ORIGINAL ARTICLE

Optimal governance of patient safety: A qualitative study on barriers to and facilitators for effective internal audit

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ABSTRACT

Objective: While internal audits are widely used, insight into the essential components of the internal audit to govern patient safety is limited. The aim of this study is to explore factors that hinder and stimulate internal audits as an effective patient safety governance tool for hospital boards.
Methods: A qualitative interview study in six Dutch hospitals. Interviews (n = 43) were held with auditees, quality officers, boards of directors and boards of supervisors. Data were collected and analysed using Grounded Theory.
Results: Barriers and facilitators were classified into 14 categories from which four themes emerged: (1) board positioning of audits, (2) organisation and content of audits, (3) competences and composition of audit team, and (4) cultural factors and attitudes towards auditing.
Conclusions: We found two themes consisting of factors related to the audit itself (organisation and content of audits, and competences and composition of audit team) and two themes consisting of contextual factors (board positioning of audits, and cultural factors and attitudes towards auditing). These may contribute to support for auditing and to the generation of reliable audit results, which subsequently could result in effective audits for governance of patient safety. Hospital boards and executives can optimise the patient safety auditing system in their hospitals by increasing active leadership engagement, by promoting audits as an opportunity for staff to learn from safety problems (rather than a mandatory examination instrument) and by providing vital resources for a smooth audit process, such as a medical specialist in the audit team.

Key Words: Audit, Clinical governance, Patient safety, Hospital, Quality improvement

1. INTRODUCTION

Hospital boards are legally responsible for patient safety.[1–3] Effective governance is increasingly valued as an important prerequisite for sustained improvement of delivered care.[1,4] However, recent healthcare incidents suggest that hospital governance is not optimal and hospital boards are in need for methods to assist them in their governance task.[5–8]

There are several sources from which hospital boards can

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gather quality and safety information, for example safety walk-arounds, patient safety indicators, incident reports, infection rates, patient satisfaction surveys, risk registers and adverse events meetings.[9, 10] In almost every Dutch hospital, boards use information deriving from internal audits.[11] The Dutch internal audit system is an "objective assurance and consulting system for detecting patients' risks of adverse events early, and it should encourage the continuous improvement of patient safety".[11] It is a method that is implemented to measure whether organisational preconditions for safe care are in place and to induce improvements when they are not.[11]

The internal audit is initiated by hospital boards and implemented top-down. Using a combination of different methods, for example interviews, observations and chart reviews, an internal audit is able to reveal underlying factors causing safety risks and poor safety outcomes, such as high mortality rates.[12, 13] Users of the information deriving from the internal audit are therefore up to date regarding the actions that must be undertaken to improve patient safety.[11, 12] The aim of the internal audit system in Dutch hospitals is described in Table 1.

Table 1. The aim of the Dutch internal audit in hospitals

An internal audit is a systematic evaluation of the quality system of a hospital. The aim of the internal audit is to improve patient safety, by measuring preconditions for safe care and performance of health care providers, and comparing these outcomes to (national) standards and guidelines. The measurements are performed by an audit team existing of internal peers (i.e. employees from within the hospital who audit other departments), hence the term internal audit.

Internal audits are widely used in Dutch hospitals.[11] However, knowledge about the critical factors for effective auditing for governance of patient safety is limited.[14, 15] Better insight into the barriers and facilitators for effective auditing could contribute to the effective implementation of audit systems and optimising existing audit systems in hospitals. By exploring the experiences and perceptions of a broad range of stakeholders involved in auditing patient safety (i.e., clinicians, auditors, quality managers, boards of directors and boards of supervisors) in multiple hospitals, this study aims to gain a comprehensive understanding of the factors that hinder and stimulate effective auditing to govern patient safety within hospitals.

2. METHOD

2.1 Study design and setting

We conducted a qualitative interview study in six Dutch hospitals. An interview study enabled us to gain a comprehensive view of the stakeholders' experiences with auditing in different hospitals in detail.[16, 17] Interviews were held in two university hospitals, two tertiary medical teaching hospitals, and two general hospitals. Tertiary teaching hospitals in the Netherlands provide highly specialised care and train doctors in collaboration with university hospitals.

In the Netherlands, the most important reason for hospitals to have implemented an internal audit system is that it is one of the conditions for external accreditation.[18] Accreditation institutes provide guidelines for the content of audits, but these are not mandatory and hospitals can include different standards in their audit system, depending on their preferences. The cycle of the audits, however, is the same in almost every hospital (see Figure 1).

