Certification for Quality in Hospitals

Exploring adoption, approaches and processes of ISO 9001 quality management system certification

by

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Summary

Introduction: ISO 9001 quality management system certification programs are used internationally to ensure, regulate and drive quality improvement in healthcare. Certifications are often described interchangeably with accreditation and positioned within external assessment programs. These external assessments programs are mostly acted by a non-state actor. Globally, the number of hospital certification and accreditation programs has grown tremendously the last two decades. As a governance strategy, it may constitute a move away from the state as the only actor performing regulatory control.

To become certified, hospitals need to adjust their systems to meet the requirements of the ISO 9001 standards. Hospitals are then assessed for compliance with the standard by auditors from an independent certification body and provided with an attestation if they comply. The certification program is intended to assure patients and other stakeholders that hospitals can deliver expected and reliable services. The ISO 9001 standard applies to all sectors and proposes generic requirements for organizational structures and systems to continuously manage and improve quality.

Certification bodies are themselves subject to external assessment by a national accreditation body, according to an international ISO standard. The standard sets requirements for the certification bodies' system, process and practices to provide ISO 9001 certifications.

Norwegian clinics and hospitals have no clear history for certification or accreditation, despite several initiatives. The first ISO 9001 certification initiatives started almost two decades ago and have been subject to different policy debates. The goal of the government's National Health and Hospital Plan for 2016–2019 was to introduce a system for quality certification. The ISO 9001 certification was highlighted since it contained many of the same elements for quality improvement as the national internal control regulation. However, no national system has yet been established.

We lack evidence that certification has a direct impact on clinical outcomes, but there are many indicators that certification has fostered organizational change and has positive implications for quality and safety management. We

still know little about why health care organizations adopt certification, how certification processes unfold and are understood, and the methods and approaches used by certification bodies, such as role repertoire, auditor's conduct (e.g., inspection or guidance) and assessment practice.

Aim: This thesis aimed to develop knowledge about: 1) external drivers and internal processes in hospital certification, by exploring certification processes in hospitals; 2) the scope, understanding and practice of certification processes and the certification regime, by exploring the perspectives of a certification body and the international standards and guidances; 3) the possible contributions to performance improvement from certification processes in hospitals, by exploring characteristics in approaches to ISO certification and examine whether these approaches can support resilience in healthcare.

Method: This thesis consists of two case studies. Case 1 was designed as an explanatory retrospective single-case design study of a first-time ISO 9001 certification process (years 2008-2012) in an emergency department. Data was collected through documentary sources and interviews and analyzed using a narrative approach. A sensemaking framework was applied to explore change processes.

Case 2 was designed as an embedded (multiple units) single-case study. Three units were addressed: 1) auditors' interaction with hospitals in certification processes; 2) one certification body's certification approach; and 3) the certification approach in international standards and guidances. Data was collected through documentary sources, interviews, and observations. Theoretical (deductive) thematic analysis was performed to analyze all the data. An auditor typology framework was applied to explore the auditors' conduct while auditing, and a governance and resilience perspective was adopted to examine certification approaches across units.

Findings: Three articles address the findings in this thesis:

Article I: An emergency department's initial decision to adopt ISO 9001 certification did not follow from a comprehensive decision-making process. Four external triggers initiated the adoption, continuation and change in favor of certification. The first two triggers (nonconformities and regional certification project participation) were situationally specific and initially

present in the adoption process. The last two triggers were institutional, derived from perceived ambiguities in relatively stable institutional structures (internal control regulation and ISO 9001 certification), that enabled the organization's search for meaning and control. The direct feedback mechanisms involved in certification and external audits in general were acknowledged as useful for making improvements.

Article II: Two distinct auditor styles — "explorer" and "discusser" — were identified among three auditors in hospital certification audits. Both styles are characterized by their preference for an opportunistic and less structured type of interview practice. All the auditors perceived both assessment of conformity to the ISO 9001 standard and guidance for improvement as embedded parts of certification audits. All three auditors adopted a prospective auditing approach, incorporating, guidance, transferring experiences and stimulating improvements. They all used group interviews instead of individual audit interviews with the auditees.

Article III: The international standards and guidances that certification bodies must comply with, embed an elasticity between formal retrospective auditing approaches towards prospective approaches, enabling guidance and improvements. Auditors then have a latitude to navigate their auditing strategy in their interaction with the auditees. Members of the certification body perceived and practiced a flexible auditing approach using opportunities to share knowledge, empower and make guidance for improvement in their interaction with the auditees. Overall, the standard and guidances and the certification body showed prospective auditing approaches. The article identified characteristics of the institution and process of ISO 9001 certification that might support resilient performance in healthcare by nurturing the potential to respond and learn.

Conclusion: This thesis contributes to our knowledge about conditions in the external environment that may trigger adoption of ISO 9001 certification and change processes in healthcare organizations. In addition, it contributes to the identification of normative and guiding elements, scoping the continuum between proactive and retrospective auditing approaches within which certification bodies must navigate. The thesis also extends our knowledge about certification bodies' approaches and practices to ISO 9001, and showed

adaptable certification approaches supporting resilient performance of hospitals. Lastly, the thesis proposes a refinement of a current auditing style framework and proposes a new multilevel model representing elements in approaches to accredited ISO 9001 certification.

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Abbreviations

AAPG	Accreditation Auditing Practices Group
AB	Accreditation body
APG	ISO 9001 Auditing Practices Group
CAB	Conformity Assessment Body
CB	Certification body
IAF	International Accreditation Forum
IEEA	The International Society for Quality in Health Care External Evaluation Association
ISO	International Organization for Standardization
ISO/CASCO	Conformity Assessment Committee
ISO/TC 176	ISO Technical Committee 176 Quality Management and Quality Assurance
ISQua	The International Society for Quality in Health Care
MLA	Multilateral Recognition Arrangement
NBHS	the Norwegian Board of Health Supervision
NA	Norwegian Accreditation
QMS	Quality Management System
TQM	Total quality Management

PART 1

1 Introduction

1.1 Background

During the 1980s and 1990s, organizations adopted more ideas, receipts and standards that strengthened management and leadership. Some of these were trendy management models, and referred to by their acronym [1-4]. Among these were Total Quality Management (TQM), business project engineering (BPR), management by objectives (MBO), supply chain management (SPC), service management, project management, and new public management (NPM). Such organizational receipts could have an unclear history, but still penetrated much of the organizational fields and became institutionalized, both in the private and public sector. Ideas could be considered as successful models that could increase the legitimacy of the organizations that adopted them [4-6]. Some of these intra-organizational management ideas incorporated different forms of external scrutiny, such as evaluation, certification, and accreditation systems. In this shift from hard to soft regulation and governance, transparency was a key component [4, 5]. Standards and standardization of organizations, processes, and performance make the organizations transparent and organized for external evaluations – in other words, "auditable" [7]. The expansion of monitoring and auditing activities has arguably reflected a decline in trust, and therefore requests for systems that make organizations transparent [7-9]. Assumptions of trust may also be addressed to the auditors and the processes and methods used for monitoring and auditing, as they are accountable for their conclusions and are themselves often subjected for external scrutiny [7, 10]. The international ISO 9001 standard for quality management systems is an example of a global governance trend that creates management structures within organizations, while serving as a basis for external audits and certification. The standard became early internationally recognized, especially in the production industry, and has become institutionalized as an exemplary organizational model for quality management and a means for legitimacy and cooperation in practice [11]. As a governance strategy, it may constitute a move away from the state as the only regulator, to different forms of non-state regulators [12], such as certification bodies. The philosophy, strategy, and methods that state or non-state regulators adopt have been subject for later regulatory developments, such as different forms of self-regulation, meta-

regulation, enforced self-regulation, responsive regulation, or smart regulation [12-16]. These developments have focused on how to be adaptable and nurture local knowledge to improve performance and reduce risks; as such, it is an orientation towards resilience in regulation regimes [17]. The explicit connection between regulation and resilience perspectives is seldom seen in the literature [18, 19]. This might be because regulation has traditionally been concerned with standards and prescriptions for the state to constrain action and sanction non-compliance, while supporters of resilience perspectives stress the development of flexible and adaptable local systems, where local knowledge and professionals' judgments are at the heart of everyday performance.

In health care, there has historically been little regulation of clinical activities, except by medical professionals. In the last two decades a growing focus upon quality improvement and patient safety in health care has been important for the development of different organizational improvement strategies and assurance activities. Systems requirements, imposed by external strategies such as regulation, accreditation, certification and standard setting, have been important drivers for quality and safety improvements. Accreditation, leadership, and legal drivers are three of the seven significant trends for the governance of quality and safety in health care [20]. Of these trends, accreditation and certification have much in common, and may be considered wholesale regimes. They both incorporate many strategies for quality and safety, such as standardization, external and internal control, assurance and improvement of systems, processes, and leadership [10]. The concepts of certification and accreditation are often used interchangeably in health care, and under the umbrella of external assessment systems [21-27]. These external assessment programs have great international coverage in health care, despite a clear debate on whether such regulatory regimes affect recognized quality measures [27-31]. Most external assessment program agree on the same basic principles: 1) standards are communicated to the participating organization; 2) the organization make changes or adjust its systems or practices to meet requirements in the standards; and 3) auditors review and assess compliance to the standards [32-34].

In ISO 9001 certification, "certification" incorporates both these three principles in addition to the final stage in which the certification body grants the organization certification or recertification [35]. In this thesis the word

"process" is sometimes added ("certification process") to emphasize that a description or discussion relates to the formal activities that happens towards the final decision of certification. These activities include interaction between the certification body and the certified organization.

In health care, much of the research on certification are included as part of the research on accreditation programs and important for this thesis's focus on ISO 9001 certification in health care. The following section reviews the research on ISO certification and related external assessment programs.

1.2 Research on certification and accreditation

Rational, homogeneous, precise, and predictable processes underpin the general beliefs about ISO 9001 certification [36-38]. These characteristics are related to the ability for reliable quality management systems and organizational quality improvement, audits and certification processes. These beliefs have been shown to be much more complex than assumed, because these processes are context- dependent and formed by the people involved. People possess different orientations towards certification and adopt, reinterpret, or reject certification requirements according to the situation [36-40]. Benefits of ISO 9001 certification and accreditation seems to be linked to both internal and external motivation [41, 42]. Internal motivations might be to achieve organizational improvement; external motivations may be related to promotional and marketing issues, government demands, and customer pressure.

In health care, certification and accreditation programs have been a contested domain. Claims about limited evidence of these programs effects upon recognized quality measures, and the limited use of rigorous study designs for a strong evidence base, have been put forward in several international publications, especially in relation to how many resources are allocated internationally to accreditation and certification systems [31, 43-45]. In 2006, a research group in Australia highlighted the complexity of accreditation program, and challenges related to the implementation of controlled studies [28]. They proposed a multi-method research design that was followed by a study of accreditation programs. They found some positive trends that accreditation programs can help promote professional development, better

management behavior and some characteristics of organizational culture [46]. Two updated systematic reviews used strong inclusion criteria to review the literature about the effects of certification and accreditation [44] or external inspections [47] upon process or clinical outcomes. They only found one and two studies that met their inclusion criteria, and no strong evidence to reach a conclusion about the effectiveness of certification or accreditation.

Earlier reviews with broader inclusion criteria report in general inconsistent findings on the relationships between certification and accreditation programs and clinical performance and outcomes [48-50]. The reviews showed a positive trend about the programs' ability to stimulate improvement work, promote organizational and cultural change, and change in professional practice concerned with quality of care. Hinchcliff [50] showed that health care professionals disagree when it comes to accreditation. Some professionals view accreditation as effective for development of high-quality organizational processes and patient safety, while others have concerns about the bureaucratic burden, the financial and human resources that are required, and the efforts needed to comply with a large number of standards.

Studies of 89 European hospitals indicate that accreditation and ISO 9001 certification are positively associated with some quality and safety structures and hospital outputs such as hospital management, clinical practice, safety, patient-centeredness and cross-border patient-centeredness. These studies demonstrated that accreditation has slightly more impact than ISO certification, but either system is better than none [22, 51] The authors concluded that there are a need for both internal quality improvement strategies and external control mechanisms in hospitals, and indicate that certification and accreditation are better than no external assessments. The EU project DUQUE with data from 73 European hospitals studied the relationship between ISO 9000 certification, healthcare accreditation and quality management. The researchers concluded that accreditation and certification were positively associated with clinical leadership, systems for patient safety and clinical review, but not with clinical practice [52]. Another study has shown that accreditation is demonstrably effective for organizational change, increasing social capital, developing relationships, stimulating cooperation, and nurturing links between healthcare organizations and other stakeholders [53]. Paccioni [54] showed that the accreditation process, and especially the initial preparation and self-assessment

phase, was an important arena for cultural control, one in which communication, participation, and collaboration about quality efforts improved.

A Danish nationwide population-based study of compliance with hospital accreditation and patient mortality showed that admission to fully accredited hospitals was associated with a lower 30-day mortality risk compared to admission at partially accredited hospitals [55]. Using an interrupted times series analysis following one hospital in Abu Dhabi over three years, the researchers showed that the positive impact of healthcare accreditation on hospital quality measures was maintained somewhat during the three-year accreditation cycle, but concluded that more focus on continuous improvement methods to sustain the positive impact form accreditation was needed, for instance frequent self-assessments or unannounced external reviews [56]. The use of unannounced external reviews was recently studied in a nationwide cluster-randomized controlled trial [57]. No difference between announced and unannounced surveys in detecting non-compliance with accreditation standards in hospitals was found.

Earlier studies of external review processes, such as ISO 9001 certification, in EU countries [58] and certification and accreditation on a global scale, [59] have showed that there is a need for a more transparent and holistic accreditation and certification process [58, 254]. Little is known about the processes and mechanisms that certification and accreditations bodies adopt. The approaches and methods that auditors use in assessment and verification processes, such as role repertoire, auditor's conduct (e.g., inspection or guidance) and assessment practice are important to investigate [50, 58, 60-62]. It raises questions about reliability and the need for deeper knowledge on how these practices shape the respective audit processes and outcomes. In external assessment systems, such as ISO certification, the auditors' experience, selection of auditors, training, support, and motivation may influence the performance, style, and reliability of the auditing (assessment) practices [26, 60, 63-65].

Based on the review of research related to certification and accreditation above, the next two sections outline the aim and structure of the thesis.

1.3 The overall aim

There is a lack of evidence that certification and accreditation have a direct impact on clinical outcomes. Nevertheless, there are many indicators that certification have fostered organizational change and have positive implications for quality and safety management. We still know little about why health care organizations adopt certification, and there is little documented knowledge about how certification processes unfold and are understood, for example, about the methods and approaches used by certification bodies, or how health care managers and professionals view certification in relation to their quality work. This thesis contributes to fill these knowledge gaps. The aim of this thesis is therefore to develop knowledge about:

1) External drivers and internal processes in hospital certification

2) The scope, understanding and practice of certification processes and the certification regime

3) The possible contributions to performance improvement from certification processes in hospitals.

I will therefore explore the ISO 9001 certification processes from the perspectives of the hospital, the certification body and the international standards and guidances for ISO 9001 certification. The research questions (see 3.5) are presented with the analytical working model (figure 6) after a review of the context of certification and the theoretical foundations of this thesis.

1.4 The structure of the thesis

This thesis consists of two parts. Part I contains 7 chapters that comprise the main body of the thesis. First the international ISO 9001 regime is presented followed by the international and Norwegian context related to policies and practices of ISO certification. Then the theoretical foundation is presented before the objectives, research questions and related working model. Further, the methodology and findings from the three associated articles are presented, before discussing the findings and present possible implications. Finally, part I concludes by revisiting the aim and the research questions and proposing

possible directions for future research. Part II presents the three associated research articles:

Article I: Johannesen, D.T.S., Wiig, S. Why adopt ISO 9001 certification in hospitals? A case study of external triggers and sensemaking in an emergency department in Norway. *Saf Health* 3, 7 (2017). https://doi.org/10.1186/s40886-017-0058-5

Article II: Johannesen, D.T.S., Wiig, S. Exploring hospital certification processes from the certification body's perspective — a qualitative study. *BMC Health Serv Res* 20, 242 (2020). https://doi.org/10.1186/s12913-020-05093-w

Article III: Johannesen, D.T.S., Lindøe, P.H. & Wiig, S. Certification as support for resilience? Behind the curtains of a certification body — a qualitative study. *BMC Health Serv Res* 20, 730 (2020). https://doi.org/10.1186/s12913-020-05608-5

2 ISO 9001 certification, accreditation and health care regulation

2.1 ISO 9001 certification and conformity assessment

The ISO has published more than 22000 international standards. The best known is the ISO 9000 series of standards and especially the included ISO 9001 standard. The ISO 9000 series consists of guidelines and requirements standards related to quality management; it is developed and maintained by the ISO Technical Committee TC 176. The ISO 9001 standard for quality management systems is the only one used for certification. The ISO does not perform certification activities and does not issue certificates. The ISO, however, develops, maintains and publishes standards; certification itself is performed by external certification bodies [33, 66, 67].

The ISO 9000 series was launched in 1987 and evolved from the UK's first management systems quality standard, BS 5750, introduced in 1978. The first ISO 9000 series of standards was inspired by traditional quality assurance standards in the manufacturing industry. To make the standard more business-focused and easier for people outside of the manufacturing industry to understand, the ISO thoroughly revised the 2000 version of the ISO 9000 family of standards, reducing the set of certification standards from three to one, the ISO 9001:2000 *Quality management system - requirements*, and introducing quality management principles and a process approach to quality management. The principles were inspired by influential quality gurus such as Deming, Juran, and Ishikawa. The shift in focus from quality assurance to quality management also became a shift from hard engineering-based requirements to softer more abstract requirements, such as management commitment and employee awareness. Even though the new requirements were more in line with modern thinking of organizational management, they were also more challenging to audit than the more prescriptive requirements in earlier versions of the ISO 9000 standards. The process approach and the fundamental principles to quality management have followed later revisions of the ISO 9001 standard [33, 68, 69].

ISO 9001 Certification is a third-party attestation of the managements system in an organization, indicating that it fulfills the requirements in the ISO 9001 standard for quality management systems [70, 71]. Certification in this perspective is a conformity assessment activity or certification audit performed by a disinterested body that is independent of the organization being certified [71]. If the organization demonstrates conformity with ISO 9001, the organization will receive a certificate of conformity. The certificate assures customers or recipients of services from the organization that they can expect reliable provision of products or services [33, 69]. Certification bodies and auditors should strive to build confidence and trust through a practice rooted in impartiality, competent assessments, and decisions based on objective evidence [35]. The ISO 9001 standard does not prescribe performance requirements. Rather, it proposes generic requirements for structures and systems that enable originations to formalize production or service processes, and to continuously monitor, document and improve its efficiency based on customer (patients) requirements and legal regulations [72, 73]. When ISO 9001 is used in the production industry, an important argument for adopting the standard is to ensure an organization's ability to provide products that fulfil customers' needs and requirements and to meet additional statutory and regulatory requirements [74]. When used in service organizations like health care services, it must also focus on customers' (patients') safety and risks, because high-quality services within health care must involve safe practice and safe environments [73, 75-77]. A certification program has a three-year audit cycle: the initial certification process, two shorter surveillance audits over the next two years, and then recertification in the third [35].

To earn public confidence in the certification process, certification bodies may demonstrate their competence to carry out third-party certification processes by becoming accredited. When an accredited certification body performs certifications, it is sometimes termed an "accredited certification" (figure 1). Requirements for certification bodies are defined in ISO/IEC 17021-1 *Conformity assessment. Requirements for bodies providing audit and certification of management systems. Part 1: Requirements* [70], developed by the ISO Policy Committee for Conformity Assessment (ISO/CASCO). The standard sets the requirements for the certification bodies' system, process and practices related to ISO 9001 certification. The standard is based on the core

principles of impartiality, competence, responsibility, openness, confidentiality, responsiveness to complaints and risk-based approach. The process and methods for certification audits of management systems required in ISO/IEC 17021-1 standard are closely connected to and make references to the generic guidelines for auditing management systems given in the ISO 19011 standard [78].

There is usually only one recognized accreditation body in each country, authorized to participate in the multilateral recognition arrangements coordinated by the International Accreditation Forum's (IAF) Multilateral Recognition Arrangement (MLA). An accreditation body that is a signatory of the IAF MLA is subject to a peer-assessment process based on the requirements stipulated in the ISO/IEC 17011 *Conformity assessment - Requirements for accreditation bodies accrediting conformity assessment bodies* standard, which is also developed by the ISO/CASCO. In both the ISO 9001 certification processes and the accreditation of certification bodies processes the ISO and IAF have published guidance notes devised by an informal group of experts, auditors and practitioners. For ISO 9001 certification the guidance notes are developed by the ISO 9001 Auditing Practices Group (APG), with quality management system (QMS) experts, auditors and practitioners drawn from the ISO Technical Committee 176 Quality Management and Quality Assurance (ISO/TC 176) and the International Accreditation Forum (IAF); and the Accreditation Auditing Practices Group (AAPG) with accreditation experts, auditors and practitioners, drawn from the ISO Policy Committee for Conformity Assessment (ISO/CASCO), the ISO Technical Committee 176 Quality Management and Quality Assurance (ISO/TC 176) and the International Accreditation Forum (IAF).

