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Transparency about internal audit results to reduce the supervisory burden: A qualitative study on the preconditions of sharing audit results

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ABSTRACT

Many working hours of healthcare professionals are spent on administrative tasks. Administrative burden is caused by political choices, legislation, the requirements of health insurers and supervisors. Coordination between the parties involved, is lacking. Therefore, we studied to what extent sharing internal audit results of hospitals with external supervisors is possible and the necessary preconditions. We interviewed 42 individuals from six hospitals and the Dutch Health and Youth Care Inspectorate.

The interviewees expressed that there is no coordination in timing and content between internal audits and external supervision. They were in favour of sharing internal audit results with external supervisors to reduce the supervisory burden. They stated that internal audits give insight into quality problems and improvements, how hospital directors govern quality and safety, and the culture of improvement within healthcare provider teams. With this information, the inspectorate can judge to what extent hospitals are learning organisations. The interviewees mentioned the following preconditions for sharing audit results: reliable and risk-based information about quality and safety, collected by expert, trained auditors, and careful use of this information by the inspectorate in order to maintain openness among audited healthcare professionals.

In conclusion, internal audit results can be shared conditionally with external supervisors. When internal audit results show that hospitals are open, learning and self-reflecting organisations, the healthcare inspectorate can reduce their supervisory burden.

1. Introduction

Healthcare professionals spend 40 % of their working hours on administrative tasks, including registering and supplying quality [1–3]. The administrative burden is caused by political choices, legislation, the requirements of health insurers, and internal and external supervisors (Table 1) [4–6]. There is a lack of coordination between the parties involved: 69 % of medical specialists and 75 % of residents indicate that they have to perform certain registration actions twice for different parties [3].

In the Netherlands, administrative costs are 20 % higher than those in other European countries [7]. Boards of directors are also increasingly confronted with new and altered quality requirements; these are primarily intended for quality improvement by healthcare professionals, but are increasingly used for supervision and enforcement [8]. Every hospital is monitored by 19 inspection services, including nine government inspectorates [9].

Solutions are being sought to reduce the administration burden of registration for accountability purposes, for example by limiting the number of performance indicators [10]. Collaboration between external supervisors, such as the Dutch Healthcare Inspectorate and the Dutch Healthcare Authority (NZa) is another example of reducing the burden of supervision on healthcare providers through mutual coordination when requesting information, planning annual themes and supervisory visits [10,11]. Regarding system-based supervision, the healthcare inspectorate

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Table 1
Supervision to guarantee quality and safety in Dutch healthcare settings.

Parties	Supervision by	Supervising agency	Method
External			
Government (Ministry of Health, Welfare and Sport)	Initiating and enforcing law and regulations (e.g. the Care Institutions (Quality) Act, the Health Insurance Act, Long-Term Care Act)	Dutch Health and Youth Care Inspectorate (IGJ)	- Inspection site visits - Annual meetings - Analyses of various types of risk information (e.g. calamities) - Monitoring indicators of professional guidelines and patient safety indicators
		National Health Care Institute	- Structural collecting and reporting data on quality of care
Healthcare insurance companies		Healthcare insurers	- Assessing national and own quality and patient safety standards - Measuring client experiences
Professional medical associations	Setting up and assessing adherence to professional guidelines	Peers	- Site visits - Medical registrations
Patient organisations	Collecting and sharing patient experiences	Representative (groups of) patients	- Assessing patient experiences - Awarding quality marks or certificates
Accreditation institutes	Assessing the presence of organisational preconditions and standards	Accreditation institutes (such as International Organization for Standardization, Joint Commission International (JCI), Netherlands Institute for Accreditation in Healthcare (NIAZ)	- Audits - Surveys
Internal			
Supervisory board	Supervising board of directors		- Regular meetings with board of directors - Document studies
Board of directors	Supervising healthcare processes and patient outcomes and experiences	Quality departments	- Regular meetings with among other things department leaders, managers and medical and nursing representatives - Monitoring steer information (e.g. patient experiences, indicators) - Internal audits - Safety walk rounds
Healthcare professionals and managers		Quality teams	- Measuring patient experiences - Analyses of various types of risk information (e.g. calamities, incidents, mortality rates, complications) - Monitoring indicators

intends to reduce supervision burden through less supervisory visits of healthcare institutions with properly functioning quality systems (Box 1) [12].