The internal audit for governance purposes starts with the board of directors approving the agenda for the upcoming audits. Preparations consist of analysis of policy documents and patient charts, a self-evaluation form for the department to-be-audited, determining the focus of the audit and looking at outcomes of earlier performed audits, tracers and visitations done by external professional bodies. After this, the audit team visits the department and performs the audit through interviews and observations. The audit team writes a report, consisting of feedback regarding improvements that must and can be made to increase patient safety (also known as recommendations). Audit results are fed back to the board of directors for governance purposes, and fed back to the audited department(s) to make an improvement plan. The results from the audit and the improvement plan are then followed up, after which the audit cycle starts again.

2.2 Sampling of hospitals

Six hospitals were purposively sampled. We used six criteria to select hospitals (see Table 2). To reconcile these criteria, we sent a questionnaire to all acute care hospitals in the Netherlands (n = 92), covering the topics that the selection criteria included. The criteria and questionnaire were based on: interviews with experts (n = 3), brainstorm sessions with the research team (n = 4) and literature on quality improvement and auditing. Based on the results of the survey, we approached two university hospitals, two tertiary medical teaching hospitals and two general hospitals, which together represented the different types of hospitals in the Netherlands and the different aspects of audit systems in Dutch hospitals. All six hospitals decided to participate in the study. The participating hospitals were located across the country and ranged in size from 536 beds up to 1,003 beds. Within every hospital, the board of directors was controlled by a supervisory board, according to the so-called governance code.[19] The roles of these boards in this governance structure are as follows: the board of directors governs patient

safety and accounts for patient safety towards the board of supervisors, and the board of supervisors supervises the board of directors.[20]

2.3 Data collection

In-depth interviews were held face to face with auditees, quality officers, boards of directors and boards of supervisors. Interviews were conducted by experienced interviewers (SvG and GH). Topics that guided the interviews were: experiences with auditing, barriers and facilitators for auditing, and perceptions about the internal auditing process in general. Participants were purposively sampled to ensure diversity (e.g., experience with audits, auditing, and type of job) and availability (i.e., convenience sampling). Interviews were audio-recorded with the participants' consent and transcribed verbatim according to a standardised format. To maximise candid discussion, interviewees were assured confidentiality by a signed declaration form. Data collection and analysis were performed based on the Consolidated criteria for reporting qualitative studies (COREQ).[21]