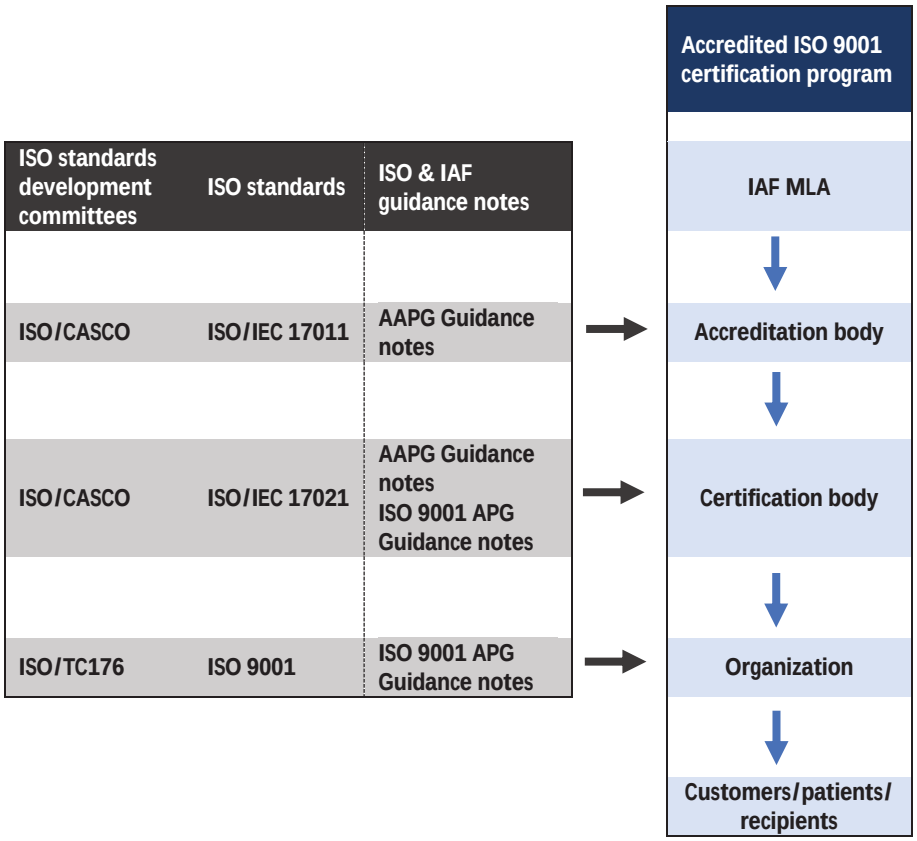

Figure 1: The process of accredited ISO 9001 certification and the associated ISO standards and guidance notes.

2.2 Hospital certification and accreditation – the international context and development

In the international context, hospital certification and accreditation are often referenced interchangeably as external assessment or review systems [21-27] even though their origin were derived from different sectors; accreditation as a self-regulatory program developed by the medical profession themselves and ISO 9001 certification as a quality assurance program derived from the manufacturing industry. Different forms of external review, assessments or audit processes seems to be an established part of the health care systems in more than 70 countries [31].

Hospital accreditation, derived from the early model in the United States[1] of the late 1910s, rapidly spread to Canada and Australia, and could be seen as a product of the developments in these three countries [32]. The practice was then emulated around the globe. The accreditation programs were essentially the same, but their relation to state regulation, funding and health services was context-dependent. These early accreditation programs started as self- or peer-assessment programs by the medical community. The development of standards and monitoring features changed from the 1980s, with the incorporation of management and quality improvement principles form the "Quality movement"[2] [32], such as Total Quality Improvement (TQM) and Continuous Quality Improvement (CQI). The emphasis on management systems and processes became incorporated into the standards, and focus shifted from the original purpose — to protect the medical profession from effects of poor environments and organizations — to the protection of the patient. These developments also lead to a change in attempts to increase objectivity in assessments of compliance to standards, and greater attention to surveyors' educational roles in assessments [32]. The approaches to external reviews processes changed from compliance testing according to standards to more holistic approaches for organizational development and learning [59, 81, 82], and have continued in later approaches [29, 52].

In 1980 the United Kingdom piloted the first accreditation program in health care. This was the first of many European governments that considered some form of accreditation program in health care [81]. However, by 2000 only three governments were operating their own accreditation program. Accreditation as an external means of assurance in health care had taken many forms in Europe, from self-regulation according to externally agreed-upon standards, to professional review systems, to traditional government inspections. There was also a turn to quality improvement and away from the assurance of quality of

[1] In 1917 the American College of Surgeons started the Hospital Standardization Program, developing minimum standards for hospitals, followed by on-site inspections. This program evolved into a joint accreditation programs by different medical associations in health care [79].

[2] The "Quality movement" comprised ideas and practices of new quality improvement principles, in a range of industries in the United States and around the world in the 1980s and 1990s [80].

these external means, leading to an increased interest in quality management approaches such as ISO 9001 and similar programs [81].

In the 1990s, the International Society for Quality in Health Care (ISQua) was at the forefront in conferences and consensus processes to align health care standards and accreditation and certification processes, including ISO 9001 certification [83]. Many countries and regions were involved in setting standards as a basis for assurance activities, often through accreditation or other external review processes, such as ISO certification. The ISQua has become a recognized global external review body performing peer-review assessment and accreditation of different national and international programs. ISQua does not directly accredit hospitals or health care providers. In January 2019, ISQua established the External Evaluation Association (IEEA) as the ISQua accrediting body (www.ieea.ch).

In 2003, a global review [59] reported over 30 countries with national accreditation programs in health care (excluding ISO certifications and other local and regional external review programs). Their programs ranged from voluntary to fully government-run. A follow-up review in 2013 reported a growth in the number of national accreditation programs, even though half of those programs reported ten years earlier had ended or were least developed. The review showed increasing interaction with governments and regulators for programs with long-term sustainability [29]. Fewer than one-third reported a formal relationship with national accreditation bodies under the ISO system. Some hospital accreditation programs have adopted the ISO 9001 requirements as part om the accreditation program. The best known current program is arguably the DNV GL NIAHO hospital accreditation program in the U.S. (www.dnvgl.us), that integrates ISO 9001 requirements with the Medicare Conditions of Participation (CoPs) for Hospitals.

2.3 Health care regulation and ISO 9001 certification in Norway

The regulation of quality and safety for health service providers in Norway is based on a functional legislation, outlined as enforced self-regulation with requirements for healthcare services to establish internal control systems [84, 85]. All hospitals, their service and health personnel are subject to supervision

by the Norwegian Board of Health Supervision (NBHS), through the 18 Offices of the County Governors. Most supervision of hospitals takes the form of system audits, whose aim is to ensure and control whether health service is in compliance with national regulations. The internal control system was stated by law in 1984 [86]. The legal requirements are not regarded as prescriptions of performance but confined to what is considered necessary for ensuring sound professional practice and safety and quality in health services [84]. This means that hospitals have the latitude to make decisions about their organization and priorities related to patient treatment, including the authority to instruct hospital personnel within the limits of legal requirements and their obligation to work according to sound professional practice [84]. The legal requirements for internal control systems were inspired by the established acts relating to working environment and the petroleum sector. When the law was enacted in 1984, the term "self-control" was used. It was a more general requirement, stating that every health provider should control its own performance, based on the assumptions for professional self-regulation in medicine and the medical practice [85, 87].

In 1995, the Norwegian Board of Health Supervision published a national strategy aimed at establishing systematic quality management in health care services. The goal was to establish internal control systems in all hospitals by the year 2000 [88]. In 2001, however, a national audit performed by the NBHS concluded that hospitals "have not reached the goal of comprehensive and effective internal control systems/quality systems in health by 2000, as set out in "National strategy for quality improvement in health care [89, Ch. 7]." It added that there was a clear and unquestionable need for a statutory regulation that clarified the law about internal control system. A statutory regulation took effect in January 2003, the year after a guide for internal control in health and social services, "How to Keep Your Own House in Order," was published by the Norwegian Directorate of Health [90]. The guide explained how the internal control system could help to increase the safety of clients and patients, and how internal control has been a valuable management tool in activities that involve risk. It described internal control as consisting of activities "[...] to ensure that the organization's tasks are planned, organized, performed and maintained in accordance with the requirements of the legislation. The main demand is the requirement for soundness" (p.7). The guide also stated that leaders are responsible for managing internal controls systems and integrate the system

into daily practice. In 2007, more than a decade after the internal control regime was enshrined in the law, a report published by the Norwegian Directorate of Health [91], made by "people from the field of practice", described the internal control as a new area in the health sector. Internal control, quality management systems and ISO certification were cited as good examples to ensure quality, especially when it came to continual improvement (p. 20).

In parallel with the challenges of establishing well-functioning internal control systems in Norway, the early initiatives of ISO 9001 certifications in hospitals started. In 2002, the Hospital Innlandet HF, Kongsvinger became the first hospital to be certified according to the ISO 9001:2000 standard [92]. Three years later, the Eastern Norway Regional Health Authority[3] adopted the ISO-9001 as a guide for all its hospitals, in order to operationalize the internal control system requirements [93]. It was argued that the lack of follow-up on the internal control system could relate to "difficult conceptualizations, vague demands, uncertainties about overall quality management systems and its advantages" [94]. In 2007, the Norwegian Board of Health Supervision carried out supervision of 27 emergency departments in the specialist health service in Norway [95]. The inspectors noted several failures and painted a picture of poor management, prioritization and patient treatment. The Southern and Eastern Norway Regional Health Authority and the Norwegian Accreditation (NA)[4] followed up on these challenges in 2008 by initiating a pilot project for certification of emergency wards in Norway according to the ISO 9001:2008. They also developed extended requirements in order to pilot the future accreditation of emergency departments [96].

The certification initiatives came at a time when the evidence base for certification and accreditation effects was both called for and questioned [23, 31, 97, 98]. In Norway, the lack of evidence was questioned both among

[3] On 1 June 2007, the Eastern Norway Regional Health Authority and the Southern Norway Regional Health Authority were merged into the Southern and Eastern Norway Regional Health Authority. There are now four Regional Health Authorities in Norway.
[4] NA is the Norwegian body for accreditation of laboratories and sampling organizations, certification bodies, inspection bodies, and environmental verifiers (EMAS). NA represents Norway in the European Co-operation for Accreditation (EA), the International Laboratory Accreditation Cooperation (ILAC) and the International Accreditation Forum (IAF). NA is also the Norwegian monitoring body for Good Laboratory Practice (GLP) inspections, according to OECD's GLP principles.

researchers at the Norwegian Knowledge Centre for the Health Services [43, 99], in policy development and in debates in the Norwegian parliament [100, 101]. The Norwegian Directorate of Health [102] reported that more hospitals and wards had started using ISO 9001 certification in regulating their quality and safety. Such approaches had been used for laboratory and technical activities in hospitals, but to a very little extent in clinics. The Norwegian Directorate of Health considered ISO 9001 as useful in following up on the requirements of internal control regulations, and mentioned that the hospital Asker and Bærum HF had, among others, gained good experience using ISO certification to operationalize the internal control regulations. However, the Norwegian Directorate of Health pointed to the lack of evidence and declined to recommend a mandatory certification or accreditation program.

In 2015, the National Health and Hospital Plan for 2016−2019 reported, "It is the Government's goal to introduce a system for quality certification of hospitals" [103]. This white paper was the first official government policy to take a stance on the establishment of certification systems in hospitals. The ISO 9001 certification was highlighted since it contained many of the same elements for quality improvement as internal control regulation.

In January 2017, the regulation on internal control systems [104] was replaced by the *Regulation on Leadership and Quality Improvement in the Health and Care Services* [105]. Both in the regulation and the associated guide from the Norwegian Directorate of Health [106] internal control concept was downplayed in favor of leadership and quality improvement. The intention was to make it clear that internal control was an integrated and natural part of the organization's management system. It also illustrates the close connection between development and application of internal control and quality management [85]. The structure of the regulation and the guide is based on Deming's four step (Plan-Do-Check-Act) management approach for control and continuous improvement of processes and products, which is also the foundation for the ISO 9001 standard [107].

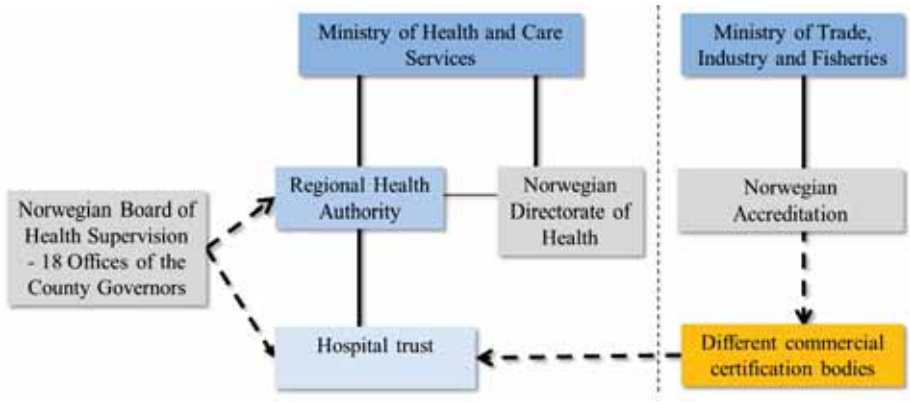

Figure 2: A simplified illustration of the organization of the health care system in Norway in relation to the system for accreditation and certification.

There seems to be a general agreement in policies for internal control and quality management in Norway that the foundational approaches in the ISO 9001 standard itself follows the same foundational principles and approaches as laid down in the Norwegian health care regulation. Despite different efforts, the government has not yet established any mandatory certification programs for quality management systems in hospitals, and the adoption of ISO 9001 certification is voluntary for health care organizations.

Five (four when data for this thesis were collected) commercial certification bodies in Norway have the accreditation to perform hospital certification according to the ISO 9001 standard [108]. These bodies are accredited to perform certification by the Norwegian Accreditation (NA), a national body under the Ministry of Trade, Industry and Fisheries. The Norwegian Accreditation is a signatory of the IAF MLA agreements related to accreditation.

3 Theory

In order to explore external drivers for hospital certification, the understanding and practice of certification processes, and their possible contribution to performance improvements this thesis draws on four theoretical perspectives. Taken together, these perspectives explore certification as an institutional and organizing construct that unfolds through interaction between inter-organizational- (macro level) and intra-organizational fields (meso and micro level). The four theoretical contributions are as follows.

1) The institutional perspective and organizations [1-4, 6, 109-113]. This perspective helps to see how macro institutional elements (e.g., management ideas, schemes or regulations) shape or trigger organizations.

2) The sensemaking perspective [114-119] helps to see how people in organizing activities (e.g., certification processes) use institutional structures to give meaning to their actions. Although certification is based on external control mechanisms, it nevertheless requires internal processes within organizations.

3) Governance perspectives [3, 5, 10, 13, 16, 34, 120-123] help to see how organizational accountability and transparency are constructed among external actors, using standards, modes and methods for information gathering and behavior modification (e.g., audits and certification), and the organizations are supposed to give account.

4) Resilience perspective [18, 19, 124-128] helps to explain complex organizations' (e.g., hospitals) potential to respond to, readjust or recover from variability and disruption, and how organizing activities (e.g., external audit) may shape resilient intra- and inter-organizational performance.

The following chapter outlines the four theoretical perspectives and how they are interrelated. At the end of the chapter the objectives and research questions for the thesis are presented along with the analytical working model.

3.1 Institutional theory and organizations

Organizations are part of institutionalized environments where they meet socially constructed norms for how organizations should be formed. Meyer and Rowan [112] describe that institutionalization "[…] involves the process by which social processes come to take on a rule-like status in social thought and action. So, for example, the social status of doctor is a highly institutionalized rule (both normative and cognitive) for managing illness as well as a social role made up of particular behaviours, relations, and expectations" (p. 341). Organizations must relate to and incorporate these socially constructed norms or rationalized myths even if they do not necessarily make organizations more effective [6, 112]. Socially constructed norms serve as cognitive constraint upon an organization. This ecological perspective has formed much of the foundation for what is often considered neoinstitutional theory [113, 129]. In particular, it is the basis of the assertion that institutions are becoming more similar (isomorphism), that organizations follow institutional norms ceremonially, that is, a decoupling between structure and practice, and that practices are typically taken for granted. Later arguments, both from the authors themselves [109, 117] and others [113, 130-132] have emphasized that institutional theories must include both institutional environment and organizations as institutions, focusing on structures, normative assumptions, and organizational processes. These arguments on institutional theories includes both macro- and micro-level perspectives [113], or what has been described as the inter-organizational and intra-organizational field [110]. Scott [113] presents a broad definition of institutions in establishing a more coherent framework for institutions and institutional analysis. He identifies important analytical elements from organizational and institutional theory, philosophically substantiated with rational and socially constructed approaches. Scott's [113] definition consists of three elements: "Institutions are comprised of regulatory, normative and cultural-cognitive elements that, together with associated activities and resources, provide stability and meaning to social life" (p.48). According to Scott [113] the regulatory element often takes the form of public regulation. In this sense, it is founded on the rational and instrumental view of rules, control and sanctions to influence institutional actions. The normative element is based on systems of values and norms. It encompasses prescriptive, evaluative and mandatory dimensions that govern how thing

should be done. The cultural-cognitive element consists of internally interpretive and socially constructed processes of social realities that frame meanings. Organizations will often unconsciously follow these culturally cognitive aspects of institutions. They form a basis for the legitimacy of opinions and activities that no one questions.

3.1.1 Organizational fields

The organizational field is a central analytical unit of institutional theory; it has changed the character and perspective from emphasis on "homogeneity" in and between organizations to the dynamic processes and change between and within organizations [4, 110, 113]. The organizational field consists of institutional systems that motivate and guide actors in their interaction. These systems may be shaped by institutional logic or socially constructed beliefs, rules, scripts or schemes that helps to shape the actors' cognition and behavior [113, 133-136]. Institutional logic emerges as a link between individual cognition and action and socially constructed practices and rule structures, and strengthens studies of meanings and change in institutions. When a collective identity becomes institutionalized, a distinctive institutional logic develops [136]. Institutional logics can as such be considered as socially constructed frames that people may use either intentionally or unintentionally to give meaning to situations [1, 113, 116]. Scott [113] identifies organizational fields as an intermediate space between individual actors and organizations at the micro level (intra-organizational) and between organizations and the wider society at the macro level (inter-organizational level). Organizational fields (inspired by Gidden’s structuration theory) are seen as simultaneously top-down and bottom-up processes [113, 117]. Higher-level structures such as governance both constrain and empower the structures and actions of lower-level actors, and involve processes such as socialization, translation, diffusion, authorization and inducements. In contrast, the lower-level actors and structures simultaneously reproduce and change through processes such as interpretation, sensemaking, identity construction, conformity, compromise, avoidance and manipulation [113]. Disruptive events, exogenous shocks or reconfigurations (e.g., disasters, regulatory changes or changes in everyday practice) are often entries to engagement in organizational fields [136]. The organizational fields then become the sites where organizations or people come

together in sensemaking processes. This thesis builds on the sensemaking perspective to explore the intra-organizational processes related to certification.

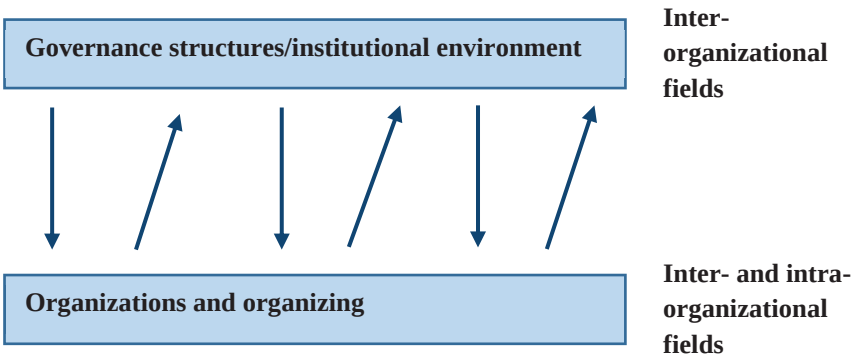

Figure 3: Organizational fields in top-down and bottom-up processes for institutional construction and change [113, 117, inspired by Gidden's structuration theory]. Higher-level structures constrain or empower structures and action of the lower level. In contrast, the lower-level actors and structures simultaneously reproduce and change higher-level structures.