In order to give the assurance of safe care to third parties (e.g. healthcare consumers and healthcare insurers) and to be accredited by the Netherlands Institute for Accreditation of Healthcare (NIAZ), internal audits should be performed in Dutch hospitals [13]. Hospitals, which opted for accreditation by the Joint Commission International (JCI), have no obligation to perform internal audits [14]. However, systematic evaluation and improving care by observing and interviewing healthcare professionals by trained auditors, similar to internal audits, are necessary to meet the JCI standards. An internal audit 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 with (national) standards and guidelines [13] (Box 2). The measurements are performed by an audit team existing of internal peers (i.e., employees of a hospital who audit colleagues of other departments). Healthcare providers and hospital boards of directors use the audit results to improve patient care and to demonstrate that the quality and safety of care meet (inter)national guidelines and standards [15,16].

There is no formal policy to request audit results by healthcare inspectors: some inspectors request the audit results and other inspectors only ask whether internal audits are taking place. Structurally sharing internal audit results with external supervisors can be a solution to reduce the supervisory burden. However, it may also involve risks, such as the loss of reliable, quality information when healthcare professionals know that their audit results are shared with external supervisors [16].

Therefore, the aim of our study was to evaluate to what extent sharing results of internal audits of hospitals with external supervisors is possible and what the necessary preconditions are for this approach.

2. Methods

2.1. Study design and setting

We conducted a qualitative interview study in six hospitals (two university hospitals, two teaching hospitals and two general hospitals) that were selected based on hospital type and audit characteristics, such as >5 years of audit experience, and participation of medical specialists in audit teams (see Appendix 1). The six

Box 1: The Dutch Health Care Inspectorate (IGJ) [17]
The Dutch Health and Youth Care Inspectorate (*Inspectie Gezondheidszorg en Jeugd; abbreviated in IGJ*) is an agency of the Ministry of Health, Welfare and Sport. It is the official regulatory body charged with supervising the quality and safety of healthcare services, prevention activities and medical products in the Netherlands. The healthcare inspectorate has organised its supervision in several ways in order to ensure compliance with professional standards and guidelines and to ensure patient safety:

- ◯ Risk-based supervision: based on a proactive and regular gathering of indicators indicating risks;
- ◯ Incident-based supervision: based on reports and indications (incidents, calamities) that have or could lead to high-risk situations;
- ◯ Thematic-based supervision: directed at high-risk aspects or areas of care, such as operative processes and high-risk medication;
- ◯ System-based supervision: directed at risks in the quality systems of care providers, networks and chains, with an emphasis on administrative/organisational roles and responsibilities for quality assurance.

If the reports from the inspectors, any reports and analyses of calamities, and/or the risk indicators show high risks for quality and/or safety of care and when there is insufficient faith in the strength and effectiveness of the hospital board to realise improvements on time, the healthcare inspectorate can impose intensified supervision on a provider of care, entirely or one of its departments (responsive risk-based supervision) [18]. Intensified supervision includes frequent announced and unannounced site visits and consultation with the hospital board. Intensified supervision will be ended when structural improvements of the quality and safety of care have been proven and the board of directors shows to be in control.

Box 2: Purposes of internal audits in hospital care
The aim of internal audits in hospitals is to structurally govern and improve quality and patient safety of healthcare to ultimately prevent patient harm and mortality [15]. The audits are initiated by the hospital board of directors and information from audits is used by healthcare professionals, managers and board of directors for multiple purposes [19]:

- preventing adverse outcomes as a result of unsafe care;
- reflection on audit results to stimulate a learning organisation;
- continuous quality improvement in the organisation;
- controlling, adjusting and guaranteeing the quality of processes;
- accountability for quality and safety of the care provided to internal supervisors.

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, by the NIAZ or the Joint Commission International (JCI) [14,20]. Our study focused on internal audits 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 [15]. This audit approach is initiated by the board of hospital directors and implemented top-down. We did not focus on corporate audits

Fig. 1. Internal audit process in Dutch hospitals.

(mainly focused on financial aspects) or clinical audits (initiated by healthcare professionals and implemented bottom-up).

The Radboud University Medical Center medical ethics review committee approved this study (registration number: 2011/332).

2.2. Organisation of internal audits in Dutch hospitals

In Dutch hospitals, internal audits are embedded in an internal audit system, involving audit procedures, audit methods (e.g. document study, interviews and observations) and employees who organise and perform audits [15]. Usually, hospital departments or healthcare processes are audited once every four years [13]. The boards of directors initiate the internal audits and delegate the execution to committees or departments. Internal audits are performed by a team of auditors who work in the hospital [13]. The auditors are trained nurses, medical specialists, allied healthcare professionals and quality officers. The total number of auditors in an audit team varies from five to more than 20 per hospital [13]. Auditors are trained on content (theory), conversation and social skills and analytical methods [21].

