter viewer/facilitator	Which author/s conducted the interview or focus group?	SvG and MZ
2. Credentials	What were the researcher's credentials? E.g. PhD, MD	1 MA, 1 PhD
3. Occupation	What was their occupation at the time of the study?	Research Fellows
4. Gender	Was the researcher male or female?	Both female
5. Experience and training	What experience or training did the researcher have?	Two researchers received training in interviewing. Both followed courses on qualitative research
Relationship with participants		
6. Relationship established	Was a relationship established prior to study commencement?	Yes, to one of them. However, we made sure to act the same as in all other interviews (sending the topic guide prior to the interview, introducing ourselves, no small talk during the interview) so that this did not affect the data.
7. Participant knowledge of the interviewer	What did the participants know about the researcher? e.g. personal goals, reasons for doing the research	Broad outlines given
8. Interviewer characteristics	What characteristics were reported about the inter viewer/facilitator? e.g. Bias, assumptions, reasons and interests in the research topic	Reasons for research
Domain 2: study design		
Theoretical framework		
9. Methodological orientation and Theory	What methodological orientation was stated to underpin the study? e.g. grounded theory, discourse analysis, ethnography, phenomenology, content analysis	Thematic analysis
Participant selection		
10. Sampling	How were participants selected? e.g. purposive, convenience, consecutive, snowball	Purposively sampled
11. Method of approach	How were participants approached? e.g. face-to-face, telephone, mail, email	Face-to-face, telephone and email
12. Sample size	How many participants were in the study?	43
13. Non-participation	How many people refused to participate or dropped out? Reasons?	Two not interviewed for lack of time
Setting		
14. Setting of data collection	Where was the data collected? e.g. home, clinic, workplace	Clinic and workplace
15. Presence of non-participants	Was anyone else present besides the participants and researchers?	No
16. Description of sample	What are the important characteristics of the sample? e.g. demographic data, date	Boards of Directors (n=5), Boards of

		Supervisors (n=5), Quality and safety directors (n=7), Quality officers (n=14), Head of department or clinical manager (auditees) (n=12). Of the interviewees, 56% was female, and 40% had six or more years of experience in their current function.
Data collection		
17. Interview guide	Were questions, prompts, guides provided by the authors? Was it pilot tested?	Interview guides were sent to interviewees prior to the interview. The topic guides were pilot tested.
18. Repeat interviews	Were repeat interviews carried out? If yes, how many?	No
19. Audio/visual recording	Did the research use audio or visual recording to collect the data?	Audiotaped
20. Field notes	Were field notes made during and/or after the interview or focus group?	Yes, after some interviews
21. Duration	What was the duration of the inter views or focus group?	30–60 minutes
22. Data saturation	Was data saturation discussed?	Yes and reached
23. Transcripts returned	Were transcripts returned to participants for comment and/or correction?	If desired; no adjustments were made by interviewees
Domain 3: analysis and findings		
Data analysis		
24. Number of data coders	How many data coders coded the data?	3
25. Description of the coding tree	Did authors provide a description of the coding tree?	Yes
26. Derivation of themes	Were themes identified in advance or derived from the data?	Identified in advanced and derived from the data
27. Software	What software, if applicable, was used to manage the data?	Atlas.ti software version 7.0
28. Participant checking	Did participants provide feedback on the findings?	No
Reporting		
29. Quotations presented	Were participant quotations presented to illustrate the themes/findings? Was each quotation identified? e.g. participant number	Yes, but not with a participant number
30. Data and findings consistent	Was there consistency between the data presented and the findings?	Yes
31. Clarity of major themes	Were major themes clearly presented in the findings?	Yes
32. Clarity of minor themes	Is there a description of diverse cases or discussion of minor themes?	Yes

Appendix 4. Topics for guiding interviews with stakeholders in the audit and governance process

1. How are internal audits set up in your hospital?
2. Is the focus of the audit determined beforehand?
3. Which framework do you use for the internal audit and why?
4. What methods do you use to gather information and why?
5. What kind of information do you get from audits and how do you use it?
6. What does an audit result say about the actual state of a department?
7. To what extent do you use the internal audit to oversee patient safety?
8. To what extent do you use the internal audit to steer patient safety?
9. To what extent are internal audit results discussed with the board of supervisors?
10. To what extent does the internal audit contribute to the feeling of being 'in control'?
11. What were the advantages or disadvantages of the internal audit for your hospital?
12. How do you oversee the quality and safety in your hospital?