3.2 Sensemaking and interpretation

When organizations adopt organizational ideas, recipes, standards, governance structures and the like, they are contextualized into local variants through editing [4] translation [1, 4] and sensemaking [115]. From a sensemaking perspective, these are organizing processes [115, 116, 118, 119]. The traditional translation perspective in neo-institutionalism has been described as providing a limited basis of analysis of dynamic intra-organizational processes of different departments and actors, due to its focus on interpretation of the institutionalized organizational idea or structure in itself [117, 137-139]. This thesis applies a sensemaking perspective to explore actors' collective interpretation in microprocesses. Different initiatives have been presented to combine macro- level institutional theory with micro-level sensemaking processes [114, 140, 141]. It has been argued that organizations seldom begins their thinking from scratch [114, 116] and therefore can be triggered by changing or stable institutional environments; micro sensemaking processes feedstock environmental transformation, institutionalization, or macro social order [114, 116, 117, 119]. Powell and Colyvas [117] desccribe these as "pulled down" and "built up" entries [117]. A pulled-down entry is associated with the

way in which elements shape, trigger, and are situated by organizations and individuals, but with less influence over what happens subsequently [114, 116]. Weber and Glynn [114] proposed three mechanisms to describe how institutions affect organizational sensemaking: priming, editing, and triggering.

An important issue with sensemaking is the way in which the unintelligible something becomes an event for organizational actors, and what this event means. In everyday life the central question is "What's the story here?" [116 p. 410]. Sensemaking emphasizes that the adoption of different management perspectives or organizational ideas does not follow rational, instrumental decision-making processes; rather, it is filled with constantly changing sensemaking processes that assign meaning to changing situations and outcomes [116, 142]. Sensemaking becomes most pronounced when new events or processes are perceived as different from previous ones or from what people had expected. It is often seen when people confront turbulence, change, crises or exogenous surprises [115, 116, 119, 136]. Weick, Sutcliffe and Obstfeld [116] are concerned with how people interact with the social environment in order to give meaning to their actions. They state that "[…] sensemaking unfolds as a sequence in which people concerned with identity in the social context of other actors engage ongoing circumstances from which they extract cues and make plausible sense retrospectively, while enacting more or less order into those ongoing circumstances" (p. 409). This description emphasizes the environmental triggers or discrepant set of cues [115] that are enacted by individuals. Weick define cues as the "minimal sensible structures" [115] that people perceive. People are then guided by institutional constraints and earlier scripts, schemes and frames to make sense of the situation. Thoughts, feelings and intentions, the "intrasubjective meanings," are merged into "intersubjective meanings" through conversations. It is a transformation from "I" to "we" [115, p 71], in which interactions and organizing occur, and scripts are written. In times of stability, individuals draw on these relative stable scripts or frames to make sense of situations ("generic subjectivity"). In contrast, in times of turbulence and change, "old" scripts no longer work. A gap needs to be filled and an intersubjective or collective sensemaking again becomes prominent, and people look for reasons to continue or resume their work. When people look for reasons to continue "[…] sensemaking is about the interplay of action and interpretation rather than the influence of evaluation on

choice" (Weick, et.al., 2005, p. 409). These sensemaking processes is not about accuracy and truth, but about plausibility. People continually redraft their stories in their search for meaning, so the stories become more comprehensive and resilient to criticism, and contain more data. When shared meanings are created people's commitments, identity (or capacity [115]) and expectations are important in mediating sensemaking processes [115, 119]. Commitments generate explanations to justify action. These can be helpful in ambiguous situations, but can also create blind spots. Identity is especially important when it is threatened. In change and crisis, identity or roles are replaced or transformed and can lead to resistance. A shared identity can therefore become an anchor for collective sensemaking. Expectations connect with cues and these expectations then become a filter that either builds confidence about the situation or constrains action [119].

Weick et al. [116] present a conceptual model for the study of intra-organizational sensemaking, obtained from Jennings and Greenwood [143]. It is underpinned by evolutionary principles and reflects how people makes retrospective interpretations when interacting with the environment. "It proposes that sensemaking can be treated as reciprocal exchanges between actors (Enactment) and their environments (Ecological Change) that are made meaningful (selection) and preserved (Retention)" [116, p. 414] (figure 4).

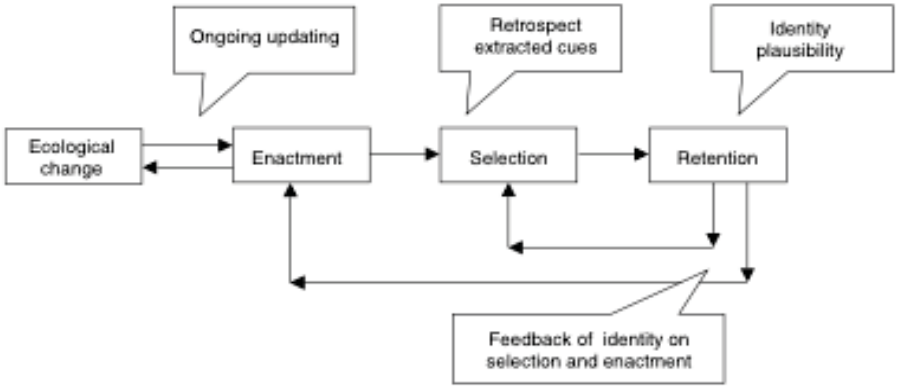

Figure 4 Relationships among environmental change, sensemaking and organizing. Adopted from Weick et al. [116]

Sensemaking takes place by categorizing different perspectives to stabilize and organize experiences: cognitive categorization. These categories or "labels" are

socially constructed. Sensemaking and organizations constitute one another through organizing processes. The organizations themselves do not create meaning, but the organizations are created through sensemaking. Communication is therefore central to sensemaking. An important factor in the study of sensemaking is that intentional actions never lead to intentional change, because many organizational processes and actions take place at the same time [116].

3.3 Governance and accountability

Over the past few decades there has been a rise in standardization and certification practices [29, 144] in health care. This increase is not unique to health care but part of a general change in the mode of regulation, towards demands for accountability and transparency, and a shift in theoretical approaches to regulation and institutional theory [4]. [2-4]. Sahlin and Wedling [4] emphasize that "focus has shifted from management to regulation, from an intra-organizational to inter-organizational focus, and from talk of efficiency to talk of transparency. In general this shift is clearly following the logic of an audit society […]" (p. 231). In the audit society [7] external actors, such as standardization organizations like the ISO and certification bodies, becomes central to drive standards and schemes, and to control organizations accordingly. It has led to an expansion of monitoring, assessments and audit activities [5, 7]. Standards, templates, schemes and external review regimes follow many of the same institutional dynamics as prototypical organizational management models, but they also have some distinctive drivers and implications [4]. Distrust, the first driver, focuses on the need for control and transparency in order to create trust. At the same time, this results in more revision, monitoring and regulation. Furthermore, allocation of responsibility is central. Soft regulation brings responsibility from the state to the practitioners. This makes the regulation diffuse and complex. The third driver is the organization's search for control. When regulation becomes diffuse and complex, organizations seek ways to control their business. Organizations becomes active in developing regulatory requirements for control. Some researchers have described this change as a form of deregulation, due to a reduction in "hard laws" and directives, and others as re-regulation [5], or de-

centered or polycentric regulation [12, 145]. Black's [145] polycentric definition of regulation is:

> sustained and focused attempts to change the behavior of others in order to address a collective problem or attain an identified end or ends, usually through a combination of rules or norms and some means for their implementation and enforcement, which can be legal or non-legal.

This perspective approach regulation as a nonlinear or a dialectic process, where the regulator and the regulatee depend on each other. What is central in these "wider" terms of regulation is the transformation of traditional state regulation into modes of governance [4, 5, 12, 34, 120, 145-147]. From a governance perspective, regulation includes and is performed by actors and networks both inside and outside of government. Regulation is often transnational in structure and includes non-binding soft rules and regulations such as standards. Such extended views on regulation are present in the literature on regulation in health care [10, 34] where third-party external review models are termed as regulatory strategies even though many of these programs are voluntary and non-state programs. These external review models most often use standards to communicate requirements and to assess compliance. This extended view of regulation is relevant to this thesis, since ISO 9001 certification is defined as a third-party conformity assessment [33], and can be used as a regulatory means of enforcement by state agencies, expected by the market or adopted for self-regulation by the organizations themselves.

The shift to soft regulations is not an either/or between the use of hard and soft laws, but most often a combination of the two [148]. The integration of standards into a hard and soft law perspective may be depicted in a hierarchical structure [148]. At the top layer are legal binding rules such as laws, orders and regulations. These may represent the traditional command and control perspective, where prescriptive rules are developed and enforced by a governmental entity. At the middle level are the private organizational standards that are adopted and enforced by the regulator; and at the bottom level are other private internal and external organizational standards, social norms and guidances. Organizations adopt or develop these standards either voluntarily, as means of self-regulation of quality and risk management and "best practices", or to fulfill functional requirements in regulation and for

internal control systems [148]. Another way to describe this interrelationship is by seeing hard regulation as imposed from the top-down perspective and soft regulations as percolating from the bottom up [148, 149]. In the top-down perspective, the regulators develop and enforce rules for organizational compliance or use references to technical standards or professional guidance to guide or instruct compliance. In the bottom-up perspective, organizational self-regulation is as described above. The middle zone is where modes of regulation are combined in a form of co-regulation, typical of regulatory regimes using functional requirements, or internal control requirements are used as a means of enforced self-regulation [15] or meta-regulation [34]. Such approaches may give organizations the freedom to choose different controls in order to fulfill the requirements. This may be to voluntarily adopt legitimate private standards for quality and risk management, such as the ISO 9001 standards, voluntarily adopt certification or other external review schemes to fulfill regulatory requirements of internal controls, or as a means of self-regulation.

3.3.1 Accountability and responsibility

Hospitals value the autonomy of their professional staff [150] and the delegation of responsibility for organizations to ensure high-quality performance. A governance system that emphasizes such values assumes that health care professionals have the freedom to develop, improve and control the systems and performance of their organizations. However, in order to reassure the public, the government and other stakeholders, that the hospitals are doing what is expected of them, there needs to be a mechanism to develop trust and to ensure that professional freedom does not become an alternative to accountability [120]. Accountability often encompasses different characteristics in the governance literature, but standard definitions mention actors being liable or required to account for their conduct, [120, 145]. Olsen [151] defines accountability as “being answerable to somebody else, to be obligated to explain and justify action and inaction—how mandates, authority, and resources have been applied, with what results, and whether outcomes meet relevant standards and principles” (p. 2). “Somebody else” from a governance perspective is usually some actor outside of the organizations, whether this be the government, the regulator, the public or professional associations. It may also be a certification body, even though these may be involved in voluntary

assurance activities. Accountability obligations may be a matter of gaining both upwards, downwards, and outwards trust [120] (figure 5). Responsibility, on the other hand, is often treated separately from accountability, referring to the internal systems of organizations, such as the delegation of management or the conduct of the organization and management [120, 152]. Responsibility means that organizations, and their managers are responsible for making sure that what is expected of them actually are being done. This could entail following up on requirements in a quality management system. To distinguish, accountability may rely to the need for some independent oversight and enforcement mechanism, such as inspectoral bodies in regulation or certification bodies in certification programs, while responsibility may rely to organizational self-regulatory strategies [120].

Figure 5: Accountability, responsibility and assurance for organizations. The figure illustrates organizational upwards, downwards and outwards accountability obligations and the associated expectations of assurance, and responsibility as managing inwards obligations and the associated internal assurance processes. Figure Adapted from [120]

3.3.2 Control, assurance and control methods

Accountability and responsibility are closely linked to questions of control and assurance. Regulatory control is related to the methods, systems and processes that organizations or regulators use to produce the desired performance.

Assurance is based upon the belief that organizations can account for their systems, processes and performance. In addition, assurance assumes that an organization can present itself for external review and originates from auditing [120, 153].

Control of quality and of risks is often related to cybernetic foundations where there are three components: standard setting, information gathering and behavior modification [120, 123, 145]. Implicit in this perspective is the belief that quality and risk can be influenced [120, 123]. The approaches to performance improvement for health care organizations, can take the form of externally imposed and internally generated controls, with the latter being voluntary adopted [10, 120]. Internal approaches focus on change from within the organization, like structures, processes, management systems and measurement tools. External approaches are designed to change the environment within which an organization operates, in order to improve organizational behavior. There are blurry boundaries between internal and external approaches, and external review or control approaches tend to combine the two [10, 85, 120].

Both the internal and external types of control can be informal/values-based or objective/formal-based [85, 120]. Both types of control bring together the organization's total management system to achieve the organization's objectives. The types of control have driven the development of different kinds of auditing to ensure accountability. The perspective of assurance assumes that an organization can account for its internal management system and processes, and submit to external scrutiny [120, 153]. The concept of internal control in a regulatory context is linked to quality control, quality management and corporate governance thinking, all of which are often based on the same management logic [85, 154].

Organizations provide assurance by permitting external scrutiny, but the responsibility to demonstrate compliance with externally imposed controls or internal controls may fall inside or outside of the organization. There are two ways for an organization to provide assurance: by allowing a total review of its performance, such as in certification audits and inspections, or by conducting its own audits or inspections while welcoming external assessments of those audits [120, 153]. Further, organizations can provide assurance either by

following externally imposed rules, such as regulations and the non-legal ISO 9001 standard, or by setting their own internal rules or professional standards [17, 85, 120]. Often a combination of internal and external assurance activities are used, and both are a form of "quality assurance of quality control" [120, p. 33]. A combination of both approaches is used in enforced self-regulation [155], meta regulation [34, 156, 157] or system- or performance-based regulations [158].

External assurance assumes that organizations can be assessed and analyzed objectively to influence organizational behavior. This notion follows rational or instrumental logics [113] that in everyday regulatory encounters, and in theories of regulation, have shown themselves highly complex and culturally dependent [10, 34, 120], especially in fields with strong professions [159, 160]. In health care, regulation is faced with a strong profession where doctors are involved in internal and external arenas [161]. There are numerous views on how regulators or external assessment bodies think of the organizational field they assess, what the crucial objectives are, and how they approach their roles and functions. The various views include different modes and methods for information gathering and behavior modification related to assessment processes (e.g., audits and certification). In regulation theory, these processes are often related to regulatory enforcement. Two models or strategies of enforcement have been described [10, 13, 123, 162, 163]: deterrence and compliance (advise and persuade). These categories are considered as an orientation towards one or the other, and in practice are often a mixture of both. In health care, the compliance strategy has been predominant in external assessments [34]. In recognition of deficiencies in these distinct orientations, hybrids have been proposed, such as the early tit-for-tat strategy underpinned by game theory [164] and others, most of which arose from the early theory of responsive regulation [15].

Motivational characteristic of the regulated organizations, and how these characteristics are seen by the regulator, are considered important for the approach or style the regulators choose [10, 13, 165]. Seen as two poles on a continuum, these organizational characteristics correspond to the deterrence-compliance orientations and are described as "amoral calculators" [165], corresponding with the deterrence strategy, and the "organizational

incompetent" [165] or "good-hearted complier" [10], corresponding with the compliance strategy.

At the outermost pole of deterrence, the regulator's energy is devoted to detecting violations, establishing guilt and penalizing violators [13]. The regulated organizations are rational actors that respond to rules and incentives. Repeatedly sanctioning violators will prevent both the violator (specific deterrence) and others (general deterrence) from reoffending. The proponents of deterrence see the regulated as amoral calculators [165] where economic calculation to comply will include whether compliance is required by law or non-compliance is likely to be detected and penalized. The regulated organizations are motivated by profit and tend to be willing to break the rules if they expect to get away with it. Deterrence strategies are legalistic and regulators make extensive use of formal standards and inspections [10, 13]. Inspectors have a confrontational style, where formal, distant an adversarial relationship is prominent. Close relationships between the regulator and the regulated may have undesirable influence on sanctioning processes when there has been a violation.

The proponents of the compliance [10] or the advice and persuasion strategy [13] treat organizations as well-intentioned, aiming to do the right things in the best way. If organizations perform poorly or the regulators detect non-compliance it is treated as ineffective circumstances or incompetence in the organizations that requests for regulators that are developmental, supportive and an advisory in their approach. This also means that there is often a closer interaction based on mutual trust between the regulators and the organizations. The threat of enforcement, such as formal sanctions or penalties is used only as a last resort.

For studies of health care regulation bodies, Walshe [10] has proposed a framework that focuses on seven characteristics: regulatory organization, regulatory goals or objectives, scope of regulation, regulatory model, direction, detection and enforcement. The first four characteristics are aimed at the environment and the context in which regulation takes place. The remaining three characteristics are concerned with control methods and the regulatory process [10, p 32-35]. They are characteristics of a regulatory regime and as such are important for studying the process and performance of certification.

Direction relates to the methods used to communicate regulatory requirements or directions to regulated organizations, such as written standards and guidelines. The ISO 9001:2015 standard for quality management systems is one such standard related to certification. Detection consists of the methods used to measure and monitor the performance of regulated organizations to determine whether they comply with regulatory requirements or directions. In ISO 9001 certification this characteristic complies with the formal processes of conformity assessments and certification audits. The last characteristic, enforcement, consists of the methods used to persuade, influence or force regulated organizations to comply with regulatory requirements or directions. In ISO 9001 certification, this characteristic is associated with certification audits, but also to the formal response to non-conformance and issuance of a certificate of conformity, and the scope of opportunities that auditor has to adopt in the encounter with the body being audited. Several typologies have been developed to explain regulatory institutional practice in the regulator-regulatee encounter, such as the characteristics of the regulated organizations [165]; regulator's perception of the regualtee [166]; inspector's inconsistency [167]; types of relational signals [168]; and surveyor's assessment of explicit/formal and implicit/opportunistic assessment styles [63].

3.4 Resilience

In recent years, the perspective of resilience and resilience engineering [125] in healthcare has become increasingly important for research and quality and safety work, and in the forefront among the Nordic perspective [169]. We are more aware that health care organizations, especially hospitals, are complex organizations or complex adaptive system (CAS) in which personnel routinely need to adjust and adapt [170]. In these systems some of the traditional approaches to quality and safety in hospitals have fallen short. Traditional approaches to quality and safety have focused on reactive and linear analyses of the causes and effects of errors. In the resilience literature, errors are not attributed to a malfunctioning predictable system, but rather to performance variability, with the acknowledgment that complex adaptive systems cannot be fully understood [127, 171]. Supporters of resilience therefore stress development of flexible and adaptable local systems, where local knowledge and professional judgments are essential for everyday performance. The system

should be able to perform under both expected and unexpected conditions. It is a departure from the traditional approach, one in which finding errors or their causes create safe systems (Safety-I), to one that looks at things that go right and supports the improvement of performance to build resilience (Safety-II) [171].

Resilience engineering defines resilience as:

> […] an expression of how people, alone or together, cope with everyday situations – large or small – by adjusting their performance to the condition. An organisation's performance is resilient if it can function as required under expected and unexpected conditions alike (changes/disturbances opportunities) [125].

According to this perspective, resilience and organizations are not a matter of whether an organization can be resilient. Instead, it is a matter of managing or supporting the *potentials* for resilient performance [125]. The potentials for resilient performance are:

1. The potential to respond: the ability to address the actual and know what to do.
2. The potential to monitor: the ability to address the critical and know what to look for.
3. The potential to anticipate: the ability to address the potential and know what to expect.
4. The potential to learn: the ability to address the factual and know what has happened.

To support the potential for resilient performance, we need to understand the organizational practice and the distinctions between what happens at the sharp end and at the blunt end. According to resilience theory, this perspective relates to the Work-as-Imagine (WAI) and Work-as-Done (WAD) distinction [172, 173]. WAI is the expected environment and situations that the organization will meet, and the ideal prescriptions (legislation, regulations, guidances, and standards) that govern how to perform, and what should happen. WAD describes what actually happens, and the practices that unfold. The resilience perspective emphasizes that safety development must rely on WAD. Related to ISO 9001 certification, WAI may represent both the international standards that

frames certification program and the certification bodies' perception and translation of these standards into internal routines. WAD may represent certification activities in which auditors access and interact with the certified organizations.

There are extensive perspectives to resilience in a wide range of societal areas and at different system levels [174-176], but the perspectives of resilience and of regulation and governance are seldom connected in the literature [18, 19, 175]. Some examples where these perspectives are connected are found in [17, 19, 124, 177]. A resent review found only 12 qualitative studies on how regulation can facilitate or hamper resilience in health care organizations [178]. The studies included varied in regulatory strategies and contexts, and some did not include external assessment activities as is comparable to certification processes. The authors concluded that regulatory activities may facilitate or promote *adaptation*, *flexibility*, *anticipation* and *learning* related to resilience, while the same elements may be hampered if regulation merely aims at compliance to rules. Most studies on resilience in general in healthcare have been performed at the intraorganizational level, and hence microlevel [175, 179]. Studies specifically related to the potentials for resilient performance in health care organizations have been applied to a lesser degree. This might be, since the complexity of healthcare organizations makes it challenging to define what factors each potential should attend to [180]. Two recent examples at intraorganizational level applied the resilience potentials to documents next of kin as important stakeholders for resilience [181] and to analyze resilience performance in an emergency department [182].