Internal audits consist of five phases: (1) preparation, (2) execution, (3) reporting, (4) developing and implementation of an improvement plan and (5) follow-up on all audit findings (Fig. 1) [13,15]. The time frame of an internal audit (phases 1–4) ranges from 1 to 7 months, with a time frame of two months being most common [13].

An audit team prepares the audit, which includes the analysis of quality and policy documents and outcomes of earlier performed audits, observations of care processes, medical record reviews and self-evaluation forms filled in by the heads of departments [13,15]. Table 2 represents the methods and instruments used within internal audits in Dutch hospitals. The quality of the audited care processes is compared with various prevailing quality and safety standards (e.g. NIAZ, JCI, ISO 9000), laws and regulations and guidelines for healthcare professionals [14,20,22]. During audit team meetings, the outcomes of the preparations are discussed and the focus of the audit is determined (e.g. which specific safety risks will receive additional attention). During an audit visit, the audit team interviews auditees and presents the preliminary audit findings to the auditees. Subsequently, the audit team writes an audit report with audit findings and conclusions based on all collected information. The audit results will be fed back to the audited department heads for quality improvement purposes and to the boards of directors for governance purposes [13,15]. Department heads are

Table 2
Methods and instruments used within internal audits in Dutch hospitals.

Audit system	
Methods	Instruments
Studying policy and quality indicators	Online self-assessment tool based on legal, national, and professional practice standards
Semi-structured interviews of health care professionals	Standardised interview forms
Systematic observations (e.g. physicians' discussions of complications and patient handovers)	Standardised observation forms
Questionnaire about team functioning of healthcare professionals	Team Climate Inventory [23]
Patient record review to measure adverse events	Standardised record review form based on a protocol originally developed by the Harvard Medical Practice Study [24]
Assessment of the quality of medical and nursing patient records	Standardised assessment forms
Appraisal of document management (e.g. protocols and procedures) and guideline adherence	Standardised assessment forms partly based on the AGREE instrument [25]
Appraisal and assessment of quality of consultation and collaboration by main internal and external partners	Standardised appraisal and assessment questionnaire [26]

obligated to develop and implement improvement plans based on the audit results. Follow-up of the audit findings and recommendations is the responsibility of department heads and is monitored by the board of directors or delegated to committees. This audit process should be repeated periodically [13,15].

2.3. Participants

We used purposive sampling to ensure a representative sample of interviewees in terms of job function: 12 department heads (all medical specialists), 10 department managers (all business experts), five board of director members (hereafter: the director) and five supervisory board members (hereafter: the internal supervisor) [13,27]. We also selected 10 hospital inspectors from the healthcare inspectorate: four were account holders of the six hospitals and six were chosen based on their work experience and availability.

2.4. Interviews

We collected data using semi-structured interviews conducted from March 2013 to February 2015. Three trained and experienced interviewers (including MH-S) conducted the interviews. The interviews were guided by a topic guide (see Appendix 2). Topics for guiding the interviews included the following themes: experiences with internal audits, the use of internal audit results for quality improvement, and the preconditions for sharing internal audit results with external supervisory bodies. The individual interviews are conducted with the four account-holding hospital inspectors of the six selected hospitals. Six other healthcare inspectors participated in one focus group interview for in-depth exploration of the topics from the individual interviews [28]. An experienced moderator (PR) led the focus group interview. One researcher observed the focus group interview and made field notes. The individual interviews lasted 30–60 min; the focus group interview took 65 min. All interviews were recorded on audio tape with the interviewees' consent.

2.5. Data analysis

All audio recordings were typed out verbatim according to a standardised format. Two researchers (including MZ) analysed the first four interviews independently, discussed the analysis and developed a framework for coding (Appendix 3). One researcher (MH-S) coded thematically using the coding framework and applied open coding to the transcriptions. Through repeated study of the transcriptions and the assignment of codes to text segments, the coded text segments were categorised into themes (thematic analysis) under the supervision of another researcher (MZ) [27,29]. Differences were resolved by consensus amongst the researchers.

The qualitative data analysis software Atlas.ti 7 was used for analysis support. Data collection and analyses of interviews were performed according to the 'Consolidated criteria for reporting qualitative studies' (COREQ) (Appendix 4) [30].

3. Results

3.1. Respondent characteristics

Of the 32 interviewees from the hospitals, 66 % were men and 34 % were women. On average, they had worked in their current job as head of department for 7 years (range, <1–15 years), as department manager for 3 years (range, 1–8 years), as director for 4 years (range, 1–7 years) or as internal supervisor for 4.5 years (range, 1–8 years). Of the 10 interviewed inspectors, 30 % were men and 70 % were women.