Appendix 5. Organization and content of internal audit

Organization and content of the internal audit in Dutch hospitals (n = 68)

	n	%
Frequency of audit[§]		
Every year	6	9
Every 2 years	7	10
Every 3 years	9	13
Every 4 years	45	66
Time frame of one internal audit		
1 month	6	9
2 months	18	27
3 months	17	25
4 months	6	9
5 months	2	3
6 months	6	9
7 months	2	3
Members of the audit team		
Medical specialists	46	68
Allied healthcare professionals	51	75
Nurses	65	96
Management	57	84
Total number of auditors in hospital		
5–10	1	1
10–20	23	34
>20	44	65
Structural training and/or evaluation of auditors?		
Training	55	81
Evaluation	50	74
No training, no evaluation	6	9
Framework for audit		
Standards of accreditation institutes	66	97
Standards set by law	45	66
Standards set by profession	18	27
Standards set by hospital itself	22	32
Other[†]	25	37
Input for audit		
Outcomes of self-evaluation by department	40	59
Outcomes of document analysis by audit team	68	100
Outcomes of interviews by audit team	68	100
Outcomes of site-visits by audit team	68	100
Outcomes of ad hoc measures by audit team	23	34
Other[¥]	14	21

[§] When responding to the questions regarding 'Frequency of audit', 'Time frame of audit' and 'Number of auditors', respondents could only choose one option, whereas when responding to the other questions, respondents could choose multiple options.

[†]ISO, VMS, HKZ, CCL, NEN, NTA, JACIE, MediRisk

¥Outcomes of other audits when present, such as audits by external experts and audits initiated by medical specialties; outcomes of satisfaction questionnaires amongst partner departments (such as an orthopedic department when the radiology department is being audited); outcomes of tracers; outcomes of chart reviews; outcomes of team climate inventory.

Research checklist
COREQ guidelines table

No. Item	Guide questions/description	
Domain 1: Research team and reflexivity		
Personal Characteristics		
1. Inter viewer/facilitator	Which author/s conducted the interview or focus group?	SvG and MZ
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3. Occupation	What was their occupation at the time of the study?	Research Fellows
4. Gender	Was the researcher male or female?	Both female
5. Experience and training	What experience or training did the researcher have?	Two researchers received training in interviewing. Both followed courses on qualitative research
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7. Participant knowledge of the interviewer	What did the participants know about the researcher? e.g. personal goals, reasons for doing the research	Broad outlines given
8. Interviewer characteristics	What characteristics were reported about the inter viewer/facilitator? e.g. Bias, assumptions, reasons and interests in the research topic	Reasons for research
Domain 2: study design		
Theoretical framework		
9. Methodological orientation and Theory	What methodological orientation was stated to underpin the study? e.g. grounded theory, discourse analysis, ethnography, phenomenology, content analysis	Thematic analysis
Participant selection		
10. Sampling	How were participants selected? e.g. purposive, convenience, consecutive, snowball	Purposively sampled
11. Method of approach	How were participants approached? e.g. face-to-face, telephone, mail, email	Face-to-face, telephone and email
12. Sample size	How many participants were in the study?	43
13. Non-participation	How many people refused to participate or dropped out? Reasons?	Two not interviewed for lack of time
Setting		
14. Setting of data collection	Where was the data collected? e.g. home, clinic, workplace	Clinic and workplace
15. Presence of non-participants	Was anyone else present besides the participants and researchers?	No
16. Description of sample	What are the important characteristics of the sample?	Boards of Directors

	e.g. demographic data, date	(n=5), Boards of Supervisors (n=5), Quality and safety directors (n=7), Quality officers (n=14), Head of department or clinical manager (auditees) (n=12). Of the interviewees, 56% was female, and 40% had six or more years of experience in their current function.
Data collection		
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Data analysis		
24. Number of data coders	How many data coders coded the data?	3
25. Description of the coding tree	Did authors provide a description of the coding tree?	Yes
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27. Software	What software, if applicable, was used to manage the data?	Atlas.ti software version 7.0
28. Participant checking	Did participants provide feedback on the findings?	No
Reporting		
29. Quotations presented	Were participant quotations presented to illustrate the themes/findings? Was each quotation identified? e.g. participant number	Yes, but not with a participant number
30. Data and findings consistent	Was there consistency between the data presented and the findings?	Yes
31. Clarity of major themes	Were major themes clearly presented in the findings?	Yes
32. Clarity of minor themes	Is there a description of diverse cases or discussion of minor themes?	Yes
No. Item	**Guide questions/description**	
Domain 1: Research team and reflexivity		
Personal Characteristics		
1. Inter viewer/facilitator	Which author/s conducted the interview or focus group?	SvG, GH and MZ

2. Credentials	What were the researcher's credentials? E.g. PhD, MD	1 MA, 2 PhD
3. Occupation	What was their occupation at the time of the study?	Research Fellows
4. Gender	Was the researcher male or female?	2 female, 1 male
5. Experience and training	What experience or training did the researcher have?	Two researchers received training in interviewing. Both followed courses on qualitative research
Relationship with participants		
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15. Presence of non-participants	Was anyone else present besides the participants and researchers?	No
16. Description of sample	What are the important characteristics of the sample? e.g. demographic data, date	Boards of Directors (n=5), Boards of Supervisors (n=5), Clinical managers (n=12), Quality Officers (n=21) (see table 2). Of the interviewees, 56% was female, and 40% had six or more years of experience in their current function.
Data collection		

17. Interview guide	Were questions, prompts, guides provided by the authors? Was it pilot tested?	Interview guides were sent to interviewees prior to the interview. The topic guides were pilot tested.
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