When exploring resilience in relation to external assessment processes, such as certification, the potential for resilient performance might be studied from at least four perspectives:

1. The certification body's potentials for resilient performance.
2. The certified organizations potentials for resilient performance.
3. The certification process's support to potentials for resilient performance of the certified organization.
4. The certification regime's support to potentials for resilient performance of healthcare

This thesis will explore possible aspects of the third and fourth perspective.

3.5 Objectives and research questions

This thesis explores the external drivers and internal organizational processes in relation to ISO 9001 certification of an emergency department in a Norwegian hospital. It also explores the understanding and practice of ISO 9001 certification processes from the perspective of a certification body, and the certification approach proposed in international standards and guidances. Lastly, it explores the contribution the certification approach might make to resilient performance in the organizations being certified. The three objectives with their accompanying research questions are examined.

1: To explore external conditions that may catalyze and trigger organizational change and internal sensemaking processes, that lead to the continuity and change in favor of ISO 9001 certification.

i. How do external environments contribute to an adoption of ISO 9001 certification in an emergency department?
ii. How does the local management make sense of the certification process?

2: To explore the audit practice as perceived and performed in hospital certification processes in Norway.

iii. What styles do auditors apply in hospital certification processes?
iv. How do auditors perceive their role in hospital certification processes?

3: To explore characteristics in approaches to ISO certification and examine whether these approaches can support resilience in healthcare.

v. What auditing approach for certification bodies is embedded in standards and guidance notes for ISO 9001 certification?
vi. How do managers and auditors of a certification body perceive and practice the certifications?

3.6 The analytical working model

To answer the research questions an analytical working model was developed (figure 6). The model demonstrates the structure of the empirical field and the theoretical contribution of this thesis. The three research articles have been added to picture the coverage of each article.

The analytical working model depicts ISO 9001 certification of hospitals as an institutional and organizing construct that unfolds through interaction between certification bodies as part of the inter-organizational field, hospitals at the inter- and intra-organizational fields and the institutional environment that constitutes the structure of the ISO 9001 certification regime and other governance structures. The institutional perspective [1-4, 6, 109-113] shows how macro institutional elements in the certification regime and other governance structures shape or trigger hospitals. The sensemaking perspective [114-119] helps to reveal how emergency department managers and personnel involved in certification processes use institutional structures from the certification regime and processes to give meaning to their actions. Governance perspectives [3, 5, 10, 13, 16, 34, 120-123] help to explore auditors interacting with auditees using standards and different approaches in certification audits. Resilience perspectives [18, 19, 124, 126-128, 183] help to explain how ISO 9001 certification processes may shape resilient performance in hospitals.

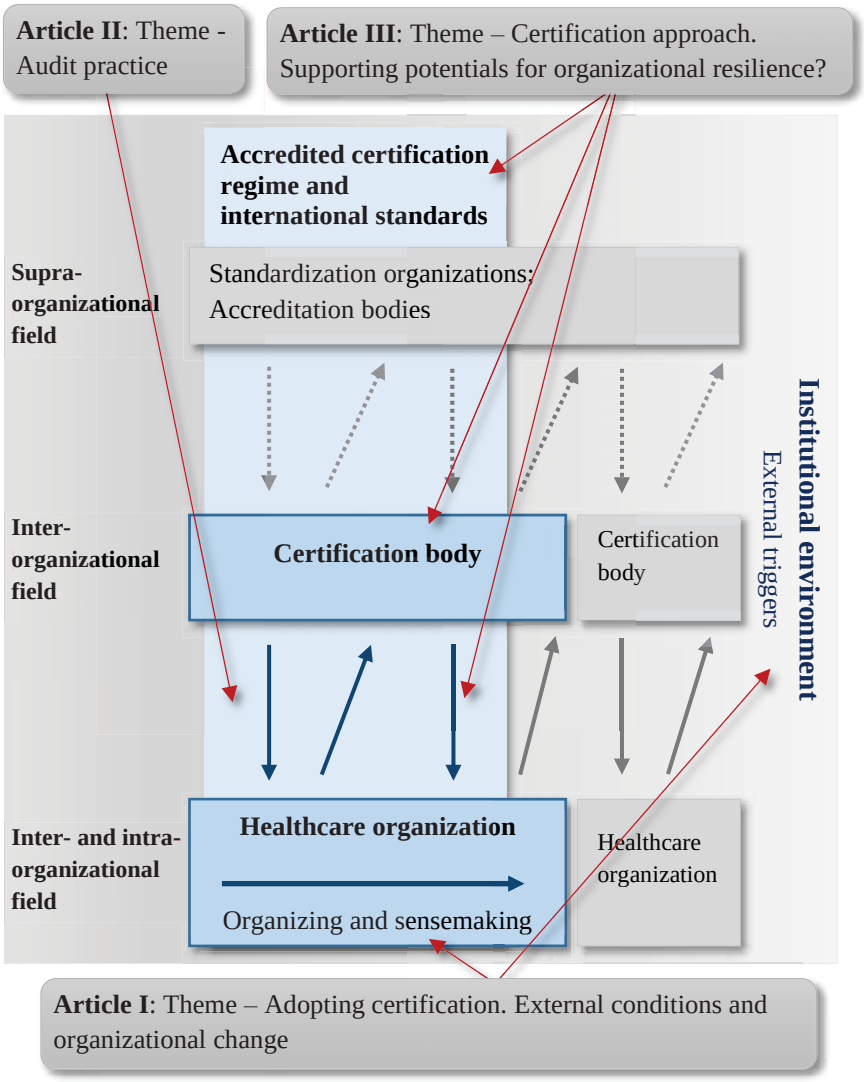

Figure 6 Analytical model for the thesis. The blue boxes and arrows include the empirical field in the study. The red arrows point to the empirical fields and levels studied in the different articles in the thesis.

4 Methodology

This chapter review and reveals my philosophy of science positioning that underpins the methodological considerations, choices and actions in this thesis. Further, it presents the research strategy, research design and the research process, concluding with reflections on research quality, limitations, ethical considerations, and choices made in the course of the research.

4.1 Philosophy of science positioning

This thesis is relevant to organizations, organizational performance and the changes associated with certification. In the study of these fields, the thesis adopts organizational institutional perspectives, sensemaking perspectives and governance perspectives. These perspectives assume that organizations and people do not act in a vacuum or in a rational instrumental way, but develops in social and institutional environments that both restrict them and provide opportunities. These perspectives are positioned within or have strong roots in social constructionist philosophy [129, 184-186] or the paradigm of constructivism [186, 187]. The perspectives of social constructionism and social constructivism are often equated [184-186, 188]. Both perspectives hold the same view on reality as social constructs, but the social constructionism calls attention to the socially shared meanings developed through social processes and agreements; social constructivism emphasizes how individuals develop and assign meaning to social interaction [188]. This thesis follows the lines of social constructionism.

Social constructionism is multifaceted. For the most radical social constructionists, reality is not naturally given, but nothing else than social constructions [184, 188]. It is ontologically relativistic, holding that reality has no objective existence apart from social interactions. There are also some milder variants of social constructionism that acknowledge different perspectives of reality [184, 188]. These are about the interest in and skepticism of the possibility of objectivity in our perceptions, or variants where the focus rests on how society is produced and reproduced by shared meanings and conventions. It means that many constructionists believe that material things, people, structures, and events in their environment are somehow independent

of their experience with them [188]. This argument is in line with the position taken in this study.

The argument that social phenomena are social constructions calls for social theories about how those constructions come to be, especially from a micro-macro perspective. Giddens' theory of structuration has made a fundamental contribution in this regard [184, 185, 189] and has inspired the institutional, sensemaking and resilience perspectives used in this thesis. Giddens theorizes the intermediate social practices or processes that connects the individual and society, and that constitute the social structures that are produced, reproduced and changed via these processes. In a wider sense, Giddens explains different aspects of social phenomena by showing how they are produced or fit into underlying structures can also be treated as one of the two main variants posited[189] as structural explanations in social science. The second variant deals with causal explanations by identifying social structures and mechanism as causes of social phenomena and holds a naturalist ontology that fits into the perspectives of critical realism.

Critical realism is often seen as an alternative to social constructionism, especially its most radical versions [184]. Critical realism seeks to identify and theorize the *real* mechanism, that unlike the positivist stance are real but possibly independent of the researchers' observation. It then becomes a counterweight to both social constructionism and positivism; to the former because it rejects the notion that nothing exists apart from social interaction, and to the latter because it emphasizes that evidence of the objective reality or the natural must not be observable. A main distinction is that while critical realism inquiries emphasize theorizing mechanisms and structures, social constructionism is concerned with praxis.

The effort of describing epistemological perspectives becomes more apparent in the critical realist perspective, in order to explain how we can acquire knowledge about hidden mechanisms, issues of representation, and generalizations form qualitative inquiries [184, 187]. Inherent in the critical realist perspective is the epistemological limit of possibilities to perform experimental closure to arguments [190]. These limits require reflexive approaches. The epistemological and methodological stance in critical realism is probably where it coincides with milder variants of social constructionism,

especially notions about interpretations, and the interpretive perspectives on how we gain knowledge in qualitative inquiries [184, 190].

Hermeneutic traditions of interpretation focus on theories about understanding social action rather than the study of physical objects [184, 189-191], and is involved in all forms of qualitative research [191, 192]. Interpretation is a representation of the world of human actors. Human actions and social practices are based upon the meanings of those involved, meanings that must be interpreted. This might be that those being studied are an active participant, understand what is going on, act in accordance to ongoing processes, take opposition and the like [190]. In a classic work, Taylor [193] emphasizes that meanings cannot be identified except in relation to others and in a field. He proposes three articulations of meaning. The first is "Meaning is for a subject," not for the situation. The second, "meaning is something," implies that humans are not separable from situations or actions. Finally, "things only have meaning in a field." In other words, meanings must be seen in relation to other meanings of other things (p. 22). Socialization is therefore fundamental, and meanings are subjective, but not individualistic; meanings are socially shared, and may be shaped by a normative and cultural symbolic context. From a social constructionist perspective, the interpretive practices in processes of inquiries involve co-constructions among actors, including the enquiry practitioner [192].

I take a middle point of view in my philosophy of science positioning. I believe that it is possible to identify mechanisms, patterns, or structures that are real, and which are fruitful to theorize, such as for the milder versions of the reality-oriented practitioners of critical realism and the more moderate social constructionists. I contend that mechanisms, structures, thoughts, and meanings are not necessarily the truth, but a result of how the truth is constructed. Further, things and events can exist in the world outside of our human minds, like a car crashing into a tree. But how we give meaning to this phenomenon, (e.g., if the car crash is an accident or not) that is a result of social constructions. To social inquiries, constructions involve rigorous reflective practices [192], whether they include positivists searching for brute evidence or social constructionists elucidating practice. This also means that I believe that we can obtain knowledge of the world from different perspectives.

The social constructionist tradition, building on a practice-oriented philosophy, is an important foundation for the exploration of internal processes of hospital certification, and for the understanding and practice of certification processes. Further, the study calls for a practice-oriented research strategy and design. The case study approach is therefore chosen and described in the next sections.

4.2 Research strategy and design

Studying organizational changes means studying the social processes that are closely connected to the everyday practice of people within an organization. This study explores ISO 9001 certification processes as practiced and perceived in hospitals and by certification bodies. For this purpose, a qualitative case study approach was chosen. Case studies are viewed in different ways in relation to methodology in social science. Yin [194] proposed case studies as a research strategy, but later [195, 196] described it as one method among others – a case study method, while emphasizing rigorous study design. Stake [197, 198] defined the term *case study* as a way of approaching the field of study or, in line with Thomas and Myers [199], as a way of designing social research.

In this sense, a case study is defined as a way of designing research about different phenomena or fields that provide an analytical frame, using different methodological orientations or research strategies. A case study approach in exploring the field of certification practices has several notable strengths. For instance, case studies concern understandings of "how" and "why" questions [196, 199]. "How" questions are prominent in this study. In addition, case studies are suitable for praxis- and context-oriented inquiries [196, 198, 199], that suits the exploration of certification processes. Case studies are also suitable for the study of complex, multilevel and interconnected systems and processes [196, 199]. Certification represents intra- and inter-organizational practices and interfaces, including interactions between internal and external factors such as hospital personnel interacting with certification auditors. Case studies are suitable for studying contemporary phenomena [196]. ISO certifications in health are relatively new in Norway, voluntarily adopted by organizations to meet the demand for quality and safety. Finally, case studies in the social sciences are suitable for interpretive methodologies and abductive research strategies [198, 199], and therefore relevant to the study of

understanding the actors involved in context-dependent practices such as certification processes.

The thesis is theory-driven in the sense that the theoretical framework developed for the case studies guides both data generations, the analyses and the analytical generalizations [196]. For this reason, the role of theory may be considered both as a form of theory-building and of theory-testing that can help raise the results to a conceptual level higher than the specific case [196, 199], or to generate *exemplary knowledge* [199].

The case study design for this thesis is presented in table 1 and is based on the case study approaches of Yin [195, 196], Stake [198], and Thomas and Myers [199]. The thesis consists of a single case study and a multiple case study [196, 199]. The basis for the selection of the cases and the cases themselves will be outlined in the next section.

Table 1. The case study design

Elements in case study designs	**Case study 1** (Article I)	**Case study 2** (Articles II and III)		
Case study subject	**A certification project in a hospital emergency department** (a key case)	**An accredited certification body's approach to hospital ISO 9001 certification** (a key case)		
Unit		**Unit 1** (article II): The certification body interacting with hospitals	**Unit 2** (article III): The certification body's overall certification approach	**Unit 3** (article III): The certification approach in international standards and guidances
Case study object	To explore external conditions that may trigger organizational change and internal sensemaking processes in relation to ISO 9001 certification. Theoretical references: Organizational institutionalism Sensemaking	To explore the audit practice as perceived and performed in hospital certification processes in Norway. Theoretical reference: Surveyor (auditor) typology model Regulation/ Governance	To explore characteristics in approaches to ISO certification Theoretical references: Regulation/Governance Resilience	
		Examine whether certification approaches can support resilience in healthcare.		
Methodological choices and process	**Single-case study: Retrospective study**	**Embedded (multiple units) single-case study: Snapshot of a current phenomenon**		
Data sources and data collection	Initial exploration: 1 initial exploratory open interview - Head of department Documents: Minutes, reports and standards Main data collection: **9 semi-structured interviews** Informants: managers, key personnel and external project leader **Document study** Documents: project description, project report, reports from supervisions, Guidelines for ISO 9001 in emergency departments, minute from evaluation meeting	60 hours of non-participant observations, and 3 semi-structured interviews with 3 lead auditors acting in 3 different hospital certification audits: - Clinic for internal service - Full hospital - Emergency department	9 semi-structured interviews: 5 lead auditors 4 Managers/ administrative personnel Case study data from unit 1: 3 lead auditors in 3 different hospital certification audits	4 International standards related to ISO 9001 certification 55 AAPG and APG international guidance notes
Data analysis- Within cases/units	Narrative analysis	Theoretical thematic analysis - Identify auditor styles practiced - Identify auditor's certification approach	Theoretical thematic analysis - Identify certification approach	Content analysis and thematic analysis - Identify certification approach
Data analysis- Across cases/units		Reflexive comparison to identify discrepancies between certification approach in Standards (WAI), certification body's approach as imagined (WAI) and – practiced (WAD).		

4.3 Case selection

Cases are parameters for the phenomenon under study, often a person, an organization or an institution, but sometimes also less concrete phenomena like a project, a process or a culture [196, 198, 199]. For this thesis, two instrumental [198] or key [199] case subjects were selected. Case 1 was related to an ISO 9001 certification project in an emergency department, and case 2 was related to a certification body's approach to certification processes. The selection of cases was done in relation to specific objectives, research questions and theoretical framework for the thesis. Thomas and Myers [199] stress the distinction between the case study *subject* and case study *object*. The former is the phenomenon or the practical and historical unit that is doing the "explaining" (the explanans), such as the project in an emergency department and the certification body's approach in this thesis. The case subjects set boundaries for the sources one can consult, such as humans, documents, statistics, practices, artefact, and time and space of the phenomenon. The case study object [199] or issue [198] explicates the purpose and the theoretical framework — the "thing to be explained" (the explanandum) which affect the further methodological choices and processes for the study (table 1). The two cases are presented in the following sections.

4.3.1 Case 1: A certification project in an emergency department

The objective of case 1 was to explore how external conditions influenced organizational change in relation to the adoption of certification regimes and certification processes in Norway (case study object). In order to find case study subjects, different considerations needed to be taken. Hospitals less frequently adopt ISO 9001 certification for the first time. In the early stages of the project it could be difficult to find a certification process to follow in real time, since no agreements had been reached with a certification body to collect data. I did not have direct access to information about possible certification processes. In the early phase of the project I learned of a pilot project related to ISO 9001 certifications of two emergency departments in separate hospitals, that had not previously been certified. These processes seemed worth exploring to meet the

objectives, and I decided to study these certification process (pilots) in retrospect [196, 199] if I obtained consent.

The Norwegian Board of Health Supervision (NBHS) in 2007 had carried out a countrywide supervision of emergency departments (ED) in Norway and found unacceptable conditions that required the management to take action [200]. As a direct follow-up the Norwegian Accreditation and one Regional Health Authority (RHA) initiated a collaborative pilot project to test the use of ISO 9001 certification to ensure internal control and management systems in these emergency departments in the spring of 2008. Two EDs were chosen as voluntary pilots [201], and one of them was included as case 1 in this thesis. The ED was one of many that had been in non-compliance with countrywide supervision. They started their project towards certification in the late spring of 2009.

The study of case 1 was designed as a retrospective single-case study, and the certification process studied ran from autumn 2008 until spring 2012. In order to explicate the case study objective, a theoretical framework was developed (see 4.5.1). For explanation building I adopted a narrative approach [202-207] or storytelling [208] to retrospectively follow sensemaking during the local ISO 9001 certification process.

To get access, an initial dialog with the head of the clinic responsible for the emergency department was established to explain my research project and get consent to perform research. Further, written information about the study and the process of data collection were sent to the clinic with an agreement to access the needed data. Both parties signed the agreement. Data was collected through documents and interviews during the spring and autumn of 2012 (see 4.4).

4.3.2 Case 2: A certification body's approach to hospital certification

The objectives of case 2 were to explore ISO 9001 certification as approached and practiced by certification bodies and auditors, and to explore whether ISO 9001 practices can support resilience in hospitals (case study object). At the time of the study, four certification bodies were accredited to perform ISO 9001

certification in Norway's hospitals. There were approximately[5] fewer than five auditors in each certification body that were qualified to be lead auditors in ISO 9001 certifications in hospitals. I conducted a thorough exploration of one certification body. A significant concern was the limited timeframe to perform extensive observations of many auditors interacting with hospitals at the sharp end of the certification processes. The exploration of auditing practices in a single certification body was therefore considered more appropriate in terms of the study objectives. It would also make it possible for me to observe variations in approaches within one certification body. Such variations of practices were important since the theoretical framework of resilience was concerned with discrepancies between what organizations claim to do and what they actually do (see 4.5.2).

Case 2 was designed as an embedded (multiple units) single-case study [196, 199]. The case study subject was divided into three units: 1) the lead auditors' interaction with hospitals in certification audits; 2) the certification body's perceived approach to certification; and 3) the international standards and guidances for certification bodies performing certifications. To explore auditors' conduct (unit 1) a surveyor typology framework was adopted, and to study the approach of the certification body a governance and resilience perspective was adopted (see 4.5.2).

4.3.2.1 Access and consent

Gaining access and consent to collect data was crucial to explore the certification practices of a certification body. All certification bodies that are accredited to perform ISO 9001 certification in health care in Norway are commercial organizations that perform certification on commercial premises. In the early phase of the study I had only secondhand information about certification bodies that were likely to perform ISO 9001 certification activities in hospital in the near future. At first, I contacted one of the certification bodies by telephone and followed up by email with information about the study. In the first contact they expressed interest in taking part in the study. I was given a

[5] Since there were only four certification bodies and because only a few lead auditors could participate in the study, approximate numbers and profiles are used to protect confidentiality of the certification body and the anonymity of the auditors included in the study.

contact person who was responsible for the organization's activities in relation to the certification of management systems. The same contact person followed the project until the end.