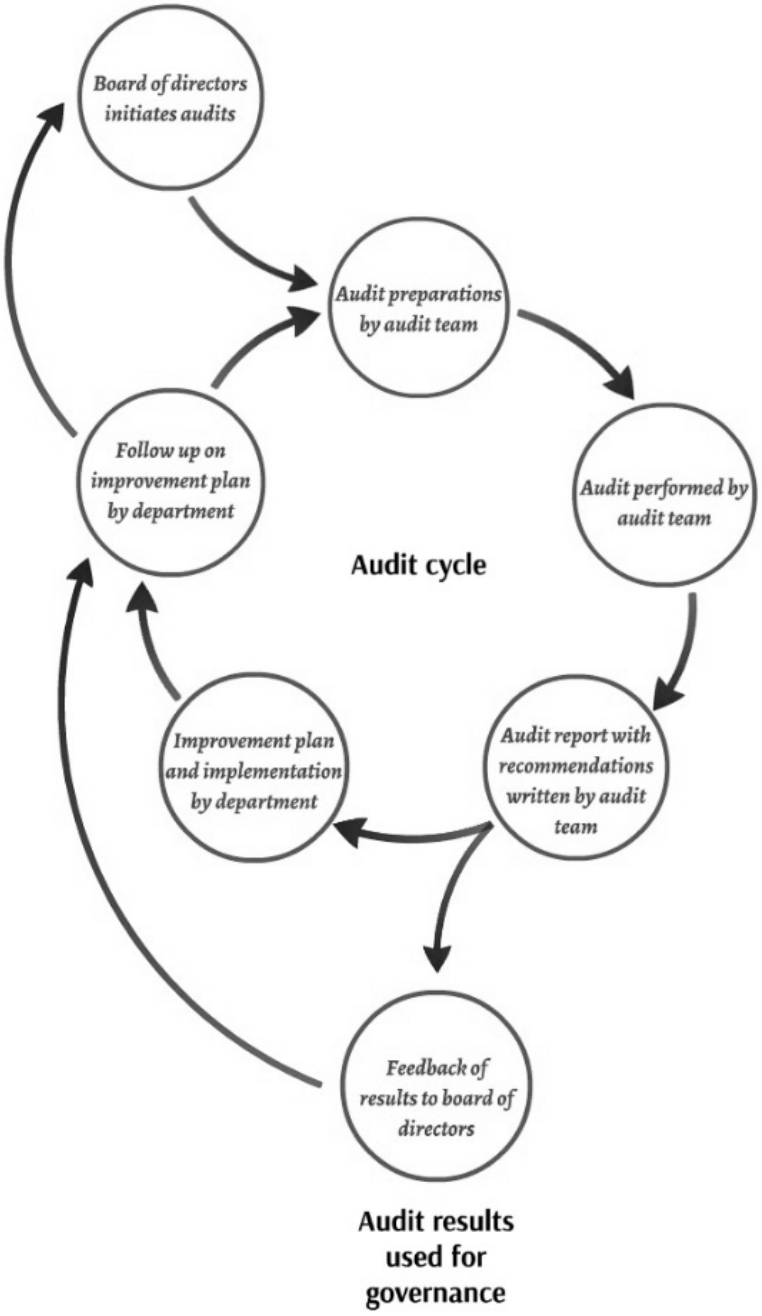

Figure 1. Internal audit cycle for governance purposes in Dutch hospitals

2.4 Data analysis

The transcriptions of the interviews were analysed using Grounded Theory.[22] The iterative character of theoretical sampling enabled us to discover and select new interview topics and participants during the interview process.[17] Transcripts were coded using Atlas.ti software version 7.0 (ATLAS.ti Scientific Software Development Company, GmbH, Berlin, Germany). Coding is an interpretative process in which conceptual labels are assigned to data. Three researchers (SvG, GH and MZ) independently analysed and discussed the content of the first (n = 4) interviews, which formed the basis of a coding framework. Two researchers (SvG and GH) independently 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 amongst the researchers (SvG, GH and MZ). On each hospital site, interviews were held until saturation was reached (i.e., no new codes were generated).[23]

Table 2. Hospital sampling criteria

Selection criterion	Description
Variation in hospital type	University hospitals, tertiary medical teaching hospitals 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[€], VMS[₴], JCI[ξ]).
> 5 years of experience with internal auditing	Only hospitals with more than five years' experience were included.
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.

Note. [€] Netherlands Institute for Accreditation in Healthcare; [₴] Safety Management System (in Dutch "VeiligheidsManagementSysteem"); [ξ] Joint Commission International

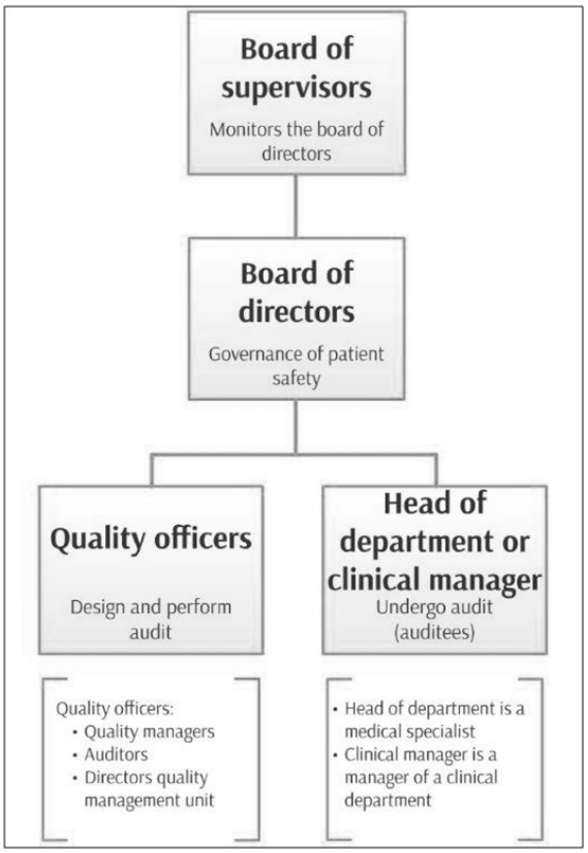

Figure 2. Description of interview partners

Table 3. Number of interview subjects and their professional and personal characteristics (n = 43)

Interview partner	*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
• Head of department[§] or clinical manager	12	28
• Quality officer	21	48
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

Note. [§]A medical specialist

2.5 Ethical approval

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

3. RESULTS

3.1 Participant characteristics

We performed 43 interviews with members of boards of directors (n = 5), members of boards of supervisors (n = 5), heads of departments (medical specialists) or clinical managers (n = 12), and quality officers (n = 21) (see Figure 2). In two cases, the request for an interview was not granted because of time constraints. Of the interviewees, 56% were female, and 40% had six or more years of experience in their current function. The distribution of interview subjects amongst the different types of hospitals ranged from 12 to 16 interview subjects per type of hospital (see Table 3).