3.2. Themes

The results were divided into five themes: (a) need for coordination between internal review and external supervision; (b) added value and limitations of internal audits; (c) use of internal audit results by the healthcare inspectorate; (d) the risks and benefits of sharing of internal audit results with the healthcare inspectorate; and (e) preconditions for effective use of internal audit results by the healthcare inspectorate. These themes are described below and are presented with representative interview quotes in Table 3.

We found relevant differences in opinions within and between the disciplines of the hospitals and inspectors; however, they were not related to the type of hospital, number of years of experience in the current job or sex.

3.3. Need for coordination between internal auditing and external supervision

The department heads and department managers emphasised that they have a great need for coordination between internal auditing and external supervision. Within short periods, they had been both audited and evaluated by their own hospital, the healthcare inspectorate and accreditation organisations; they had also been inspected by scientific associations and assessed by various patient associations to obtain a specific quality mark. Consequently, they had spent much time preparing and performing audits and

Table 3
Quotes from interviewees about sharing internal audit results with the healthcare inspectorate.

Theme	Representative quotes
Added value and limitations of internal audits	- Department head: 'I think that the audit is very good, in the sense that you can anonymously mention certain things and therefore bring issues to light, for example the team climate and workload. Thus, I like that and occasionally I also think it gets far too detailed, which makes me think: does it need to be so deep?' - Department manager: 'I think it is very good that with an internal audit you have the security that "this does not get out". Therefore, with an internal audit you can get even more to the core of what's going on. This is better because it does not entail any threat that our image will be ruined or something like that. And I think that critical issues in an external audit, or an audit that involves the healthcare inspectorate, do not get addressed. People simply do not discuss the issues when an external party is involved. And I find it very valuable when these issues become known within the hospital, not publicly outside the hospital. The internal audit has served as a kind of crowbar and has led to improvements.' - Inspector: 'The fact that a hospital has indeed included an audit cycle in its quality system indicates that it has thought about the PDCA; the cycle is complete and you not only improve, but you also test whether the improvement has the desired effect. And an audit is a tool for that.' - Internal supervisor: 'What is negative about the internal audits is the workload, but that is the case with all these things.'
Need for coordination between internal testing and external supervision	- Department head: 'At one point within a year and a half, we had nine different audits and visitations. We had a training review, external quality visitation, and internal audits. Well, I cannot even remember them all; I have made a list and there were nine. At that point it was just too crazy.' - Department manager: 'In addition to the internal audits, you will hear from trade unions and patient associations. It is almost as if I now actually have a visitation company; I can continuously work on this. The question at any given moment is: what is still effective, what do you want to achieve with your quality system and what kind of dosage should you use in that? I get the idea that the dosage that is currently being used is occasionally an obstacle to the effectiveness of audits and visitations.'
Risk and benefits of sharing internal audit results with the healthcare inspectorate	- Department head: 'But we're going in that direction anyway, to that openness, and that's good too. I mean, no, I'm not fundamentally against sharing audit results with the inspectorate and professional associations, but you have to be careful that no one is harmed. And that is sometimes possible because individuals are sometimes traceable in what you can find in these audits, but in itself I do not object to that.' - Director: 'I am very transparent for the inspection. And that is also appreciated by the inspectorate. The fact that you are transparent gives the inspectorate a lot of confidence.' - Director: 'What you see is that my supervisory board, who also feels pressure from various supervisors such as the inspectorate. Then I also have to take a closer look. And they do not know have any idea where to look. It is a very complicated company, the hospital company. And they basically have to trust and ask me the right questions. But what you see them do, they almost want to sit in the driver's seat because they do not really know where to look and what to ask and want to do it themselves. And then I think: "you should not want that at all".' - Inspector: 'But where there is a commonality, and what new colleagues also quickly become familiar with, is the caution with which we therefore deal with retrieving internal information. As a new inspector you will soon become aware of that.'
Use of internal audit results by the healthcare inspectorate	- Inspector: 'It is never just: "You have done an internal audit, so it is good." But it is always a highly appreciated additional source of information. And where does that extra valuation come from? It comes from the fact that there is also effort on the part of the healthcare institution. You can really assume that since they made the effort to perform an internal audit, it is worth the effort and you get an extra commitment to the problem. In that sense you look a little more deliberately than when they are merely indicators.'
Conditions for effective use of audit results by the healthcare inspectorate	- Inspector: 'If I look at our supervisory role from the inspectorate, these must be relevant subjects for patient risk. Moreover, that also means that they have to be specific for that hospital, because that hospital is at risk in those areas.' - Inspector: 'Of course, you expect that an audit team has someone from the quality office to properly monitor the process and also to look at critical questions and to ask connecting questions within the audit team. They can do that very well, of course, but at some point when it comes to a subject, there must be experts on the team.'