Concerns that were initially discussed with the certification body pertained to anonymity, confidentiality, sensitivity to commercial interests, consent from the individual participants and consent from the customers (the certified organizations) who interacted with auditors during certification audits (see 4.4.2.1). Anonymity and confidentiality were concerns since there were only four certification bodies and very few lead auditors in each certification body who were involved in the field of health care certification. A specific concern at that time was a recent experience in which a master student had gained access to study their practices, but had been less concerned with confidentiality and sensitivity to commercial interests, and then drawn conclusions based on insufficient data. The certification body claimed the right to read manuscripts before they were published in order to protect the organization's right to confidentiality. Both parties signed a written agreement for access to data collection and protection of confidentiality. The certification body also stipulated that a study of the approach to certification should include extensive observations of certification audits and practices, and that the researcher needed to gain consent from the certified organizations. This view was in line with the intentions of the study and constituted a proper point of departure.

A half-day meeting at the certification body's office was held with two representatives from the certification body, the head of the management system certification activities and one of the lead auditors performing certification in hospitals. The objectives for the meeting were for the participants to get acquainted with each other, to learn about the study project, get an overview of the certification body's activities concerning ISO 9001 certification in hospitals, and to explore opportunities for data collection. The main data collection took place from autumn 2012 until spring 2013. The next sections describe the process of data collection and sources.

4.4 Sources and data collection

Supporters of case studies endorse the use of a variety of sources and methods when studying praxis-oriented and complex social phenomena [196, 198, 199].

In this thesis a triangulation of sources and data collection methods will elucidate ISO 9001 certification practices. Primary data was collected in a qualitative tradition based on document analysis, interviews and observation [188, 209]. The term "data collection" in this thesis is synonymous with "data generation" or "data production" since the practice of interviews and observations adopted a constructionist approach in which conversations and dialogic practices are also a form of co-construction of data between the informants and the researcher [204, 210, 211] and for the study of documents where data are generated through the researcher's meaning-making processes of reading and rereading textual sources [212, 213].

Table 1 summarizes the sources and methods for data collection, and the following sections will elaborate.

4.4.1 Interviews

Interviews were indispensable to data collection for this thesis. All the interviews were semi-structured [214] or general [188]. In other words, the interviews did not follow a strict question-answer format. The topics were listed in the interview guide (appendix 5,6,7), but the interviews reflected the importance of narratives in eliciting important institutional practices and meanings [210, 215, 216]. These narratives became an important part of data collection, even though telling stories is often seen only as a way of contextualizing the interview situation or themes, not as a source of scientific data [204].

Stories and narratives are process-oriented and therefore comprehensible when studying organizational change and practices [202, 203, 205]. This understanding underpinned the planning of interviews about certification processes in the emergency department (case 1) and the certification body (case 2). The interview guides in both case studies consisted of three parts: 1) the interview subjects' role, the organization and approaches to quality and safety work (in the emergency departments) or the ISO 9001 certification (for the certification body); 2) the certification process; and 3) ISO 9001 certification and regulation in healthcare. Open questions were used, along with bullet points about related concerns. Questions were also often followed by preplanned or spontaneous probing questions, to help interview subjects recall and tell more

detailed stories about their experiences with the ISO certification process. Examples could be: "Can you recall when you first started to think about certification and tell me about that?" or, "Can you tell me about the certification bodies role and their methods?" Typical probing questions were "Who did you experience was a key actor in the process?" "Did you meet any opposition?" and "Were there any 'wake-up calls'?"

4.4.1.1 Recruitment and consent to conduct interviews

A clearance for staff interviews was obtained from the hospital and certification body prior to the interviews. All informants received a written invitation to participate, followed by a written and oral invitation prior to the recorded interview. The invitation explained that the interview was part of a research project, that the results would be used anonymously for analysis and publication, and that participation was voluntary and could be terminated at any time. All informants gave oral consent. All interviews were audio recorded and transcribed verbatim by a professional firm. A written data processor agreement covering the terms of data storage and confidentiality was signed by the firm doing the transcriptions before the audio files were forwarded.

4.4.1.2 Interviews in case 1 – Emergency department

An exploratory interview with the head of clinic was conducted in June 2011. The intention was to get information about the emergency department's role in the pilot project and the certification process, to identify process documents to study, refinement of themes for interviews, and identify informants for subsequent interviews. The following research interviews took place in the emergency department in June and August 2012. The interviews lasted from 45 minutes to two hours.

The 12 informants purposefully selected for interviews were:

- Head of department
- 2 heads of section (middle managers in the department)
- 3 nurses in the department (possibly included in the process)
- 1 health secretary/administrative personnel
- 2 doctors affiliated with the department (involved in the process)
- 2 persons from support departments, such as radiology or laboratory
- 1 person from the Quality and Research Department

After eight interviews were completed, a distinct picture of a key local project group (the project management) for the certification process emerged. Five of the eight informants comprised the local project group, and four of them also belonged to the permanent management of the emergency department. The five informants in the local project group were Head of Department, Head of Section, Head of Unit 1, Head of Unit 2, and a Quality Advisor from the Quality and Research Department, acting as an advisor in the local project group. The sixth informant was a leader of the regional pilot project for certification of emergency departments, and an external contact person and advisor for the local project group. The last two interviews were done with the Head of the Quality and Research Department and the Head of doctors in the Department of Internal Medicine. These two interviews produced valuable insights and confirmation about the actors and the legitimacy of the certification process.

The eight interviews together revealed a distinctive local organizing and sensemaking process, especially that of the local project (and the management of the emergency department, since managers were represented in the project group). The interviews did not reveal any clear indications of people who had been unintentionally excluded as informants but were part of the local collective sensemaking process. Therefore, no additional interviews were conducted.

4.4.1.3 Interviews in case 2 – Certification body

Informants were identified and recruited with assistance from the contact person at the certification body. Ten informants were initially selected. Five were key managers and administrative personnel involved in conformity assessment and system certification activities; five were lead auditors performing ISO 9001 certification in healthcare.

Nine research interviews were conducted: five with lead auditors and four with managers and administrative personnel. Three lead auditors had been observed when practicing hospital certification audits weeks earlier. All the managers and administrative personnel interviewed had sporadically served as lead auditors in ISO 9001 certification processes, but not necessarily in healthcare. All interviews were conducted at the certification body's central office in connection with a yearly seminar, except one interview that took place by

telephone. The informant interviewed by telephone was one of the lead auditors observed earlier. The interviews lasted 45 to 75 minutes.

4.4.2 Observations

Observations [188, 217] in this thesis were done to explore the certification body interacting with hospitals in ISO 9001 certification processes (unit 1 in case study 2). The objective was to explore the certification auditing practices of the certification body. In dialogue with the certification body, it seemed that performing observations of the on-site certification audits, following the audit teams, would be a good way to explore the certification body's interaction with the auditee.

The audit teams consisted of two members, one lead auditor, whose conduct was the focus of this thesis, and one technical expert. The lead auditor is responsible for planning the audits, coordinating the teams during audits and communicate and report the final conclusions. The technical expert provides specific knowledge to the audit team about the organization, processes, or activities to be audited. All the technical experts in the audit teams observed were physicians.

4.4.2.1 Recruitment and consent

The recruitment of auditors to observe was done with the assistance from the certification body. According to the objectives, the certification body identified three lead auditors and was the first to ask the auditors to participate in the study. Each auditor led certification processes in different hospitals. All members of the three audit teams observed gave oral consent to participate after receiving written and oral information about the study. In one of the audit teams the technical expert had not received information about the study in advance. The process for consent followed the same steps as for interviews as described in section 4.4.1.1.

All hospital departments or clinics were contacted to get their consent to observe the interaction of the certification audit team with the hospital. The certification body's contact person in the hospital was initially contacted by phone, and then sent written information about the project and an agreement to

be signed by management. All parties signed the agreement before observations began. In the opening meeting[6] on the first day of the audits, all participants from the hospital were given oral information about the research project and observations. I introduced myself and described the study and observations at the beginning of each assessment meeting. All participants were given the opportunity to refuse to be observed at any point in the certification process. It was agreed that if someone did not want to be observed, I would leave and exclude that part of the audit. None of the personnel declined to be observed.

4.4.2.2 The selected auditors and observation focus

The first auditor to be observed, auditor 1, had less than one year of experience but was a lead auditor in training: a lead auditor during the certification audit, but under the supervision of a senior lead auditor. This was the final stage of training to become an independent lead auditor. In this certification audit, the senior auditor observing was also a technical expert in the audit team. Auditor 1 conducted certification audit in a clinic for internal services. The audit lasted for two days (about 15 hours). The second auditor observed, auditor 2, had 5-10 years of auditor experience, mainly in healthcare. The auditor conducted certification audit of a full hospital, lasting three days (about 22 hours). The third auditor observed, auditor 3, had more than 20 years of auditor experience in healthcare and other industries. The auditor had previously worked for the certification body but was now an independent subcontractor who performed certification audits in an emergency department. The audit lasted for three days (about 22 hours). Approximately 59 hours of non-participant observations were conducted.

I followed the three auditors through all on-site audit activities from the opening until the closing meeting. These activities began with an opening meeting to introduce the audit team, confirm the audit plan and scope, and to verify the procedures and communication that would be used. In the next phase, information related to the audit objectives, scope and criteria was collected and verified. The audit conclusions were then prepared. Methods of collecting

[6] All certification audits start with an opening meeting where the audit leader informed the organization being audited about the agenda and process of the auditing activities and introduced the audit team. The opening meeting is mandatory for everyone who would be participating in the audit process.

information included interviews, observation of processes and activities, and review of documentation and records. Finally, the audit team held a closing meeting to present and discuss conclusions and non-conformities and agree on follow-up actions [35, 70, 218, 219]. To observe the interaction with the auditees, observations centered on the conduct of the lead auditors (team leaders) during their interviews and conversations (review process) with representatives from the organization under certification. The observations focused less on the auditors' on-site walk-arounds, where they had informal talks with hospital staff and reviewed physical processes and activities.

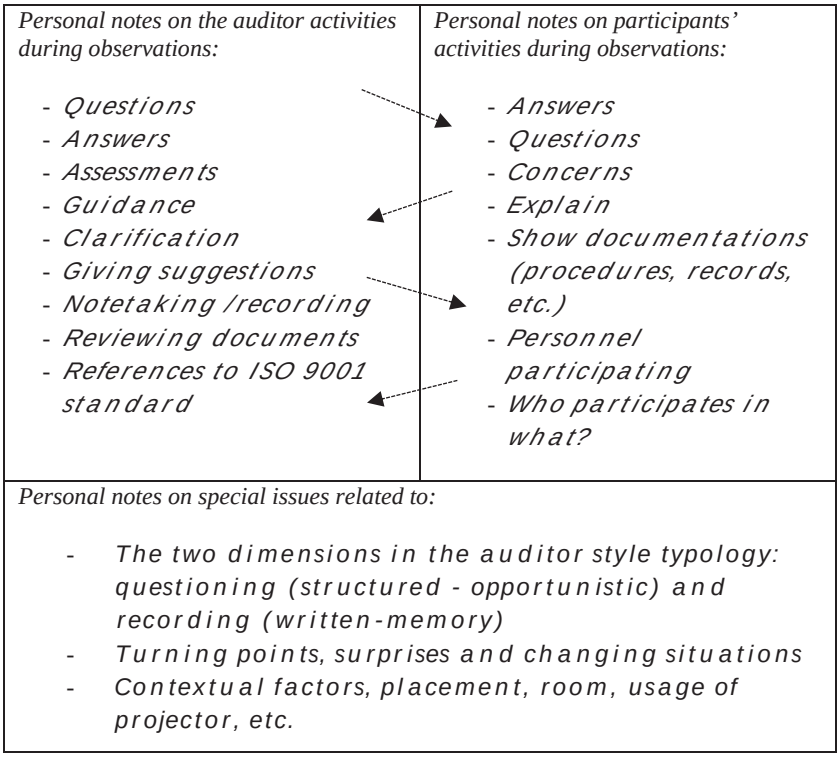

Figure 7: Personal fieldnote structure during observations. The arrow represents how notes were taken to represent a dialog or a two-way interaction: e.g. question – response, concerns – guidance

I usually sat at the table with participants in the audit interview and assessment. I tended not to enter the conversations. The focus for the observations followed an observation guide (appendix 9). All personal notes were taken openly and tried to capture the processes and dialogues between the auditors and participants (figure 7). Topics covered were interaction and communication,

methods of interview, personal style and the overall approach between formal conformity assessments (retrospective focus) and guidance for improvement (prospective focus). The two dimensions in the auditor style typology, questioning and recording, guided the observations and note taking [63].

4.4.3 Documentary sources

The documentary sources for this study include governmental reports, supervision reports and recognized standards that are available to the public, in addition to internal documents, such as policies, minutes, process documents and procedures. The ISO standards that originated in private organizations have since been made publicly available to purchase. All document sources in this thesis were purposefully selected [188].

The study of documents takes its point of departure from four analytical perspectives: 1) the content of documents; 2) the production of documents; 3) how documents are used by actors and function as a resource; and 4) how documents are treated as an actor independently of their producers [220, 221]. In this thesis, content, use and function were subject to analysis.

In case study 1, documents were selected to inform the construction of the story of the certification project in the emergency department. The content of these documents was subject to analysis. Documents took the form of guidelines, project description and project report from the Norwegian Accreditation and the Regional Health Authority, supervision reports from the Norwegian Board of Health Supervision, and minutes from the evaluation meeting in the emergency department.

In case study 2, documents were included for the exploration of the certification bodies approach (case unit 2) in relation to the potentials for resilience. The documents included were international recognized normative standards and guidances regulating the certification body's approach to ISO 9001 certification regime (see section 2.1). The content, use and function of the documents were subject to analysis for the following reasons. The content of these international standards and guidances is intended to constitute the certification bodies' demands and opportunities in certification processes. The standards and guidances may also be used by certification bodies as resources when

developing structures, competences and methods for the purpose of certification activities. Finally, the international standards and guidances themselves becomes independent organized entities [222] or actors and brings different degrees of legitimacy to the processes and practices of ISO 9001 certification, and as such may be used by the certification bodies to bring legitimacy to their decisions and approach in certification processes.

Table 2. Standards and Normative References included in case study 2

ISO/IEC 17021:2011	Conformity assessment: Requirements for bodies providing audit and certification of management systems
ISO/IEC 17000:2004	Conformity assessment: Vocabulary and general principles
ISO 19011: 2011	Guidelines for auditing management systems
ISO/IEC Guide 60	Conformity assessment: Code of good practice

Documents included in case study 2 were the ISO/IEC 17021:2011 conformity assessment standard for bodies providing certification of management systems and three other related standards and normative references (table 2). An additional 55 international guidance notes offered guidance to conformity assessments practices and audits in accredited ISO 9001 certification, and were included in the study. The guidance notes were developed by two international auditing practice groups: the ISO 9001 Auditing Practices Group (APG) and the Accreditation Auditing Practices Group (AAPG) (see section 2.1).

4.5 Data analysis

The two cases were analyzed independently. The analytical processes are presented next.

4.5.1 Analysis case 1 – Emergency department

In case 1 a narrative approach [202-207] or storytelling [208] was used to retrospectively follow the emergency department's adaption of ISO 9001 certification and the ensuing certification process. The narrative approach makes it possible to demonstrate process characteristics of organizing and

change [202] and is comprehensive when studying sensemaking processes [115, 203].

For the analysis process, I used the principles of narrative [223] and antenarrative[7] analysis [207]. To construct the narrated story, I followed the characteristics of a narrated plot [204, 207, 223], where beginning, middle and end of the story guide the plot of the narrative. To frame the timeline, a retrospective reconstruction often starts with outcomes. The guiding outcomes for this study were the emergency department's adoption of ISO 9001 certification and the receipt of the certificate.

The first analytical step was to arrange the data elements chronologically and construct a baseline story. The baseline story was based on the first interview (interview notes and transcripts) and then modified in an iterative process of reading and rereading as new interviews and documents came to inform the story. Rather than treating interviews and documents as constituent parts, I retrospectively synthesized and configured data into a coherent baseline story. For example, analysis of documents, such as the project plan and reports, sketched out processes and contextual elements that when synthesized with stories from people in the emergency department were weakened, confirmed or added new perspectives. To work with the stories from informants and documents I needed to keep in mind that stories of organizational processes seldom are linear. They are often nonlinear and fragmented; in other words, *antenarratives* [207]. The baseline story was treated as an early account of the initiation and the continuation of the certification process. In the next step of the analysis I identified elements that contributed to action and outcome [223]. For this purpose, the baseline story was categorized into the analytical framework of organized sensemaking [116] (figure 8). A further description of the categories is given in article I, part II. The categories were used to trace key elements of the intra-organizational processes of enactment and sensemaking that contributed to continuity and change in favor of ISO 9001 certification in an organization.

[7] *Ante* means "before," and is also gambling term. An *antenarrative* is the stories preceding the narratives [207]. Narratives add plots and coherence to antenarratives. Boje [207] sees antenarrative both as *being before* and a *bet* (a form of speculation about events).

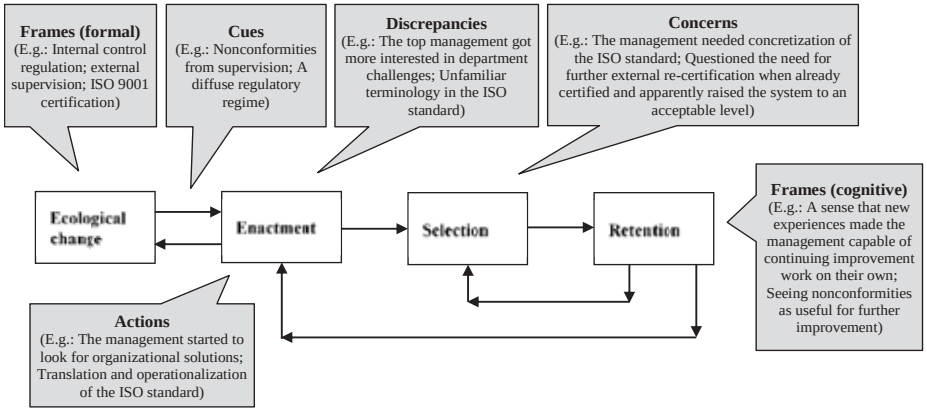

Figure 8: Analytical categories. The analytical categories shown in callouts were used to emphasize the key elements in the conceptual relationship among enactment, selection, and retention [116]. The figure is adapted from Jennings and Greenwood [143] and Weick 1979 [116]. Examples from the present case study are put in parentheses.

The final analytical step was an ongoing construction (writing, categorizing and rewriting) of the narrative into a *temporally patterned whole* [223]. To make the final analysis more transparent, I visualized in brackets the categorization of the final written narrative. The final narrative is presented in full in article I, part II.

4.5.2 Analysis case 2 – Certification body's approach

The analysis of case 2 were guided by an analytical model (figure 9) related to the certification body's approach to ISO 9001 certification. The model represents the organizational field [110, 113, 224] where the certification approach materialized as a connection between the key elements in the resilience perspective: work as imagined and work as done [172, 173].

The model included (A) the international standards (normative references, A) and guidances for certification bodies and certification processes (Work as Imagined), (B) the certification bodies' audit approach as documented and perceived (Work as Imagined) and (C) their certification practices where auditors from certification bodies interact with the auditees in the auditing encounter (Work as Done). Ideally, elements A, B and C were harmonized. There could be discrepancies among A, B and C, represented in the model as

possible discrepancies 1, 2 and 3. The model assumed that the certified organization (auditees) also assessed, from an internal perspective, if their documented quality management system were consistent with the ISO 9001 standard.

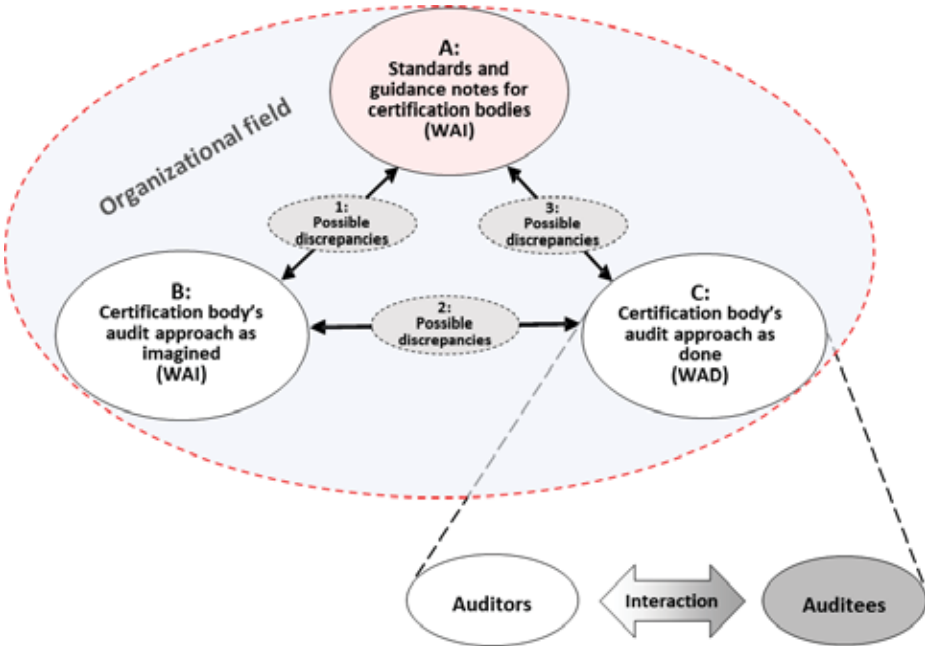

Figure 9: Analytical model for the organizational field where ISO 9001 certification processes materialize.