The analysis resulted in the creation of 14 categories, from which four themes emerged: (1) board positioning of audits; (2) organisation and content of audits; (3) competences and composition of audit team; and (4) cultural factors and attitudes towards auditing. Table 4 shows these themes and categories, illustrated by quotes.

3.2 Theme I: Board positioning of audits

Two categories emerged within this theme: (1) prioritisation of audits by the hospital board; and (2) dissemination of audit purposes by hospital board.

3.2.1 *Prioritisation of audits by the hospital board*

Interviewees, in particular quality officers, expressed that a committed-board of directors is a prerequisite for effective auditing. According to several interviewees, the board of directors and hospital managers do not sufficiently prioritise audits as a useful tool to monitor and improve patient safety in their hospital, and that this may lead to a perceived lack of value amongst staff. An explanation given for insufficient prioritisation is that the attention to audits by the board of directors in everyday practice is weakened by competing priorities, such as urgent financial and human resource interests. Several interviewees mentioned the importance of the board of directors taking internal audits seriously and staying focussed on auditing (i.e., supervising quality improvement actions following the internal audit and coming up with repercussions for those responsible who do not carry out the imposed actions). Interviewees stated that it is vital to formalise this follow-up in the managerial chain in the hospital's planning and control cycle.

3.2.2 *Dissemination of audit purposes by the hospital board*

Several interviewees stressed that boards should pay more attention to promoting internal audits as a learning opportunity for employees. They mentioned that when employees perceive internal audits as an examination tool only implemented because of external obligation, it might make employees less motivated to use the internal audit as a driver for improvement: they only get feedback on what they did wrong and do not experience the added value. Several interviewees indicated that there is a link between a culture in which the audit is seen as a chance to improve and the motivation of healthcare professionals during an audit. They mentioned that hospital boards would benefit from motivated employees who cooperate more actively during audits (i.e., being available for interviews, being open and honest about problems, etc.), because this provides a complete image of a department.

3.3 Theme II: organisation and content of audits

Five categories were identified within this theme: (1) audit preparation and coordination; (2) department versus healthcare pathway as audit focus; (3) structure versus process and outcome assessment; (4) facts versus feelings; and (5) dissemination of audit results.

3.3.1 *Audit preparation and coordination*

Most interviewees experienced that the lack of thorough preparation negatively impacts the auditing process and its results. Clinical managers interviewees mentioned the use of a "process coordinator" as a facilitator for a smooth audit process; this person structures and coordinates the audit process, increasing the efficiency of the process and the uniformity and quality with which the audit results are reported. Interviewees, in particular quality officers, mentioned that communication about an upcoming audit is an important facilitator. A well-planned and -communicated audit adds to the commitment of auditees and helps to create support from the management. The experience of interviewees is that personnel are not always informed about a visit from the audit team and the purpose of the audit, and that this negatively impacts the availability of interview subjects and the quality of the interviews. Several interviewees mentioned that they have interviewed healthcare professionals who were not aware that an audit was taking place. They sensed that these auditees lacked openness and honesty during interviews, because they were caught off guard.

3.3.2 *Department versus healthcare pathway as audit focus*

Several interviewees expressed that audits in their current form lack a complete overview of process coordination and integration of provided care. Audits that focus on healthcare pathways would provide more insight into inefficiencies and adverse patient outcomes as a result of miscommunications and poor collaborations between care providers around one patient. Some interviewees spoke about their positive experiences with so-called "process audits", which can involve, for example using tracers on medication safety or following a patient from hospital admission to discharge.