PDCA = plan-do-check-act.

visitations (measuring quality of care) instead of implementing improvement interventions. They therefore wondered to what extent this is effective for quality improvement and why information between the inspection authorities was not shared.

3.4. Added value and limitations of internal audits

According to the interviewees, including the inspectors, internal audits provide insight into the following three points: (a) quality problems and the underlying causes; (b) the quality improvements implemented and the results; and (c) the improvement culture in healthcare provider teams. In addition, feedback of the audit results makes employees aware of their performance. Additionally, internal audits offer the inspectorate insight into how a director acts on negative audit results and is therefore a tool for risk-based supervision (see Box 1 for definition). Internal audits provide valuable information for inspectors in addition to all other quality information which are gathered and triangulated by the inspectorate such as risk indicators and incident reports of patient care (Box 1).

The limitations of internal audits, according to the interviewees, are that they are labour-intensive for the executive auditors and the healthcare professionals undergoing the audit, and associated high costs.

3.5. Use of internal audit results by the healthcare inspectorate

The inspectors indicated that they generally do not ask audit reports unless: (a) there are indications of unsafe care (risk-based supervision); (b) they are for specific topics such as 'Supervision of the surgical process', 'Emergency care' and 'High-risk medication' (theme-based supervision); or (c) when they themselves have requested an internal audit, for example after a calamity (incident-based supervision) (see Box 1).

The inspectors generally did not request audit reports because they believed that an internal audit is an instrument for internal quality improvement in hospitals: the hospitals and their directors are responsible for carrying out internal audits and guaranteeing the quality of care. This is why inspectors inform if internal

audits are used for quality improvement, the audit outcomes, the improvement measures implemented and the results during their inspection visits. In addition, inspectors do not request the entire audit report because they realise that what the inspectorate receives can be made public by law (WOB).

Moreover, the inspectors indicated that they have limited time to review the contents of audit reports and that they have other, sufficient instruments to measure quality and safety of healthcare, such as quality indicators, annual interviews, calamity reports and inspection visits. However, the inspectors did not simply assume that quality and safety of care would be in order when internal audits are performed. They wanted to be able to assess this themselves and form an opinion about it. System-based regulation has the opportunity for inspectors to supervise the quality system of the hospital [9].

3.6. Risks and benefits of sharing internal audit results with the healthcare inspectorate

Most of the interviewees were in favour of sharing internal audit results with the healthcare inspectorate, because it is the social and common responsibility to be transparent about quality and safety of care, so that patients can be confident of receiving the best care.

However, the department heads, a few directors and one department manager brought up some risks. First, employees may become more cautious about sharing information about the quality and safety of care when they know that the results will be shared with the healthcare inspectorate, with the risk that healthcare professionals are less open about safety risks during internal audits. Second, in the Netherlands, citizens can legally request all information from government agencies—via the Dutch Government Information (Public Access) Act (*Wet Openbaarheid van Bestuur, WOB*)—and therefore also any audit results, in case the inspectorate has this information. Third, the healthcare inspectorate may draw the wrong conclusions because it was not involved in the audit. System-based regulation offers a solution for this problem [9]. In addition, the participants wondered, in view of its staffing, whether the inspectorate can process this level of detailed reporting and whether its interest is based on this detailed information.

The directors, internal supervisors and inspectors felt that sharing internal audit results runs the risk of the inspectorate taking over the director's role. One director did not share this fear, because his experience was that the inspectorate is particularly interested in how directors manage and take measures regarding the quality and safety of care.

3.7. Conditions for effective use of internal audit results by the healthcare inspectorate

The inspectors set the following six conditions for internal audits to ensure effective use of audit results: (a) execution by an independent, experienced and content-based audit team (the hospital's quality officer monitors the audit process and asks critical questions; training of auditors is necessary); (b) the subjects assessed are relevant and specific to the risks of patient care at the hospital; (c) the audit information is factual, based on scientific standards or norms and is recognised by the audited employees; (d) the audit results provide sufficient tools for the audited employees to perform improvement actions; (e) the director checks and ensures the implementation of the improvement measures; and (f) the audits are part of the quality improvement cycle (PDCA cycle) and contribute to quality improvement. If these conditions are met, inspection of the main results of internal audits with the proposed improvement measures and their follow-up would be sufficient.