In case 2, data from observation, interviews and documents were subject to theory-driven thematic analyses. The analyses were theory-driven in the sense that the main themes explored were identified a priori [225], or as a form of "theoretical" thematic analysis [226, 227]. For unit 1, an auditor typology framework [63] was adopted to thematically analyze data to identify auditor styles. To elucidate the certification body's certification approach, the broad opposites of *deterrence* and *compliance* approaches to enforcement in regulation [10, 13] underpinned the applied themes used to analyze and compare data from all three case units. The opposites were operationalized as predefined themes: *assessing conformity against requirements*, focusing on retrospective auditing practices (inspect and control), and *quality improvement work*, focusing on prospective auditing practices (offer guidance, educate, transfer experiences and give advice). There is no clear distinction between

deterrence and compliance, but their respective characteristics constitute a continuum. Neither is there a distinction in the way in which these opposites materialize in the empirical field. In this thesis the two themes were applied to explore certification practices (case unit 1), the certification body's perceived approach (case unit 2) and the formal international standards and guidances for certification bodies (case unit 3). A pragmatic and reflexive approach [188, 227] was used for the analysis, drawing attention to the preservation of the narratives ("stories") generated from observations, interviews and documents, rather than the use of strict coding segments of the data. This form of *thematic narrative analysis* [227] is applied for the purpose of the thesis's exploration of context-dependent practices. Descriptions of the analyses for each case unit are given in the next sections.

4.5.2.1 Unit 1 - Auditors

The analysis of auditors' conduct and perceptions of their interactions with auditees draw on data from observations of certification audits and interviews with lead auditors. Already during the observations and the work of making field notes, ideas about the direction for the analysis occurred and became a form of data reduction [188, 217], in order to capture central aspects of the auditors' conduct. Observations were done some weeks before the interviews and therefore made it possible to ask the auditors about their auditing conduct and role. Together, the data from the observational field notes and the transcribed interviews were subjected to thematic analysis [226, 227] of each of the three auditors.

First, data from observations were categorized according to the two dimensions in the auditor style typology framework [63]: *questioning* and *recording* (figure 10). The two dimensions reflected the auditors' approach during auditing meetings, and were employed as the following themes in the analysis: The questioning dimension was a continuum between (a) a *structured*- and (b) an *opportunistic* questioning approach; the recording dimension was a continuum between (c) an *explicit* (written)- and (d) an *implicit* (memory) recording approach. The analysis identified the auditors' conduct that matched or contradicted with the auditor styles in the framework. Further, data from the observations were analyzed according to the opposite themes of certification approaches: (e) assessing conformity against requirements and (f) quality

improvement work. This analysis of the auditors' conduct in certification encounters identified «work as done» in terms of resilience [172].

Second, NVivo 10 was used to explore and thematically analyze the interview data to reveal the auditors' perception of their auditing approach. The same themes were used to analyze data from interviews and data from observations. Data from the interviews were then related to data from the observations and compared reflexively to explore whether the auditing style and conduct as observed were consistent with the auditors' perceived approach. The analysis was first conducted for each auditor, and then compared across auditors to highlight similarities and differences.

Then, the results from the auditors' assessments and the auditees' own assessment were matched, discussed and negotiated in the interaction between auditors and the auditees, to identify non-conformities or areas of improvement.

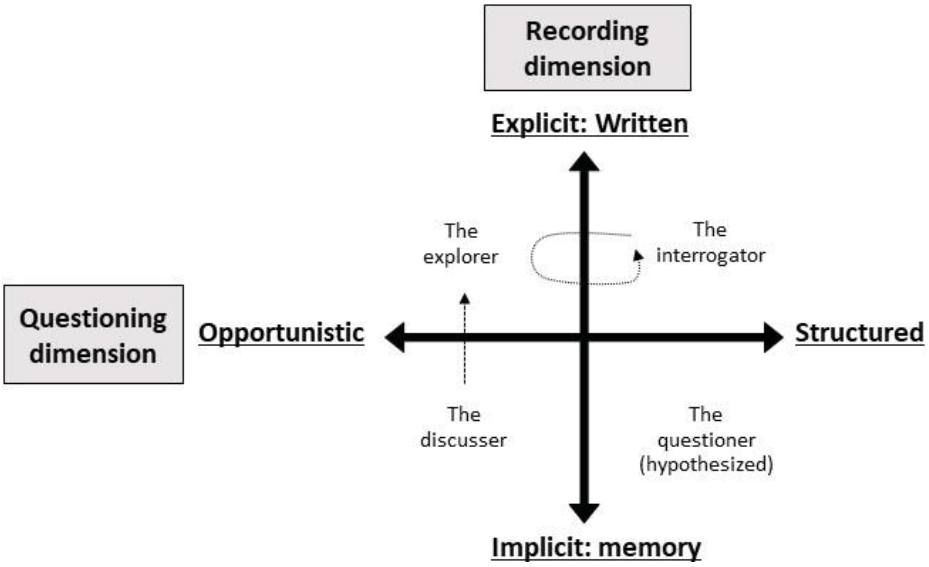

Figure 10: Auditor style typology adopted from [63]. The interrogator conducts interviews in a formal and structured question-and-answer manner, and the answers are systematically recorded. The explorer conducts a more opportunistic interview. The explorer begins with open-ended questions and takes unstructured notes. The discusser prefers a more interactive interview that is like a conversation and takes unstructured notes after the interviews. The questioner conducts a structured interview and recordings are conducted implicitly. The arrows show that the interrogator sporadically used opportunistic questioning, and that the discusser took unstructured notes after the interviews.

4.5.2.2 Unit 2 - Certification body

NVivo 10 was used to thematically analyze [226-228] data from interviews with managers and auditors from the certification body about their approach to organize and perform certifications. These were the opposites between (e) assessing conformity against requirements and (f) quality improvement work. The analysis focused on the contextual stories that co-constructed the contours of the certification body's approach to certification. It was important to be considerate of the tendency to treat data from interviews more as individual meanings than as data from observations of practices, where choices are treated more as a result of social interaction than individual meanings [210, 211]. The analysis of the perceived approach to certification identified «work as imagined» in terms of resilience [172].

4.5.2.3 Unit 3 - International certification standards and guidances

The ISO/IEC 17021:2011 conformity assessment standard, its related standards, and guidance notes, were analyzed for content [221], by an iterative process combining content analysis and thematic analysis [228]. The analysis process included a superficial examination (skimming and summative content analysis), followed by thorough examination (reading and rereading, reding concepts in context and thematize) and finally interpretation [228]. The analysis of standards identified the certification bodies' scope of opportunities in the certification encounter, by using the same themes for case units 1 and 2: (e) assessing conformity against requirements, and (f) quality improvement work.

The guidance notes were explored for concepts by a summative content analysis [228, 229]. The qualitative research software NVivo 10 were used for the content analysis. First, a word frequency query was performed, including all words with a minimum of four letters grouped with stemmed words. This produced a list of 1800 words. Second, the results were reviewed, and words that were prospective and related to development work were identified. These words were *guide, utilize, encourage, stimulate, instruct, recommend, suggest, propose, warn, consult, assist, advice, support, give*, and *help*. Third, the identified words were used for a text query within all the guidelines. The query was spread to a broad context within the guidances. Fourth, the results from the

text query were explored and compared with results from the thematic analysis of the conformity assessment standards.

The analysis of standards and guidances framing the scope of opportunities for certification bodies identified «work as imagined» in terms of resilience [125, 173].

4.5.2.4 Reconciling case units

Finally, a comparison of results from the auditors' certification practice (WAD, case unit 1), the certification body's perceived approach (WAI, case unit 2), and the certification approach in standards and guidances (WAI, case unit 3) was done reflexively to look for discrepancies [196] among the case units (elements A, B and C in the analytical model. (figure 9).

4.6 Research quality - trustworthiness

Criteria for evaluating the quality of research vary by tradition and research paradigm. Contemporary criteria on qualitative research recognize the validate interactions and relationships between participants and the researcher [230]. It means that in order to validate research, democratic stances are becoming more important than ever for qualitative inquiries. Lincoln and Guba [231] are critical of the notion that a strict application of traditional criteria for evaluation of research reveals some absolute truth in social science, while there may be several accounts of social reality. They have therefore developed four criteria to achieve trustworthiness in qualitative inquiries: credibility, transferability, dependability and conformability. These criteria have their counterpart in criteria for validity and reliability in quantitative research: credibility parallels internal validity; transferability parallels external validity; dependability parallels reliability; confirmability parallels objectivity [231]. In the following sections I describe how these four criteria are addressed to ensure to ensure quality and trustworthiness of the research project.

4.6.1 Credibility

To enhance credibility means to bring about confidence in the findings by ensuring that the research is carried out according to recognized research

practices that bring credibility or truth value within the study [231]. I used several techniques that have been suggested to enhance credibility, prolonged engagement in the field: persistent observation, triangulation, peer debriefing, and member checking [231]. These steps may also influence the information power of the participants in the study [232], and considerations about sample size (section 4.6.2).

Engagement in the field of certification was obtained through hours of observations of certification practices. Several years as an emergency room nurse have given me an important supplement to prolonged engagement [231] in the field of study. This contextual experience seemed to add to my credibility as a researcher when interacting with research participants in the emergency department, and when performing observations in hospitals. Persistent observation of the sharp end practices of certification were performed to explore and understand the interactive processes between auditors and auditees. To enhance credibility, observations were guided by a theoretical framework, together with sporadic interaction with the participants observed, in order to discuss and clarify different aspects of the observations. As mentioned, the certification body insisted on persistent observations if a researcher was to explore and understand their practices. The certification body's support for observations of their practices seemed important for the positive atmosphere and interaction with the auditors and access to the places where observations of interactions with the auditees were taking place. The observations of the sharp end practices were an important base of understanding when interviewing members of the certification body. Triangulation was ensured by both data and method triangulation. Peer debriefing was done by discussing findings with my supervisors, and by presenting preliminary findings and analysis of different parts of the project in a PhD seminar, at two international research seminars, and at two international research conferences (one poster presentation and one oral abstract presentation). Member checks were performed for all three articles. Informants received a late draft of each article. For articles I and II, all informants had an opportunity to read and respond to analysis and results. For article III the certification body was invited to read and respond to a late draft.

4.6.2 Transferability

To enhance transferability, the findings and conclusions of the study should be valuable in other contexts [231]. This means that I needed to provide rich and detailed descriptions of the context and field studied, so that other readers could judge the applicability of these findings in other contexts. I have given as much room as possible to descriptions of contexts and data in each article and elaborated on the external context in this thesis to increase accessibility. For example, in article I the narrative of a certification process in an emergency department presented was highly contextual, while rich in data about the process, it allows for comparison to processes in other contexts. Further, theoretical perspectives were used in all articles to guide both data collection and analysis to strengthen the applicability to other contexts. This technique is often considered in case studies as theoretical or analytical generalization [196, 199, 233]. Purposeful sampling is another way to enhance transferability [188, 231].

The number of participants in this thesis merits critical scrutiny. According to the logic of statistical representation and generalizability, the selection is small. Purposeful samplings were used in this thesis [188, 231] focusing on the purpose of the study objectives, analytical or theoretical generalization, and information power [232]. To bring sufficient confidence or information power to the findings, steps taken in the planning and data collection, such as study aim, sample specificity, use of theory, quality of dialogue and analysis strategy, will influence the number of participants needed [232]. Malterud, Siersma and Guassora state that [232] “Information power indicates that the more information the sample holds, relevant for the actual study, the lower number of participants is needed” (p. 1759). Dimensions influencing information power are aspects of credibility and transferability that were more valuable for the purpose of this thesis than saturation, which is probably the most frequently addressed criterion to judge sample size and rigor in qualitative health care research [234]. An important reason for this was the thesis’s objective to explore organizations, organizing and organizational approaches related to certification, embedded in institutional theoretical perspectives. This means that the number of informants may be limited by organizational structures and the roles of each informant. Two essential points here are the epistemological considerations and methodological collectivist stances related to the

institutional foundation of the study [235, 236]. I hold a social constructionist epistemology, one with a weak sense of constructionism. This means that I acknowledge that data collection is a form of data production or co-construction, while accepting that some interpretations may be viewed as better than others. Knowledge claims and meanings can and do take place within different frameworks. Whether or not the meanings coming into being are coherent is a matter of social interaction and negotiation, both between the participants and me as a researcher, and between my co-authors and me. As a researcher, it was important for me to bear in mind that meanings may be results of the informants' experiences from social interactions. Researchers tend to treat answers from interview informants more as individual meanings than as results from observations in which the researcher observes the actual context and treats conversations more as a result of social interaction [210, 211]. In this study observations made an important contribution to understanding that the auditing practices expressed during interviews were a result of highly dynamic interactions between auditors and the auditees.

When studying institutions and social processes in this thesis I needed to consider most of the positions that were related to the system and contexts I was studying. For example, when studying how the local management of an emergency department made sense of a certification process, I realized that the certification process was closely connected to a local project group established for the certification project. I therefore had to take into account that some informants at least had two formal positions that were essential for the process being studied: being a manager and being a member of the project group. I encountered another example when exploring a certification body's approach to certification. Two managers, who sporadically acted as lead auditors, differed in their answers to questions about their certification practices; one spoke from its own experiences with the sharp end auditing practice, and the other more generally about how an auditor (should) act in accordance with the certification bodies' internal procedures. I therefore needed to ensure that the interview subjects were activated to bring richer descriptions, instead of passively answering questions in the traditional way [236]. The positions represented in the system, and the possible subject positions expressed during the interviews, were therefore more important than counting the single embodied individual. Either because each subject position brings different

perspectives to the topic, or just because all individuals in an organization or department management actually are included. The applied theoretical perspective, the specificity of the key informants and the strong dialogue searching for rich descriptions during interviews enhanced the information power [232] in this thesis.

To enhance the transferability of the small selection of the three auditors observed in case 2, a purposeful sample of auditors from one certification body was chosen. Selecting auditors from the same certification body increases the information power more [232] than would selecting three random auditors from different certification bodies. It makes it possible, to some extent, to argue about the approach to ISO 9001 certification performed by a certification body.

4.6.3 Dependability

To enhance dependability, consistency of the research process, stability over time and the possibility to repeat the study are proposed features [231]. Dependability is closely linked to credibility. If the research strategy and design are considered suitable, then dependability would be established through a consistent and thorough follow-up throughout the research process. Techniques to establish dependability may be triangulation, stepwise replication and inquiry audits [231]. For this thesis, dependability was strengthened by triangulating data sources and methods, such as interviews, observations and documents study. For example, the auditing processes explored by both observations and interviews gave consistent findings of the auditors' approach to certification processes. Consistency and replication were enhanced by a repeated use of interview- and observation guides. The technique of inquiry audits is a form of external audit of the research process and results that also enhance the criterion of conformability [231]. External audits assume that the research process is recorded and possible to review, such as records of interviews, fieldwork notes, interview transcripts, data analysis and decisions. For this study the project proposal, interview transcripts, fieldwork notes and data analysis records were kept during the research process available for external scrutiny and for supervisors. All interviews, interview transcripts and guidance notes for certification bodies performing ISO 9001 certifications were transferred to NVivo 10 for recording and analysis. No independent external audit of the research project as a whole (as intended by Lincoln and Guba [231])

has been performed, but my supervisors have followed my research process throughout the project period and co-written all the articles. All articles have also been peer-reviewed by international journals, where article I and II are published and article III are in review after a second revision. In addition, as described for the criterion of credibility, different parts of the project have been made available for scrutiny in research seminars and international research conferences.

4.6.4 Confirmability

Confirmability is the neutrality of the research and the making explicit of possible researcher biases, such as different subjective motivations and interests for me [231]. This to say, full objectivity is impossible in social research and hence necessitates the interpretive approach. A confirmability audit [231] is a form of external review as described for dependability, that may help to prevent unnecessary biases that hinder findings, interpretations and conclusions from being thoroughly supported by the data. In my study, feedback from supervisors and research seminars led to reassessments and stronger findings. Thick descriptions and a thorough recording (audit trials) of my research process as described for dependability, has been important in facilitating feedback from supervisors and peers.

4.7 Ethical considerations

The PhD study underpinning this thesis was funded by the Ministry of Education and Research in Norway and conducted with the approval of the Norwegian Social Science Data Services (Project No. 27543, see appendix 1). The study did not involve patients, patient information or next-of-kin and was therefore not obliged to seek approval from the Regional Committees for Medical and Health Research Ethics. Ethical considerations related to information and consent-seeking activities needed to be taken for the individual research participants, hospitals and the certification body involved in the study. These activities are described in more detail in sections 4.4. A data processing agreement under the Personal Data Act was signed with the company transcribing research interviews. To ensure ethical expectations for this thesis, I identified and reflected upon ethical issues [188] as part of the research work.

In the following I present some of the ethical dilemmas that needed special attention.

4.7.1 Entering the empirical field - dilemmas

Matters of concern involved in all entries into the field are the negotiation with gatekeepers and physically entering the field [188]. The first ethical dilemma was to balance strategic negotiations with protecting the integrity of the study, when interacting with those controlling the entry to the certification body and hospitals. For me this involved establishing trust and rapport with the organizations involved (see also section 4.6.1 credibility). I therefore met with representatives of the hospital in case 1 and of the certification body in case 2 several weeks in advance of data collection. In these meetings I presented the objectives and relevance of the study, we discussed possibilities for data collection and how information and results would be treated, protected and reported. I obtained signed written agreements from all organizations involved in data collection (see appendix 2 for an example). The certification body claimed the right to read my work and if necessary, remove business-sensitive information before I published it. They also claimed the right to remove specific statements from informants if these were not in agreement with what the informants had tried to express, or if statements were not in agreement with the certification body's policy. After consultation with my supervisor I accepted these terms. This is a commercial industry that has been difficult for researchers to get access to. In dialogue with the certification body it became clear that any conclusions made by this thesis should be attributed to the researchers.

Two ethical dilemmas needed special attention during my observations in the hospitals. The first arose from my presence in certification auditing meetings with hospital personnel. The auditors had been informed and had given their consent in advance of observation. The dilemma was how to ensure that all meeting participants knew about my presence as a researcher, that they consented to my presence and were confident that the confidentiality of whatever they discussed during the audit meetings would be protected (See chapter 4.4.2).

The second dilemma was how to be present in hospitals but not in clinical settings where patients were being treated. The audit activities observed did not

allow auditors to observe clinical practices. All transfers and walk-arounds in the hospital took place in corridors and rooms reserved for personnel and visitors. I did not enter clinical settings where patients were being treated. In one hospital I sign a declaration of confidentiality before doing observations.

4.7.2 Research participants - Proper information, voluntary participation and confidentiality

Research within organizations with limited participants raised two central dilemmas. The first was to safeguard confidentiality internally in the organization while reporting findings. The second dilemma was to ensure voluntary participation while using managers to recruit participants. I needed to ensure that participants were properly informed about the study and their voluntary participation before, during and after data collection. Another strategy to strengthen informed voluntary participation was to let all informants read a late draft of articles I and II. One quote was removed from the manuscript in response to concerns from informants. The interpretations of the findings in the manuscript were not affected.

Special considerations were taken for case unit 1 (article II) where only three participants (lead auditors) were observed and interviewed. The auditors risked having their conduct during the audit revealed to their employer when the research was published. To ensure that they saw how they were represented in the results and had the option of withdrawing from the study, each auditor was allowed to review a late draft of the manuscript that showed the results only from their own contribution. Only after all the auditors had given their response, was the full manuscript sent to the certification body.

5 Findings

To fill the knowledge gaps related to certification in health care, this thesis develops knowledge about external drivers and internal processes in hospitals certification, the scope, understanding and practice of certification processes and the possible contributions to performance improvement from certification processes in hospitals. I therefore explored ISO 9001 certification processes from the perspectives of a hospital, a certification body, and the international standards and guidances. Table 3 demonstrates how the three articles contribute to the aim of the thesis.

Table 3: The connection between the thesis's articles, the empirical perspectives to ISO 9001 certification processes and the elements in the aim of the thesis. The parentheses represent a weak or an indirect connection to the theme in the aim.

Elements in the aim	**Contributing articles**	**Empirical perspectives**
External drivers and internal processes in hospital certification	I (and II)	- Emergency department in a hospital - (Certification body – auditors)
Scope, understanding and practice of certification processes	II, III (and I)	- Certification body – managers and auditors - International standards and guidances - (Emergency department in a hospital)
Possible contributions to performance improvement from certification processes	III (I and II)	- Certification body – managers and auditors - International standards and guidances - (Emergency department in a hospital)

This chapter describes what research questions are addressed in each article, summarizes the findings, and discusses the articles' relationship and connection to the aim of the study.