Table 4. Themes, categories and representative quotes

Theme	Category	Representative Quotes
Board positioning of audits	• Prioritization of audits by the hospital board	• Quality officer: *Good positioning, this system is not like 'someone does this on the side, and then a piece of paper comes along with something written on it and you can do whatever you want with it'. No, it is a closed circle (...) with status in this hospital. Regular follow-up of the results by the board of directors in the quality improvement cycle, the board of directors that has more than enough attention for it.*
		• Interviewer: *And how do you experience the monitoring of the improvement actions?* Head of department (medical specialist): *Yes, I think that it's necessary to prevent the audit from being too informal. Because even doctors are only human, you know? So if you receive an audit report and you just put it in your drawer without doing anything with it, that doesn't seem right.*
	• Dissemination of audit purposes by the hospital board	• Member of the board of supervisors*: If you're asking for preconditions; I need to see that it's real, and that there is a real problem that we try to solve together by looking at data. And that it's not some sort of trick that we do because someone is doing an assignment for his internship, or that we do because it looks good as justification to the outside world. It really needs to be part of internal quality improvement activities.*
Organization and content of audits	• Audit preparation and coordination	• Quality officer: *It's just not possible... a bad preparation has a direct effect on an audit. We can tell straight away, that at the end of a morning like that, we say 'Yes, we missed out, that didn't go well (...) we should've taken that with us during preparations'.*
		• Quality officer: *And the support from especially the top management, so that they are informed, you see, a common excuse used to be 'Well, we are very busy right now', or something like that. If you receive the schedule for upcoming year in November or December, you say, 'Yes, but you should've notified us way earlier' (...).*
	• Department versus healthcare pathway as audit focus	• Quality officer: *What I regret (...) is that it's really focussed on islands, if I can say it like that, and less on the pathway of the healthcare process of a patient.*
	• Structure versus process and outcome assessment	• Quality officer: *So there is a lot of structure, but little process. And I find the relation, as long as the structure is in place, as long as the medication is up to date (...) as long as there are soap-dispensers, that's lovely, but I want to know whether people actually wash their hands. So I think that there are not enough process audits.*
		• Member of the board of directors: *It contributes only slightly, in the way that when the head of the quality and safety department tells me that the audit program (...) is being executed, I have the feeling that the infrastructure policy is in place. It does not contribute, because at the end the goal of auditing is the improvement and governance of quality, and it does not contribute to the feeling that the quality and safety are under control. A direct link between having audits and the feeling that quality and safety are actually under control, that I do not have.*
	• Facts versus soft signals	• Quality officer: *Sometimes you sense 'Hey, there's something here. I can't put my finger on it, but something is happening here, between sections of a department' (...) of which you feel 'Ouch, people need to have a good conversation here'. But you cannot put stuff like that in an audit report. That's not neutral enough. Not objective enough. We don't say that out loud either, while sometimes that might be something that the department especially needs to work on in order to proceed with other improvements.*
	• Dissemination of audit results	• Quality officer: *Well, if you'd ask me personally, I wouldn't want it to go just to the head of the department, because I think that every employee of the department should be able to have a look at the audit report, without it being only available by request. (...) I understand that heads of departments sometimes want to filter the results, but I think that the dissemination of the report doesn't always happen, especially not at departments where things aren't smooth to begin with and where the information of the audit report is important for the employees.*
		• Head of department (medical specialist): *And what I find difficult is the switch from 'Well, here's the audit report' to 'How do I get my department on the move to make the change?'. And I think that support after the audit, that's something that if you don't have that in place, then you shouldn't do the audit at all.*
Competences and composition of audit team	• Competences of auditors	• Clinical manager: *The biggest threat of an audit is (...) making your subjective opinion known. Yes, and objectivity; people need to trust you to be objective. And integrity, not like you did an audit and the next week you're standing in a bar talking about it. So integrity, and preaching that, I think that's important.*
	• Composition of audit team	• Quality officer: *A difficult thing is the availability of people, especially the medical staff, there are only two medical specialists in the audit pool and they're already gone. So the participation of medical staff might be the largest barrier. (...) Because ideally you'd like to see an audit performed by an audit team that's multidisciplinary; always a medical specialist, always a paramedic (...). But that's impossible, that's a utopia. (...) that's, yes that's a barrier, the time that people have, the availability.*
	• Training and evaluation auditors	• Quality Officer: *But it wouldn't be a bad idea to take a look at the quality of the individual auditor (...), when they are less suited to be an auditor, then it would be better to no longer have them in the audit team. But we haven't actually done that.*
	• Patient involvement in audits	• Head of department (medical specialist): *I think that, maybe it would be ideal to have a patient in the audit team as well. But, a patient is not a professional. You can say 'I'm going to train patients to perform an audit', but then there are a lot of ifs and buts. Because , who are these people who offer to do that anyway? What is the reason for them to offer their participation? Sometimes you see that people participate in forums or something like that, because they want to get their way, or straighten out a certain discomfort.*
Cultural factors and attitude towards auditing	• Presence of an audit culture	• Head of department (medical specialist): *Well, the willingness to participate. And obviously, it takes some explanation and information, but yes, especially when it's about patient and quality, every healthcare professional would participate.*
	• Transparency and learning attitudes of personnel	• Quality officer: *Preconditions are openness, the department needs to give us insight in what is going on, and the more open the department, the better we can assess. The barrier is when a department is not inclined to be open because there is a blame culture. You know, saying what is wrong, but getting blamed for that.*
	• Negative attitudes toward auditing	• Member of the board of directors: *So I'm, I feel, a little sceptical about the audit calendar. You know, and it has everything to do with the fact that there is so much... that we have to do. It's a lot for the people who have to actually do it. ... I hear them groan and moan.*
		• Member of the board of supervisors*: Well, I think that the most important precondition, for auditing as well, that as a subject, as the person who is undergoing this, that you feel that you get something out of it. So I feel that's it's a really important precondition for everything that has to do with quality, (...) that you know and see what's the added value for you.*

3.3.3 *Structure versus process and outcome assessment*

According to interviewees, audits mainly focus on structure indicators (e.g., availability of policies, presence and quality of technical equipment and protocols). They feel that this focus does not provide sufficient insight into the performance of healthcare providers and adverse outcomes at the patient level, while other interviewees stated that these measures are important safety issues necessary for hospital boards to have a sense of control.