The department heads and managers, directors and internal supervisors set one clear condition for sharing internal audit results: the inspectorate must handle the audit results with care. If, for example, in the eyes of healthcare professionals, unreasonable or disproportionate sanctions follow an audit or if persons or the image of the hospital are damaged, then those involved will be less open and transparent about sharing information.

The inspectors were aware that they must request internal audit information with care: 'You have to think very carefully about what you want to know as an inspector, what you can do with it and what the side effects can be.' They indicated that they had encountered no difficulties when requesting internal audit reports.

4. Discussion

Healthcare professionals, managers and hospital boards have a great need for coordination between internal audits and external supervision. Structurally sharing internal audit results with external supervisors can reduce the supervisory burden for hospital boards and healthcare professionals and promote the effectiveness of external supervision of supervisory bodies. After all, the number of external demands is growing [31]. Many governments around the world are consolidating the regulation of medical professionals and institutions [32]. Hospital boards are obliged to implement laws, rules, (professional) standards, guidelines and to measure and report publicly quality indicator sets [31]. It is impossible for them to comply with all these requests. Healthcare professionals are overwhelmed by the growing number of associated administrative tasks diverting time and focus from providing actual care [1,2]. Also, the benefits of external inspection in terms of organisational, provider and patient level outcomes are not clear [16].

Medical department heads, department managers, directors, internal supervisors and the state inspectors supported sharing outcomes of internal audits with the proposed improvement measures and their follow-up with external supervisors. It is essential for external supervisors to know whether a hospital has a properly functioning quality system in which all healthcare professionals are aware of quality problems and work systematically and continuously to improve quality and safety of care, and how directors govern quality of care. System-based regulation, which is a way for supervision by the healthcare inspectorate, invites hospitals to develop and make explicit their own design and management of internal governance and control systems. Inspection then focuses on these self-designed 'management systems' and restricts its supervision when healthcare institutions can demonstrate that their quality system guarantees quality and safety and risk management [6,12,33,34]. Thus, for system-based regulation of the healthcare inspectorate, it is important that the internal audit information is reliable, relevant and risk-oriented and has been collected by content experts, trained auditors. Since the introduction of regulated markets, existing institutional arrangements and the new ones are layered on top of each other [6]. Consequently, hospitals have to deal with the fragmentation of quality demands. Internal audit information summarises all information about the quality and safety of care. After all, internal audit results do not only show compliance to standards (NIAZ, JCI), but also show for example, patient outcomes and patients' experiences with hospital care, the level of professional collaboration among healthcare providers and a learning culture within hospital care. Sharing audit results with external supervisory bodies will assist hospital boards in justifying the care provided.

Sharing audit results could have also implications for risk-based, incident-based and thematic-based supervision. These methods of supervision together with system-based supervision are complementary [9]. It is through the combination of these methods that a good picture of quality and safety of care is provided. Combination of information from supervision methods and existing sources

of information about quality and safety of care (e.g. internal audit results) broadens the horizon of the healthcare inspectorate [9]. By sharing audit results, inspectors can obtain more trust in the quality system of the hospital. Supervision can then become more effective and there is less need to gather data through risk-based (this in particular), incident-based and thematic-based supervision. Consequently, the supervision-related administrative burden will be reduced and the responsibility for quality and safety of care clearly stays with the hospital.

Inspectors generally do not request audit reports but inform about the audit results and the corresponding improvement measures. Sharing the complete audit report is also not desirable, because sharing of detailed information can damage the image of healthcare professionals and hospitals if the information becomes public by law. Thus, the audited healthcare professionals might become more reticent when discussing quality and safety issues, at the expense of the completeness and reliability of the audit results. This would have an adverse effect on the original purpose of internal audits: creating a confidential environment in which people are open about quality problems and with which valuable information is generated for internal quality improvements. Mistrust of healthcare professionals in the inspectorate's regulation can lead to more reticent in their dealings with the inspectorate and to distorted information provided to the inspectorate [35]. Therefore, an explicit precondition for sharing internal audit results is that the healthcare inspectorate handles this information with care.