5.1 Summary and findings in article I

The first article is titled, “Why adopt ISO 9001 certification in hospitals? A case study of external triggers and sensemaking in an emergency department in Norway.” The research objective was to explore external conditions that may catalyze and trigger organizational change and internal sensemaking processes, that lead to continuity and change in favor of ISO 9001 quality management system certification. The following research questions were addressed:

i. How do external environments contribute to an adoption of ISO 9001 certification in an emergency department?
ii. How does the local management make sense of the certification process?

An explanatory retrospective single-case design, using a narrative approach, was used to follow a first-time ISO 9001 certification process in an emergency department in a Norwegian hospital. The study applied a sensemaking framework [114-116] to explore the local managements sensemaking process towards certification.

The article shows that the initial adoption of the ISO 9001 certification did not follow a comprehensive decision-making process in the emergency department. Nevertheless, the management experienced much help from the certification process on how to improve and started to work differently towards their quality management systems. The process was experienced more as guidance than as control. The certification auditors created confidence with their ability to identify salient improvement points, transfer experiences, and bring expert knowledge on systems and change processes.

Four external triggers initiated the adoption, continuation and change in favor of ISO 9001 certification. The first two triggers (nonconformities and regional certification project participation) were situationally specific and present initially in the adoption process. The last two triggers were institutional [114], derived from perceived ambiguities in relative stable institutional structures (internal control regulation and ISO 9001 certification), that enabled the organization’s own search for control.

The first situationally specific trigger was the nonconformities received from a countrywide supervision conducted by the Norwegian Board of Health Supervision. The supervision concluded that inadequate management and leadership interfered with the day-to-day running of Norwegian emergency departments; the emergency department studied in the article received two nonconformities from the supervision. This external disruption visualized longstanding organizational challenges in the emergency department that threatened the managers' shared identity. A search for meaning of the challenges became prominent. The second situationally specific trigger was the occasional possibility for help by an externally initiated pilot project for ISO 9001 certification of emergency departments. Taking part became a quick and plausible solution for the emergency department that would lead to immediate actions and thereby reduce uncertainty.

The first institutional trigger consisted of the stable institutional structures inherent in the internal control regulation for healthcare organizations in Norway. The project for certification of emergency departments intended to use certification as a mean to operationalize the regulatory requirements for internal control. The scope of the requirements was wide and challenging to operationalize in healthcare. The requirements became ambiguous for the emergency department, and the work on concretizing the requirements set in motion important sensemaking processes around continuity and change towards developing a proper local internal control system as part of the certification process.

The second institutional trigger was the implementation of ISO 9001 certification. The ISO 9001 standard consisted of general and unfamiliar concepts and systems that prompted the emergency department to find ways to translate and contextualize these ambiguities, in their efforts to make sense of the standard. Seeing the ISO standard as a trigger relates to the same institutional mechanism as the former trigger. What was different about the institution of ISO 9001 certification was that it involved external auditing process and therefore integrated direct feedback on progress during change processes. Direct feedback or external assessments were acknowledged by the emergency department as useful for improvement.

5.2 Summary and findings in article II

The title of the second article is "Exploring hospital certification processes from the certification body's perspective: a qualitative study." Its research objective was to explore the audit practice as perceived and performed in hospital certification processes in Norway. The article addressed the following research questions:

iii. What styles do auditors apply in hospital certification processes?
iv. How do auditors perceive their role in hospital certification processes?

To explore auditors' practices, a qualitative explorative single embedded case study was performed by observing and interviewing three lead auditors, all from the same certification body, in three different ISO 9001 certification audits in Norwegian hospitals. The role repertoires and conducts identified were analyzed according to a surveyor (equivalent with auditor) styles typology framework [63], defining the auditor conduct within two dimensions, the questioning dimension (structured vs. opportunistic), and the recording dimension (explicit: written vs. implicit: memory).

Two distinct auditor styles — the "explorer" and the "discusser" — were identified in the three auditors during certification audits. Both styles are characterized by their preference for an opportunistic and less structured type of interview practice. One of the auditors was more likely to turn to a more direct and closed type of questioning than the others during audit interviews. Two auditors used a template to guide their interview according to the normative ISO 9001 standard, but none used structured preplanned questions. There were significant differences in how the auditors recorded the interview results. Two auditors took detailed written notes during the interview —- one more frequently than the other. The third auditor only wrote down a few words occasionally and was more oriented to the opposite side of the recording dimension – implicit note taking. All the auditors perceived both assessment of conformity to the ISO 9001 standard and guidance for improvement, without giving specific advice, as embedded parts of certification audits.

Taken together, the findings demonstrated a multifaceted certification reality in which guidance and stimulation for improvement were incorporated to the

assessment processes. All three auditors adopted a guiding approach (e.g., reflections on findings, stimulating improvements, transferring experiences form other hospitals) rather than a highly inspectoral manner when interacting with the auditees. The use of group interviews instead of individual interviews during certification audits was the rule of the auditors' practice.

5.3 Summary and findings in article III

The title of the third article is "Certification as support for resilience. Behind the curtains of a certification body — a case study." The research objective for this study was to explore whether ISO 9001 certification can support resilience in healthcare, by looking at characteristics in the objectives and methods of certification. This article was concerned with certification processes from the certification bodies' perspective embedded in the ISO 9001 certification regime, and addressed the following research questions:

v. What auditing approach for certification bodies is embedded in standards and guidance notes for ISO 9001 certification?
vi. How do managers and auditors of a certification body perceive and practice the certifications?

One of Norway's four certification bodies in healthcare was studied, using an explorative embedded single-case design. The study relied on data from the international standards and associated guidance notes for certification bodies, observations and interviews. Results were discussed in relation to perspectives of potential for resilient performance [125].

The findings show that the international standards and guidances for certification bodies performing ISO 9001 certifications embed an elasticity from the formal and consistent assessments identifying possible non-conformities toward appeals to holistic approaches enabling recognition of opportunities for improvement, the provision of generic solutions, and the sharing of best practices. The auditing standards' proportions of structure and system requirements for certification bodies were more extensive than the description of methods defining how auditors should conduct the on-site certification audits (e.g., especially methods to collect and analyze information and interact with the certified organization). This left auditors a great deal of

latitude to "translate" requirements and navigate their auditing strategy in their interaction with the auditees. A comparable picture was found in the certification body's approach, where the structure and management system established to control and perform reliable certifications were formalized to a greater extent than the sharp end practices of auditors.

Findings in the article further showed that members of the certification body perceived and practiced a holistic approach to certification auditing and were concerned with improvement and to add value to the certified organization. Auditors in the sharp end used opportunities to share knowledge and make guidance and empowered local improvement initiatives as an implicit part of their assessment practice.

The article identified characteristics of the institution and process of ISO 9001 certification that might support resilient performance in healthcare by nurturing the potential to respond and learn. The potential to respond related to the way in which the certification body practiced guidance to healthcare organizations to reduce their extent and complexity of procedures and prescriptions, and rather focus on the functionality and appropriateness for those working in the sharp end. The potential to learn related both to the possibility for holistic and developmental certification approaches, and the centralization of knowledge that certification bodies are in possession of and might spread across healthcare organizations.

5.4 Relationships among the articles

The results from the articles have contributed to address different elements in the overarching aim of the thesis (table 3) in the following ways. Articles I and II contribute to findings related to *the external drivers and internal processes in hospitals certification.* Article I identified the situational and institutional external triggers that contributed to the adoption and continuation of certification in an emergency department. Article I illustrate that the interaction with auditors was an important driver of the ongoing process towards certification. It was clear that the emergency department management acknowledged the auditors' approach to improving systems and providing guidance. Findings in article II underpin the perceptions of the emergency

department and show that an integrated approach to assessment and guidance were an intended practice for auditors towards certification processes.

Articles II and III, and to a lesser extent article I contribute to findings related to the scope, understanding and practice of certification processes. Article III shows that ISO 9001 certification integrates possibilities for a holistic certification approach. Both the standards and guidances for certification and the understanding of the certification body (article III) and the sharp end practice of certification audits (article II) emphasize added value for the certified organizations as an integrated part of certification. To do this, the results show that both sharing experiences and guidance in parallel with assessments should be within the scope of certification. Article I indirectly confirms that the holistic certification process might add value. The management in the emergency department reported that the feedback from the certification body was valuable in changing and improving their systems. The management's attitude changed during the certification process, acknowledging external assessment of their quality management systems, both internal (performed by internal auditors) and external assessment performed by certification bodies.

Article III identifies elements that may give possible contributions to performance improvement from certification processes, in terms of resilient performance. Articles II and III mentioned a certification approach from the certification body's perspective that integrated guidance to healthcare organizations to reduce complexity of prescriptions and focus on the functionality and appropriateness, and as such may support the potential to respond. Results in article I report that the emergency department started to work differently towards improvement and quality management systems, which may demonstrate the certification process's support for resilient performance. The results across papers demonstrated a holistic certification processes, where transfer of experiences from other health care organizations or sectors were part of auditing practices and acknowledged by the certified organization. This might support discussions about the certification processes' support for the potential to learn within and across healthcare organizations.

6 Discussion

In this chapter I will discuss the main findings of the thesis and describe the possible contributions to research and practice. Discussion of the findings are organized according to the three elements in the central aim of this thesis: 1) findings related to the external drivers and internal processes in hospital certification; 2) findings related to the scope, understanding and practice of certification processes; and 3) findings related to the possible contributions to performance improvement from certification processes.

6.1 External drivers and internal processes in hospital certification

Hospital certification and external assessment processes have been a contested domain, because the evidence of the effects upon recognized clinical outcomes is scarce [31, 43-45]. Despite this, more evidence is giving positive results regarding the effects upon organizational structures, cultures, change and performance associated with quality and patient safety [22, 46, 48-53, 55, 237]. This rising evidence base for intra-organizational performance improvement makes the idea of certification as a means to ensure quality and safety in hospitals more relevant.

6.1.1 The institutional environment - Three drivers for hospital certification

Findings in case 1 disclosed the Regional Health Authority's initiative for external assessment and ISO 9001 certification of emergency departments. This initiative mirrors the general shift in modes of regulations towards governance, and the expansion of external assessments and audit activities in general [2-4, 7, 145] and in healthcare [20, 29, 34]. Three inter-organizational institutional drivers and implications have been described in the literature for this general shift: "Distrust, allocation of responsibility, and [organizations'] search for control [4, p.233]." Similarities identified among these institutional drivers in the wider society and findings in case 1 made it possible to extend the discussion of drivers for hospital certification in this thesis.

Distrust focuses on the need for control and transparency to create trust. At the same time these dynamics often lead to more revision, monitoring and regulation [4, 5, 7]. Findings in case 1 indicates that distrust may have been the driving force for the Regional Health authority for more external assessment and monitoring. The regional improvement project introduced external assessment and ISO 9001 certification to be tested as an external mean to ensure, improve and operationalize internal control regulation and quality management in emergency departments. The initiative was a response to the poor performance of emergency departments found by a national supervision [200], and a response to the well-known lack of follow-up on the statutory regulations to establish internal control systems for quality and safety in hospitals [89, 91, 94]. The regional project considered correspondence between internal control regulation and the ISO 9001 standard. Such correspondence has been proposed elsewhere in the Norwegian context [94, 100, 238]. Further, the ISO 9001 standard had already been adopted by a Regional Health Authority as guidance for hospitals to ensure internal control [93].

The project for testing of ISO 9001 certification as a means of assurance and improvement can be explained as a search for control with the performance of the emergency departments in their region. As a driver, a search for control of performance becomes evident when regulations are diffuse, complex and difficult to operationalize [4, 5, 145], such as in soft regulations [5, 148], and the internal control regulation in Norway.

What is noteworthy is that the implication for the regional health authority, in its search for control of performance, mirrors the third driver: the allocation of responsibility [4]. The regional health authority hardened the incentives to follow up on internal control and quality management, by introducing a non-governmental third-party actor for ISO 9001 certification, to ensure quality and safety. Such an allocation of assurance activities transforms traditional "hierarchist" regulations within governments [239] into networked escalation, by widening to the regulatory capabilities of other actors [163] and into modes of governance [4, 5, 34, 145, 146]. The consequence is that it extends the external accountability obligations for hospitals, as was true for the emergency department in case 1.

6.1.2 External triggers driving change inside organizations

In the Norwegian context, the Norwegian Board of Health Supervision performs imposed supervision (mainly as system audits) of compliance with the legal regulation for internal control with quality and safety in hospitals. In contrast, non-governmental external assessment of quality systems, such as for ISO 9001 certification, has been adopted by hospitals on a voluntary initiative. Such initiatives raise questions about why hospitals choose to be assessed by someone from the outside, or to become certified. Case 1 showed that decision to adopt a certification process in the emergency department was not followed by comprehensive and informed decision-making process, such as for rational instrumental decision-making processes [116, 142, 240] or planned change and implementation in health care [106, 241]. Rather, by applying a sensemaking perspective [114-116] this thesis showed that organizational disruption prompt action and plausible decisions when the emergency department decided to join a project integrating ISO 9001 certification. This thesis found two external situationally specific triggers that drove the first face to adoption of certification, and two external institutional triggers that drove the continuation process to become certified.

The first situational trigger was related to the non-conformities the emergency department received from a countrywide supervision and the environmental turbulence due to challenging performance in emergency departments in Norway. For the emergency department, the non-conformities mirrored known performance challenges. What the management perceived as different was the increased attention to these challenges from the hospital's top management. Such an increased focus can be explained by demands to follow up on non-conformities through institutional coercion [6, 113] or regulatory enforcement [13]. But what seems to be more important here, is that the known challenges in the emergency department now became "visible" [2] for other parts of the organization and especially the top management. The challenges became "visible" even though they had been there for a long time. The disruption or "surprise" trigger action and sensemaking [115] that eased change.

The second situational trigger was evident when the management occasionally got an external invitation to take part in a quality assurance project, integrating external assessment and ISO 9001 certification. The management's uncertainty

about proper solutions had challenged their social identity [115, 119] or collective capacity [115], since they were responsible for the quality and safe running of the emergency department. Such threats to a shared identity are entries to sensemaking processes where plausibility and belief about current action, rather than accuracy about the future, are salient [115]. The external possibilities for assistance and support were a solution for the emergency department, that would lead to an immediate action and currently reduce uncertainty. The findings showed that the choice to take part was done without knowing the real extent of what ISO 9001 certification was all about and the consequences for the department. The management's shared belief prompt action, rather than change resistance that are often seen in organizations whose identity has been challenged [118, 119].

The third trigger related to institutional structures in the current internal control regulation, including supervision, and the fourth trigger was related to the institution of ISO 9001 certification. Both regimes are marked by relative stable institutional governance structures. The findings from case 1 were that both the internal control regulation and the ISO 9001 standard consisted of unfamiliar concepts and requirements that was challenging for the emergency department to operationalize. When considering Weber and Glynn's [114] institutional triggering mechanism, these relative stable external structures became ambiguous for the emergency department and led to further internal sensemaking processes [115] toward certification.

The legal internal control regulation uses functional requirements that give a wide scope and possibilities for organizations to choose among a variety of tools for quality work [85]. This is customary in regulatory structures for enforced self-regulation [15, 16, 156]. The ISO 9001 standard builds on a general process approach and principles to quality management, and has moved away from hard engineering-based requirements to softer and more abstract requirements [68, 69]. External "soft" requirements that are (too) diffuse, may trigger organizations to make sense of these and search for control, sometimes by integrating new management tools [4, 5]. The emergency department did not have an internal management system that was clearly built up around the legal requirements for internal control, and the ISO 9001 standard was new for the department. The discrepancies between new external requirements and their current internal references set collective sensemaking processes in motion.

Because, as Weick [242] emphasizes, "maps" (the new requirements) are helpful only in familiar organizational contexts that have already been charted. To be familiar with the certification process, the emergency department had to find ways to operationalize the general ISO 9001 standard (the "map"), that gave a shared meaning for them and their internal system and processes. This internal organizing process drove the process towards certification.

Findings from case 1 shed light on internal challenges related to the operationalization of general and diffuse external requirement. These findings support other research arguing that a lack of competence in developing internal control systems in healthcare makes it difficult to adapt to Norway's internal control regulation [243]. Moreover, research from healthcare accreditation emphasizes the importance of perceived coherence between requirements and the internal organizational context for successful accreditation [244].

Following findings from case 1, ISO 9001 certification was used by the regional project to establish internal control in the emergency department. Even though the requirements may correspond between these two governance structures, the difference is, to become ISO 9001 certified, the process includes external auditing. Findings in case 1 showed that the emergency department considered the certification process more towards internal improvement than external assessment. It was reported that interaction in the auditing encounter integrated assessment, guidance and feedback to ongoing internal certification processes. Ongoing feedback, like sensegiving perspectives [114, 116, 245] seemed important for driving the internal sensemaking process in the emergency department towards certification. These findings are supported by research from hospital ISO 9001-based accreditation programs, suggesting that the external auditors are keys in the program, helping hospitals to direct their attention to the most important elements for improvement [248]. Professional interaction between the accreditors and health care organization is also suggested to help build standards coherence with the health care context [244]. Other research has found that when assessors are collaborative and supportive in their approach, it may increase the likelihood of successful implementation of standards [42, 246].

Treated institutionally, external auditors seem to be important external drivers or triggers [114, 117] to generate internal processes in the ISO 9001

certification regime. Further findings form case 1 indicate that the yearly external surveillance audit was an important feature to keep up the improvement focus among the management in the emergency department. The same experiences of recurring external assessment in health care have been reported elsewhere [56, 238, 247]. Other research indicates positive experiences with more frequent (annual) ISO 9001 audits in hospitals than traditional three-year accreditation cycle [248]. Such experiences raise questions about whether the presence of external auditors is important to trigger quality work. Obviously, one cannot base an external evaluation scheme only on presence. But if the presence of an external body strengthens the legitimacy and motivation towards organizational improvement efforts, it is important knowledge to bring forth when developing governance policies. For example, in Norway there may be years in between the Norwegian Board of Health Supervision's on-site external assessments of clinical departments in hospitals. If such governmental external assessment is an important trigger for organizational quality work, in addition to ensure compliance, then considerations about the frequency of their external assessment of hospitals are relevant. In section 6.3 a further discussion is taken on how external assessment could be a mechanism to support resilience [125] by fostering critical reflection on internal system and performance.

6.2 Scope, understanding and practice of certification processes

6.2.1 Scope of certification

Hospitals are complex systems [150, 170, 249, 250]. This means that hospital comprise of nonlinear systems (in contrast to traditional linear organizational perspectives) where interacting activities can happen routinely or sudden and unpredictably. Within the changing environments, relatively stable formal and informal social structures evolve, such as professional networks, groups, and teams, working and interacting at different levels, inside and outside of the hospital. Thoughts about interactions in complex health care systems include both humans and artefacts; among others, patients, professionals, managers, equipment and different technologies [251]. In general, it is within such contexts that hospitals build their quality management systems, and which

certification bodies, and hence auditors, must assess and understand the essence of, in order to conduct ISO 9001 certification. The certification body and their hospital certification processes explored in this thesis were normatively directed by the generic international certification standards [35] in which the they have little or no influence over [222]. In general, the international certification regime intends to bring consistency, legitimacy and trust to the certification bodies performances [33]. It assumes that, if the standard is properly constructed, an alignment between the standards certification approach and the certification bodies' approach will strengthen the likelihood of successful certification processes. It means that certification bodies, such as the one included in this thesis, must translate and operationalize the standard into certification practices. Such intra-organizational translations may take many forms when generic standards "travel" between countries and organizations [1, 4].

As demonstrated previously (4.5.2) the certification body's expectations and prescriptions of their performances (WAI) will always be different from the actual practices (WAD). This distinction between Work-as-Imagine and Work-as-Done is a core element in the resilience theory [172, 173]. This thesis adopted this perspective when studying the alignment between the certification approach embedded in a) the certification standards and guidances (WAI), b) a certification body's perceptions (WAI), and c) a certification body's practices (WAD).

Overall, the findings show an alignment between the three elements, practice, understanding, and standard and guidances, towards a compliance approach in the auditing encounter [10, 13, 162, 168]. This means that guidance, education and transfer of experiences, in addition to assessing conformity with the ISO 9001 standard, were integrated in the auditing scope, and intended to give added value to the certified organizations. To follow this approach, the ISO 9001 certification regime left auditors with a latitude to navigate their auditing conduct towards the respective organizational context during their interaction with the certified organizations.