3.3.4 *Facts versus soft signals*

Almost every interviewee stated the importance of only including validated (e.g., auditors hearing a statement more than once) findings in the audit report. Several hospitals work with a procedure in which the department checks the audit findings prior to finalising the audit report. According to interviewees this check contributes to the departments' acceptance of the auditing results and support for improvement actions. In contrast, some members of the boards of supervisors and members of the boards of directors expressed the need for more insight into soft signals indicating potential safety problems originating from more diffuse social and cultural aspects of healthcare (e.g., distrust, conflicts, rivalry between staff members).

3.3.5 *Dissemination of audit results*

Some interviewees, in particular the quality officers, noted that, for an effective audit, they would like to see that the audit results are automatically disseminated to every individual employee instead of via the head of the department, in order to engage employees in improvement actions. Other interviewees, however, stated that they feel that not every employee will understand the audit report and that dissemination to all employees may result in confusion about audit results. They experience this as a barrier for improvements. A few interviewees, in particular department heads, expressed the necessity of guidance for departments in translating audit results into improvement actions in an effective manner, for example by a special committee.

3.4 Theme III: competences and composition of audit team

Four categories emerged within this theme: (1) competences of auditors; (2) composition of the audit team; (3) training and evaluation of auditors; and (4) patient involvement in audits.

3.4.1 *Competences of auditors*

Almost all interviewees indicated that the quality of audits depends on the competences of auditors. According to interviewees, an auditor requires the following qualifications: objectivity, impartially, independence interview skills and integrity (i.e., being a trusted person for auditees to open up to). Knowing the auditees personally before performing the audit is perceived as a barrier to an effective internal audit by some interviewees.

3.4.2 *Composition of audit team*

All interviewees stressed the importance of a well-composed audit team. They stated the importance of having a medical specialist as a part of the audit team. First, they mentioned the medical expertise that is needed when visiting and evaluating certain types of departments, like surgical, diagnostic and contemplative specialities. Second, they mentioned that for medical specialists it is important to talk with a peer during an audit. Finally, they said that the audit is perceived as more credible by other medical specialists, when they see that a medical specialist is part of the audit team.

One interviewee (a quality officer) stressed the importance of having "high-profile" (i.e., respected) individuals amongst auditees to gain support for the audit. Several interviewees stated that another facilitator is that the audit team is a reflection of the department that is being audited (i.e., a multidisciplinary team), in contrast to an audit team consisting of only (non-clinical) employees from the quality management unit. A multidisciplinary team creates support within the whole department, is able to evaluate a department because of its expertise on different aspects of care, and, because of its broad knowledge, is able to obtain incisive information.

Although every interviewee expressed an ideal vision of a multidisciplinary audit team, not every hospital has available medical specialists and nurses who are willing and suitable to perform as auditors. Some interviewees mentioned the unavailability of medical specialists as auditors in their hospital as an important barrier for effective internal audits. They stated that the participation of medical specialists in every audit team is not feasible because most specialists feel so heavily occupied that they do not have time for other tasks.

3.4.3 *Training and evaluation of auditors*

All interviewees stated that in their hospitals, all auditors have received training prior to the first audit they conduct. They recognised a trained auditor as a prerequisite for an effective audit. Moreover, they argued for an evaluation of each auditor (i.e., on interview skills and quality of reporting skills). Not all interviewees stated that this evaluation was a standard procedure in their hospital.

3.4.4 *Patient involvement in audit*

Some interviewees stated that there is too little room for patient perspectives in the audit. They mentioned that they would like to improve patient participation in auditing, for example by inviting patients to take part in the audit team.

However, they felt that there are a few a barriers that hospitals need to overcome. First of all, they must be aware of challenges regarding the confidentially of the audit. Secondly, some interviewees experienced that an audit ended up as a tour instead of a professional evaluation of the department. Finally, some interviewees mentioned that patients may introduce bias in the evaluation of healthcare, because of their own personal experiences as patients.