Although the organisation of care in each country has its own characteristics, the context of regulation of each country is different and audits are set up very differently, the same two problems still play a role everywhere: 1) the number of accountability mechanisms (external and internal) is increasing and thus becomes a complex whole in which coherence is no longer always visible or present. This does not benefit the effectiveness of accountability and may even be detrimental to quality and safety of care; and 2) associated with this, also internationally, healthcare professionals are spending more and more time on accountability, which they cannot spend on patient care and what is worse, it might even demotivate them [36]. For each healthcare system, it is advisable to experiment in order to better adjust the different parts of the accountability cycles to one another (both internal and external) and in doing so, to reuse available information as much as possible in order to prevent duplication of work and to continue to motivate healthcare professionals to share in the accountability. This study shows that for such experiments the opinion and ideas of actors are relevant and offer room to take concrete measures that have sufficient support in the field. Measures are, for example, ensuring that the audit data are reliable and collected by an independent, experienced and content-based audit team and showing to external supervisors that the hospital board monitors the progress of audit-based quality improvement (e.g. in regular quality meetings with department heads). Healthcare inspectors are then able to focus in their inspection work on quality assurance of hospital care according to principles of system-based supervision.

Strengths of our study were the selection of six hospitals based on the variety of their audit system and hospital type and sampled purposeful interviewees in terms of job function and experiences with internal audits to maximise diversity. We combined individual interviews and a focus group interview to enhance trustworthiness of findings [27]. There were several limitations of our study which should be considered when interpreting these findings. We excluded hospitals with ≤5 years' experience with internal audits. People who have less experience with internal audits may have different views about sharing audit results with the healthcare inspectorate. An evaluation study is needed to measure if sharing internal audit results actually decreases the burden of supervision and associated administrative tasks. Based on these outcomes, concrete policy decisions can then be made.

5. Conclusion

More effective use of internal audit information can be an important step in the battle of healthcare professionals to drastically reduce administrative tasks [4]. The burden of supervision can be reduced by sharing internal audit results with external supervisors. However, a good quality of the internal audits and careful use of the audit results by the healthcare inspectorate should be guaranteed. The results of our study provide a sufficient rationale to begin with structurally sharing of internal audit information with the healthcare inspectorate and to investigate the effect thereof on healthcare professionals and supervisors. A next step is to explore whether internal audit results can also be used to limit quality demands from other parties, such as health insurers or medical associate professions.

Contributors

Marieke Zegers, Paul B. Robben and Hub Wollersheim conceived the idea for the study. Mirelle Hanskamp-Sebregts and Marieke Zegers led the writing of the manuscript as well as analysed and interpreted the interview data. Paul B. Robben and Hub Wollersheim contributed to the writing and revising of this manuscript. All authors contributed substantially to the writing of the manuscript, and all reviewed and approved the final draft.

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Data sharing statement

No additional data are available.

Declaration of Competing Interest

None declared.

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Appendix A. Supplementary data

Supplementary material related to this article can be found, in the online version, at doi:https://doi.org/10.1016/j.healthpol.2019.11.013.

References

[1] Woolhandler S, Himmelstein DU. Administrative work consumes one-sixth of US physicians' working hours and lowers their career satisfaction. International Journal of Health Services 2014;44:635–42.
[2] Erickson SM, Rockwern B, Koltov M, McLean RM. Putting patients first by reducing administrative tasks in health care: a position paper of the American College of Physicians. Annals of Internal Medicine 2017;166:659–61.
[3] Hanskamp-Sebregts M, Robben P, Wollersheim H, Zegers M. Sharing internal audit results with the Inspectorate; interviews on the possibility and preconditions. Nederlands tijdschrift voor geneeskunde 2018:162.
[4] Shaw C, Groene O, Mora N, Sunol R. Accreditation and ISO certification: do they explain differences in quality management in European hospitals? International Journal for Quality in Health Care 2010;22:445–51.
[5] Botje D, Ten Asbroek G, Plochg T, Anema H, Kringos DS, Fischer C, et al. Are performance indicators used for hospital quality management: a qualitative