3.5 Theme IV: cultural factors and attitudes towards auditing

Three categories were identified within this theme: (1) presence of an audit culture; (2) transparency and learning attitudes of personnel; and (3) negative attitudes towards auditing.

3.5.1 *Presence of an audit culture*

A few interviewees, including board members, expressed the importance of having an audit culture within the hospital. A shared notion amongst the staff that audits are an important aspect of their clinical work is perceived as a facilitator for effective audits, because it increases their willingness to participate in internal audits and ultimately the reliability (i.e., feasibility and completeness) of audit results. Interviewees claiming to have an audit culture in their hospital stated that their colleagues do not accept ignoring an internal audit. Interviewees who sensed a lack of audit culture in their hospital, expressed difficulties in getting medical specialists interested in participating in internal audits (as auditees or auditors).

3.5.2 *Transparency and learning attitudes of personnel*

Several interviewees considered an open learning culture as another important facilitator for effective audits – that is, a department where the staff values constant reflection of clinical practice and transparency is considered to be the norm. Auditors are able to assess a department much better and gain a more realistic picture of important safety issues within the department, if there is a social environment in which staff members feel able to speak out freely. Furthermore, interviewees stated that a learning culture stimulates the commitment to improvement actions that derives from an audit. They indicated a relation between being used to giving and receiving feedback, and being able to improve after an audit.

3.5.3 *Negative attitudes towards auditing*

Some interviewees often experience unmotivated staff undergoing internal audits and resistance of staff towards internal audits. For example, staff members resist audits by ignoring interview requests or not providing adequate information relevant for performing an effective internal audit. Many interviewees addressed the considerable time investment of audits, compared to other types of inspections and providing urgent medical care, as a main cause for resistance amongst staff to participating in internal audits. One interviewer sensed tiredness of auditing amongst the personnel in his hospital.

4. DISCUSSION

This study provides a comprehensive overview of the barriers and facilitators for effective auditing within Dutch hospitals. Barriers and facilitators are classified into four themes: (1) board positioning of audits, (2) organization and content of audits, (3) competences and composition of audit team, and (4) cultural factors and attitudes towards auditing. Our findings show that the quality of audits can be affected by the degree of support throughout all levels of the hospital.

First, the quality of audits is influenced by the extent to which hospital boards and employees value audits as a useful safety measurement and improvement tool. Earlier studies have found that lack of perceived value can be a barrier in auditing.[24,25] The added value of audits is not directly visible in terms of improved safety outcomes such as reductions in mortality rates or adverse events. This low visibility makes it hard to create a sense of urgency and commitment amongst board members and employees, and hinders adequate and systematic use of audits. This finding is in line with multiple studies addressing that safety auditing often loses the battle for attention against more visible problems, such as financial deficits, obtaining new technology, or labour shortages.[14,26]

Second, the quality of audits is influenced by the presence or absence of a learning culture. A culture of transparency about errors and eagerness to learn from safety problems is known to be an important prerequisite for safety improvement.[27,28] However; this has not been found before in the context of these audits.

Third, the quality of audits is affected by the organisation and the content of the audit. In line with earlier studies, we found that the structural evaluation and training of auditors,[14,25] a multidisciplinary audit team[15] and a thorough audit preparation[14,24] seem to be important facilitators for obtaining a complete, valid and reliable insight into the safety (risks) within hospital departments. Our study reveals that the quality of audit findings may be challenged by the lack of available and competent medical specialists, a patient or representative in the audit team and the lack of focus on complete healthcare pathways.

Our findings show that there are different perceptions within the hospital regarding the output of audits. According to members of the board of directors and the board of supervisors, the lack of soft signals hinders them from fully over-

seeing important safety risks within a department, whereas quality officers and heads of departments argued that the audit report should only be based on hard facts. To our knowledge, this tension between the needs of the hospitals boards to govern patient safety versus the need to perform an objective safety assessment has not been addressed before.

We found that the four themes were interrelated. One example is the link between an audit culture at department level and the dissemination of the value of the audit by boards. In hospitals in which boards did not value the audit at all and failed to disseminate any audit purpose, there was no positive attitude towards audits at department level.

In contrast to earlier studies we interviewed all stakeholders involved in auditing. We selected six hospitals based on the variety of their audit system and hospital type, enabling us to investigate what we think is a reflection of hospitals in The Netherlands. Moreover, we believe that our findings are representative of other hospitals given the substantial internal consistency in identified themes that interviewees from the different hospitals mentioned. However, our study has several limitations. First, the audit system in Dutch hospitals might differ from the audit systems in hospitals in other countries. Therefore, generalization to other countries might be limited. Second, members of the board of directors and board of supervisors of one of the hospitals did not participate, because of lack of time. Third, we did not examine audits in care facilities other than hospitals. Therefore, the findings may not be representative of other healthcare services, such as elderly homes or mental health centers.

Our findings have several practical implications. Effective audits require active leadership by the hospital board: by active monitoring of the follow-up of audit results and by committing departments to implement and evaluate improvement actions. The importance of leadership is underlined by earlier results on effective quality management systems and governance.[1,9,23,29] Our findings also point to the need for creating and sustaining a culture in which employees perceive participation in auditing as being part of their medical or nursing profession rather than a mandatory element of their work used for administrative and blaming purposes. We found that the emphasis on an audit as a learning opportunity might be a way to steer away from the audit as a "tick-box" activity, which is in line with literature on other types of audits.[30,31] Finally, boards should provide the right preconditions to ensure high quality audit findings. For example, this would include the presence of a medical specialist and patient in the audit team, sufficient (human) resources for a systematic audit, the use of safety walk-arounds to systematically grasp soft signals[32] and inclusion of audits of health care pathways.

As this is a qualitative study to explore every possible barrier and facilitator, more research is needed in order to investigate the factors we found. We suggest a model for future testing that derives from our findings (see Figure 3). We have found two themes related to the audit itself (the inner ring): organisation and content of audits and competences and composition of audit team. These themes are influenced by contextual factors (the outer ring): board positioning of audits and cultural factors and attitudes towards auditing. The arrows in the circle show how the different themes inside the rings interact with each other. The importance of the factors and the interaction between the different factors need to be validated and verified with quantitative research. Also variation in factors between type of hospital can be studied with quantitative research.

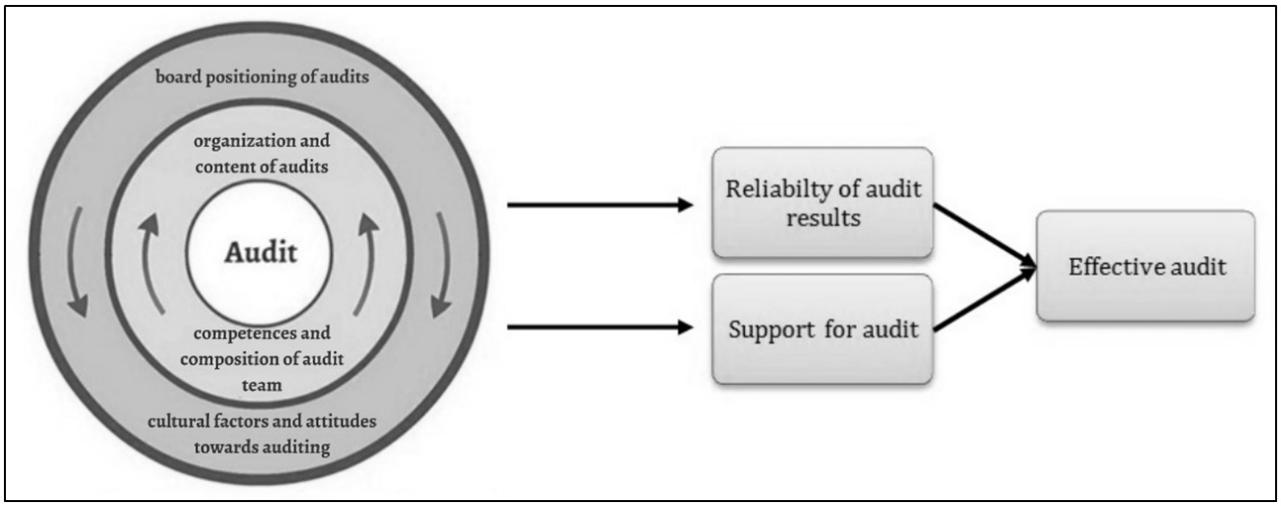

Figure 3. Factors that influence effective internal audit

In conclusion, this study contributes to the knowledge of barriers and facilitators for effective auditing, from the perspectives of auditees, quality officers, boards of directors and boards of supervisors. By providing a deeper understanding of the critical factors and preconditions, hospitals can optimise their audit systems, ultimately leading to more reliable information for hospital boards to ensure patient safety and subsequently enabling hospital boards and executives to become more "in control" when it comes to patient safety in their hospital.

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AUTHORS' CONTRIBUTIONS

SvG carried out the qualitative research and drafted the manuscript. GH carried out the qualitative research and helped to draft the manuscript. MZ conceived the study, contributed to the design and coordination of the study, drafted the manuscript and helped to carry out the qualitative 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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CONFLICTS OF INTEREST DISCLOSURE

The authors declare that they have 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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