interview study amongst health professionals and quality managers in the Netherlands. BMC Health Services research 2016;16:574.
[6] Van de Bovenkamp HM, Stoopendaal A, Bal R. Working with layers: the governance and regulation of healthcare quality in an institutionally layered system. Public Policy and Administration 2017;32:45–65.
[7] Himmelstein DU, Jun M, Busse R, Chevreul K, Geissler A, Jeurissen P, et al. A comparison of hospital administrative costs in eight nations: US costs exceed all others by far. Health Affair 2014;33:1586–94.
[8] Blume LH, van Weert N, Busari JO, Delnoij D. Guideline adherence: how do boards of directors deal with it? A survey in Dutch hospitals. Journal of Hospital Administration 2016;5:21–9.
[9] Robben P, Bal R, Grol R. Government supervision by the health care inspectorate, a sectorial outline. Web publication no. 62. The Hague: Scientific Council for Government Policy (WRR), 2012.
[10] The Health and Youth Care Inspectorate. https://english.igj.nl/. (Accessed 29 March 2019).
[11] The Dutch Healthcare Authority (NZa). https://www.nza.nl/english. (Accessed 29 March 2019).
[12] Stoopendaal A, de Bree M, Robben P. Reconceptualizing regulation: formative evaluation of an experiment with system-based regulation in Dutch healthcare. Evaluation 2016;22:394–409.
[13] Van Gelderen SC, Zegers M, Boeijen W, Westert GP, Robben PB, Wollersheim HC. Evaluation of the organisation and effectiveness of internal audits to govern patient safety in hospitals: a mixed-methods study. BMJ open 2017;77:e015506.
[14] Joint Commission International. https://www.jointcommissioninternational.org/. (Accessed 29 March 2019).
[15] Hanskamp-Sebregts M, Zegers M, Boeijen W, Westert GP, van Gurp PJ, Wollersheim H. Effects of auditing patient safety in hospital care: design of a mixed-method evaluation. BMC Health Services Research 2013;13:226.
[16] Flodgren G, Gonçalves-Bradley DC, Pomey MP. External inspection of compliance with standards for improved healthcare outcomes. Cochrane Database of Systematic Reviews 2016;(12).
[17] Kool RB, Kleefstra SM, Borghans I, Atsma F, van de Belt TH. Influence of intensified supervision by health care inspectorates on online patient ratings of hospitals: a multilevel study of more than 43,000 online ratings. Journal of medical Internet Research 2016;18:e198.
[18] Black J, Baldwin R. Really responsive risk-based regulation. Law & policy 2010;32:181–213.
[19] Hanskamp-Sebregts M. Improving patient safety in hospital care: the implementation of internal audits (thesis). Radboud University medical center; 2018 https://repository.ubn.ru.nl/handle/2066/197547.
[20] The Netherlands Institute for Accreditation in Healthcare. https://www.niaz.nl/english. (Accessed 29 March 2019).
[21] Van Gelderen SC, Hesselink G, Westert GP, Robben PB, Boeijen W, Zegers M, et al. Optimal governance of patient safety: a qualitative study on barriers to and facilitators for effective internal audit. Journal of Hospital Administration 2017;6:15.
[22] NEN-EN-ISO 9001 2015 nl Quality system -requirements 2015. https://www.nen.nl/NEN-Shop/Norm/NENENISO-90012015-nl.htm. (Accessed 18 March 2019).
[23] Ouwens M, Hulscher M, Akkermans R, Hermens R, Grol R, Wollersheim H. The Team Climate Inventory: application in hospital teams and methodological considerations. BMJ Quality & Safety 2008;17:275–80.
[24] Brennan TA, Leape LL, Laird NM, Hebert L, Localio AR, Lawthers AG, et al. Incidence of adverse events and negligence in hospitalized patients: results of the Harvard Medical Practice Study I. New England journal of medicine 1991;324:370–6.
[25] Terrace L. Development and validation of an international appraisal instrument for assessing the quality of clinical practice guidelines: the AGREE project. Qual Saf Health Care 2003;12:18–23.
[26] Overeem K, Wollersheimh HC, Arah OA, Cruijsberg JK, Grol RP, Lombarts KM. Factors predicting doctors' reporting of performance change in response to multisource feedback. BMC Medical Education 2012;12:52.
[27] Pope C, Mays N. Qualitative research in health care, 3rd edn. Oxford: Blackwell Publishing; 2006.
[28] Kitzinger J. Qualitative research: introducing focus groups. BMJ 1995;311(7000):299–302.
[29] Braun V, Clarke V. Using thematic analysis in psychology. Qualitative Research in Psychology 2006;3:77–101.
[30] Tong A, Sainsbury P, Craig J. Consolidated criteria for reporting qualitative research (COREQ): a 32-item checklist for interviews and focus groups. International Journal for Quality in Health Care 2007;19:349–57.
[31] Blume LH, van Weert NJ, Busari JO, Delnoij D. Optimal use of external demands in hospitals-a Delphi study from the Netherlands. BMC Health Services Research 2016;16:72.
[32] Healy J, Braithwaite J. Designing safer health care through responsive regulation. Medical Journal of Australia 2006;184:S56–9.
[33] Gilad S. Process-oriented regulation: conceptualization and assessment. In: Handbook on the politics of regulation; 2011. p. 423.
[34] Coglianese C, Mendelson E. Meta-regulation and self-regulation. Regulation 2010, 12-1.
[35] Hout F, Nienhuis E, Robben P, Frederiks B. Supervision by the Dutch healthcare inspectorate. European Journal of Health Law 2010;17:347.
[36] Healy J. Improving health care safety and quality: reluctant regulators. London: Routledge; 2016.