This thesis document flexible and dynamic certification encounters. The auditors studied used preplanned audit agendas with topics from the ISO 9001 standard to guide their certification audits. These features contributed to some

consistency despite dynamic interactions with the auditees. Further, auditors were concerned with dialogues with the auditees and encouraged reflections in their search for information during audit interviews. They also included activities such as identifying and recording opportunities for improvement, sharing non-confidential information from elsewhere, and sharing best practices to bring added value to the certified organization. These dynamic and holistic auditing practices are in line with auditing practices shown in other research on external assessments in health care [60, 252, 253]. In general, organizational development approaches seems to increase in external assessments programs in health care [31, 254, 255].

There is no consensus on the effects of the different auditing conducts in hospital certification or in regulation theories in particular [7, 10, 15], but research from external assessment in health care indicates that auditors' professional knowledge and the ability to align expectations and requirements to the respective context in organizations are important to encourage improvement [244, 246, 248].

The certification body emphasized the need to align with the maturity of the hospitals management system and the organizations motivation for certification. Transfer of practices and guidance's were most appreciated by the certified organization, and motivated and strengthened the auditor-auditee relationships. A holistic assessment approaches can shape expectations and legitimacy to the certification process. In health care particular concerns have been related to the expectations of consistency and reliability of compliance oriented external assessment program [60, 248, 252], and general concerns have been related to expectations of independence and power relations [8, 10, 148, 168]. Different structures influence consistency and reliability in external assessment programs in health care, such as certification programs itself, standards, workforce management, and documentation. These structures assume a greater influence on consistency and reliability involved in external assessments, than the specific auditor conduct and the dynamics in the auditor-auditee encounter [26, 60, 64, 65]. These assumptions mean that context sensitive and flexible auditing encounters in certification processes, such as those found in this thesis, may be of less concern for the overall consistency and reliability involved in certification processes.

6.2.2 Organizational independence in external assessment programs

Concerns about independence in external assessment programs may be related to two dimensions: organizational independence and operational independence [7, 8]. Organizational independence is linked to the degree of formal independence and power relations between the auditor and the auditee, and may describe variations in external assessment approaches. Formal independence is a leading principle in third-party audits such as the ISO 9001 certification and relates to the relationship between the auditor and he auditee. In all cases studied in this thesis the certification processes were voluntarily initiated by hospitals as a self-regulatory mean. The external accountability obligations [120, 151] to become certified were not very strong in Norway, since ISO 9001 certification is neither legally mandatory (upwards accountability obligations) nor an institutionalized norm [113] expected by the professional community, patients or the general public (outwards or downwards accountability obligations). When the external accountability obligations to become certified are weak, it may also reduce the power asymmetry in the auditor-auditee relations, since the consequences of not becoming certified are small. The result may be that the certification body have a certain pressure for taking part in organizational improvement activities. As mentioned above, such auditing activities is what the certification body included in this thesis understood to be what the certified organizations appreciated the most. When certification bodies are engaged by hospitals, they also have commercial interest that may influence on the organizational independence and the power relations in these auditor-auditee relationships. The power balance between hospitals and certification bodies may change if there becomes a change in the external accountability obligations. This could potentially happen if ISO 9001 certification becomes enforced by the government as a regulatory mean or expected by the professional of public community. Hospitals will then be more dependent on complying with the ISO 9001 standard, and the consequences of non-compliance, not being certified, or withdrawal of a certificate would be higher.

6.2.3 Operational independence in external assessment programs

The dynamic and flexible interaction between auditors and auditees found in this thesis may be further explained by dimensions related to operational independence [7, 8]. External auditors need information to "diagnose" an organizations management system [166, 167]. The operational independence focus on how auditors get access to and must depend on this information (*informational* independence [7]), and the knowledgebase auditors use to draw independent conclusions (*epistemic* independence [7, 8]). There is an asymmetry between what auditors know about the health care organizations under certification and what the organizations know themselves. Such asymmetry may be reduced by using a more interactive and collaborative auditing style, as shown in this thesis, in order to get the relevant information Likewise, the hospitals' voluntary participation in certification audits may have reduced the auditors' uncertainty involved with information provided by the hospitals and made it easier to take part in mutual dialogues.

The generic and process-oriented ISO 9001 standard, used to asses compliance with the hospital quality management systems [72, 73] might explain the orientation towards a more flexible and prospective certification encounter documented in this thesis. The epistemic independence expect that detailed standards imply more inspection-oriented role, such as in deterrence perspectives, than assessment against generic standards [8, 148]. Further, auditing complex service settings necessitates degrees of epistemic dependency [8] which requires negotiating activities in auditing encounters in hospitals.

6.2.4 Modes of audit interviews

The ISO auditing standards studied in this thesis, highlighted interviews as one of the main methods to collect information and audit evidence, but gave limited information on how audit interviews were going to be practiced [35, 218]. The standards' descriptions seemed to assume audit interviews with individual informants. The same is seen in the revised version of the auditing standards [70, 78, 256]. The descriptions on interview practices in auditing standards and guidances are scarce compared to the methodology literature on research and evaluation, where interview methods are subject to rigorous scrutiny about how

they are able to give or produce evidence [188, 216, 257, 258]. The methodology literature also emphasizes how group interviews or focus groups may empower participants, moving the interviewers' control towards the participants and increasing collaboration [259-261]. The auditing practices observed in case 2 showed that using group interviews was preferred and the auditors' general practice during certification audits. Other research on external assessment processes in hospitals have showed that auditors' use of group interviews had positive effects for their successful participation and collaboration with staff [42].

As the findings shows, there are some possible discrepancies between expectations for interview practices as set out in the ISO standard and what are perceived and practiced in the certification encounter. The interview and dialogic practices involved in certification may relate to methodology issues, such as reliability [60, 248, 252] and empowerment, that should be discussed and developed further in future revisions of the ISO standards and guidances. This thesis proposes a new dimension related to audit interviews (in addition to the questioning and auditing dimension) to refine the auditor style typology framework [63] applied in this study. The new dimension is an *Interview method dimension,* implying an auditing approach that favors either *individual interviews* or *group interviews* when interacting with the auditee.

6.3 Possible contributions to performance improvement

Using the resilience perspective [125, 127] in exploring ISO certification, regulation by authorities or interorganizational fields in healthcare, seems to be a novels approach within research (see 3.4). However, it may be useful in exploring how an ISO 9001 certification processes can contribute to better performance and improvements in hospitals. There is not necessarily a correspondence between complying well with the requirement in the ISO 9001 standard and support for resilient performance. This thesis explores characteristics of the certification processes that might support potentials for resilient performance of the certified hospital. It has not studied the specific requirements in the ISO 9001 standard and the relationship to the potentials for resilient performance.

The ISO 9001 hospital certification processes explored in this thesis were all voluntarily adopted and there were no clear financial incentives or tradeoffs with being certified. Therefore, the initiatives may indicate a certain level of resilient performance enabling the organizations to gain insight, evaluate and improve their performance. It can also be an initiative to ensure accountability to external stakeholders. Research across sectors confirms that the organizational improvements from ISO 9001 certification are more far-reaching if the motivation for certification are internally derived [41].

6.3.1 Collective sensemaking

Activation of collective sensemaking is described as a resilient characteristic in health care research when organizations meet disturbances and changing demands [179]. Findings from case 1 showed that an emergency departments process of becoming ISO 9001 certified, sat in motion important internal sensemaking [116] processes, triggered and supported by interaction with certification auditors, that drove improvement of the quality management system towards certification (see 6.1.2 above). As found in case 1 and 2, auditing practices may trigger disruptions to daily activities that uncovers and make visible opportunities for improvement or call into questions poor performance or cultures. Such disruption may lead hospitals to trigger resilience by activating collective sensemaking processes and purposeful reorganizing [176]. The auditing practices in hospitals found in case 2 were characterized by the auditors' adaptation to the certification context and the auditors' interaction, negotiation and dynamic communication with the auditees (see 6.2 above). These auditing practices seems to be in line with creation of reflexive spaces and responsiveness in the auditor – auditee encounter, characterized by trust, dialogue, respect and a psychologically safe atmosphere, foundational for creating conditions from regulation that nurture potentials for resilience in healthcare [177].

As discussed above (section 6.2), dynamic auditing approaches are possible since the ISO 9001 standard builds on generic requirements that expands the auditors' latitude to "translate" the requirements to specific organizational contexts [39, 262-264]. The ISO 9001 standard gives hospitals room to choose between different management tools to meet requirements and use flexible guidelines and best professional practices that follows current developments

and progress. This is also in line with the current regulation on leadership and quality improvement in Norway, that assumes hospitals to choose sufficient quality improvement tools and use guidelines and standards of best practices [84, 265]. Such *flexibility* for self-regulation within a regulatory regime is an important mode in order to contribute to resilience [17, 148, 178].

6.3.2 The resilience potentials and ISO 9001 certification

The four potentials in the resilience engineering perspective, proposed to be necessary for an organization to perform resilient, is to *respond*, *monitor*, *learn* and *anticipate* [125, 127]. These potentials are inevitable interdependent, while at the same time serve essential functions in their own right. The assumptions have been challenging to operationalize in healthcare research, since the complexity of activities in healthcare organizations and regulation regimes makes it unclear what each potential should include and attend to [178, 180]. It can also be unclear what boundaries that should define the scope or the sociotechnical system where these basic functions intend to be potentials for resilience, such as a team, a department, a hospital, a health care system, or even a community. This thesis's exploration of the certification processes' support to the four resilience potentials in hospitals is not exhaustive, and has been associated with some ambiguity, e.g., related to the potential to monitor. When auditors perform certification audits in a hospital, the audit activity is clearly a way of monitoring the certified organizations quality management system. But the monitoring (audit) activity does not necessarily mean that the hospitals potential to monitor its own performance has been strengthened. On the other hand, the regular external monitoring (audits) extend the total (internal and external) capacity to monitor the quality management system of the hospital.

This thesis has identified characteristics in certification practices that applies to at least two potentials for resilient performance in hospitals that certification processes might support: the potentials to respond and learn [125].

6.3.2.1 Supporting the potential to respond

There has been an understanding between sectors that ISO 9001 certification is concerned with organizational prescriptions and procedures [38, 41], but

compared to other standards in external assessments regimes in healthcare, ISO 9001 lacks detailed, clinical-specific, requirements [26, 266]. To produce detailed procedures and prescriptions were not in focus of the certification body studied in this thesis. Rather conversely, there were concerns about the complexity and high number of procedures observed in hospitals. In general healthcare organizations are often assumed to desire standardization and procedures [267]. The auditors were concerned with the functionality and appropriateness of the quality management systems they assessed, and not only the management structures established to comply with the ISO 9001 standard. Different examples of this approach are shown in findings from case 2 (article 3) and one of them relates to auditor's response to a challenging complexity of hospital procedures. In one of the examples the auditor was concerned with the availability and functionality of procedures, even though the procedure complied with the ISO 9001's requirements on documented procedures. Improvement possibilities became inherent in conversations between the auditor and the auditee. The auditor gave rhetoric questions and comments in order to get the auditee to reflect about the daily practices and the contextual reality for those using the procedures. A department showed a complex operational procedure that included much information and links to references that were not operationalized into practical useful information to the employees. Examples of questions and comments the auditor used: "How and where would a nurse in a department find or try to find these?", "Think from the bottom up"; What is relevant for the employees?". Such auditing approaches may be important for a organizations ability for resilient performance [19, 124], and may apply to the potential for *responding* [125]. Hollnagel [125, p. 73] suggests the following guiding question for organizations when diagnosing and improving the potential to respond: "We revisit and revise our list of events and action plans on a systematic basis (p. 73)". Actions plans within this perspective may take many forms and include daily procedures to known and expected events. To maintain a readiness to respond, the perspective suggests regular reviews of the relevance of procedures and to make proactive adjustments (rather than the traditional reactive adjustments) to the needs of expected events [125]. The auditors and the auditees' dialogue and review of the hospitals plans and procedures, were important to be prepared to meet different daily or sudden conditions and events. The auditors' approach reflected thoughts on resilience that implies that

too many detailed standards, checklists or procedures might undermine the discretion and autonomy of the health professions working in hospitals [19, 268]. Procedures and prescriptions supporting flexibility and adjustment rather than narrowing their scope and constrain their action are important for resilient performance [269, 270].

6.3.2.2 Supporting the potential to learn

The centralization of knowledge that certification bodies provide, can be important for learning, and hence resilient performance, across an entire healthcare system [19]. Such learning may happen between departments, hospitals or between hospitals, municipal health care and organizations in other sectors that undergo certification. This study exposed that auditors took initiatives and used their opportunities to transfer anonymous general experiences and good practices they had learnt in other healthcare organizations to the auditees. Such centralized knowledge might be learning from success or lessons learned from disruptive events with adverse impact in hospitals. Learning form success in a resilience perspective is not related to the success in a traditional quality improvement approach in healthcare, such as in the safety I perspective (see section 3.4), where the preoccupation with and absence of failures, or to prescribe and perform without tradeoffs, are favored [267, 271]. Success in a resilience perspective relates to everyday work practice, and the ability to adapt responses to variations and surprises that happens in complex systems such as hospitals. As described above, the certification body in this thesis included both dynamic conversations with the auditees and direct observations of work activities in the hospitals. Such auditing activities provides the certification body with a knowledge base that can be important for "scaling up" resilience [272, p. 127] across an entire healthcare systems, by activating structural or systemic resilience and spreading information through their networks [176, 272]. A challenge when expecting certification bodies to be formal mediators for learning between hospitals or across sectors, is that their accountability obligations change [120, 158]. E.g., if learning from failure has not led to learning between hospitals, and the same failure happens again in other hospitals, the certification bodies expected to enhance learning can be held to account, either formally or informally.

6.4 Proposing a multilevel model for the approach to accredited ISO 9001 certification

The overall analytical model applied in case 2 (see 4.5.2, figure 9), integrated the distinction between *work as imagined* and *work as done* when exploring approaches to certification in a resilience perspective [273]. The model was inspired by Lindøe and Kringen [274]. For this thesis, the model represented the empirical unit of analysis as seen from a researcher's perspective. But, derived from the explorative work in this thesis, the analytical model was further developed to represent elements involved in different levels of the accredited ISO 9001 certification regime (figure 11). The mid level of the model (the blue field) represents auditors from a certification body performing certification in hospitals (the orange field). During the certification, auditors assess from an external perspective the documented and described hospitals quality management system, in in addition to observe and collect evidence on how the quality management system is practiced (WAD). There may be discrepancies between the WAI and WAD. The auditors also assess how these two elements correspond with the ISO 9001 standard. In the same way as the auditors assess from an external perspective, the model assumes that the hospitals themselves also assess and evaluate their own documented quality management system, from an internal perspective. The two evaluations are then matched, discussed, and negotiated in the interaction between auditors and the auditee, to identify non-conformities or areas of improvement. This thesis does not have data from processes of accreditation at the accreditation body level, but the structure and activities that accreditation bodies (the green field) performs in conformity assessments, may coincide with the structure and process of certification. It is therefore possible to see these processes in a multilevel model as proposed.

The model contributes to the lack of multilevel perspectives in the literature on resilience in health care [180, 272] and how the interface between the different levels and actors in ISO 9001 certification can be addressed in order to reduce the gap between WAI and WAD in health care organizations. The model also emphasize that certification or accreditation involve interactional activities between auditors (assessors) and the auditees (assessed). The accredited certification regime assume organizational independency between actors at the different levels, but nevertheless, these vertical links include interactional

elements and operational dependencies that may involve challenges, such as, different knowledgebases, professional understanding and "language", availability of information, conduct and trust [8, 10, 275]. While the accreditation body in Norway is rooted in the state authority, the certification bodies are private commercial bodies performing certification activities that are not publicly made available (except for the certificate stating conformity to the ISO 9001). This multilevel regime, anchored in international standards, is described as a "faceless" regime due to its diffuse couplings to authorities and formal accountability structures [222].

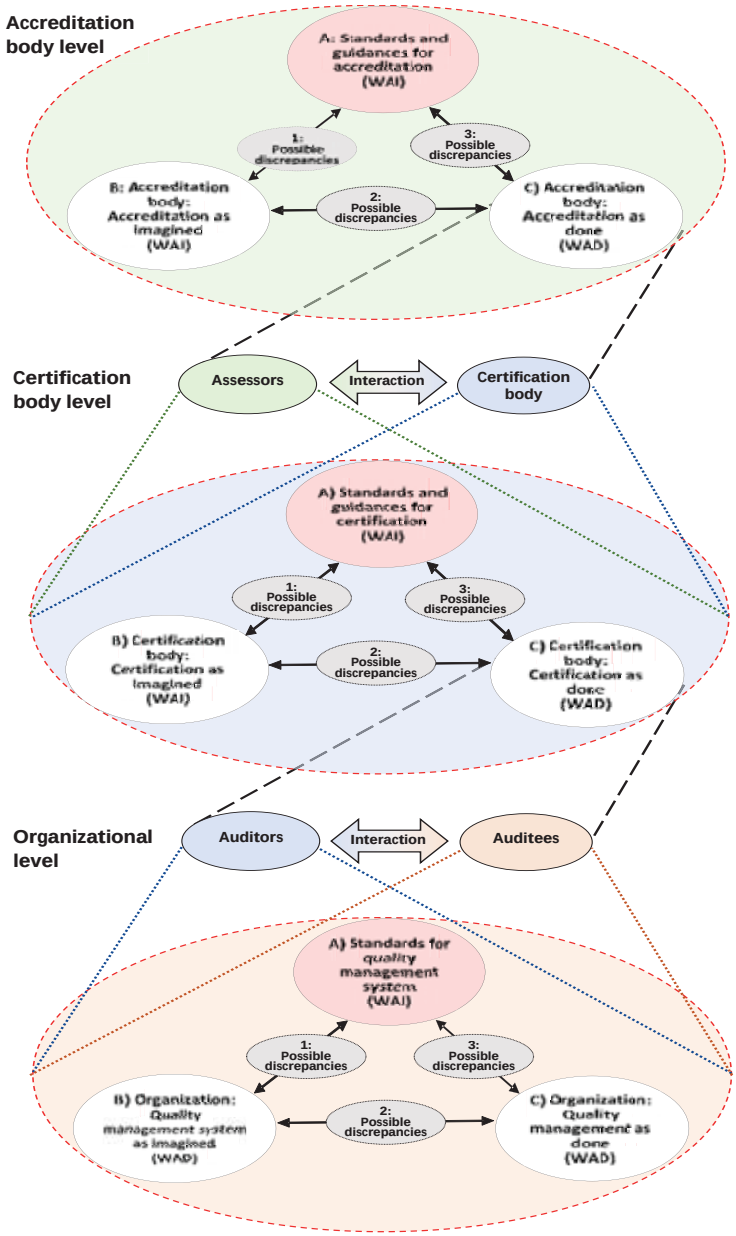

Figure 11: Multilevel model representing the international accredited ISO 9001 certification regime. The accreditation and certification practices represent assessment activities and interaction with the organization being assessed, where the assessor and the assessed alone and together evaluate possible discrepancies (and, if applicable, look for possible improvements) between what the assessed organization describe and say they do (B) and the actual practices (C), and how these understandings and practices match the normative standards (A).

6.5 Implications

This thesis got a rare access backstage of a certification body, to explore their certification approach. By looking behind the "curtains" of a certification body it provides new insight to our knowledge gap in the field of certification practices.

The documented flexible auditing approach involved in ISO 9001 certification gives abilities to create reflexive spaces, discussions, and support improvement as part of certification. These approaches break with more traditional thoughts of ISO 9001 certification and should be part of future policy debates related to adopting certification in hospitals. Moreover, these approaches should evolve further if ISO 9001 certification intend to support resilient performances in healthcare in the future.

This thesis' exploration on how environmental structures, and certification audits in specific, can trigger change and organizing processes in hospitals call attention to the need for policy makers to consider the frequency and regularity of external assessment to activate improvement. Such considerations are useful in the Norwegian context, where the Norwegian Board of Health Supervision performs mandatory external supervision with a more variable frequency, often with years in between.

Case study 1 applied the institutional trigger mechanism in Weber and Glyns' [114] theoretical perspective to explain how structures in the environment triggered occasions for sensemaking. The application of this institutional triggering mechanism contributes to extend the foundation of studies combining institutional theory with organizational perspectives to explain occasions for change due to institutional structures other than institutional constraints. Explaining external triggers for the adoptions of new management tools, such as certification, are important since organizations rarely leave others at the same time and can make healthcare more complex.

The finding points at reflection and clearance upon how audit conducts and audit interviews should be performed and organized. Such reflections should include both elements of reliability included in auditing practices and empowerment of the auditees. Further, an additional dimension related to audit interviews is proposed to improve the auditor style typology framework [63].

The proposed multilevel model (figure 11) illustrates how certification in organizations is an interactive process including alignments of WAI and WAD at different levels. Pointing at these elements the model could be a guidance towards further research and development of the ISO 9001 certification regime. This can be to consider and adjust the certification approach and requirements, based on a traditional safety I perspectives [271], that happens in the interface between the different levels and to reduce the gap between WAI and WAD and the interactions

6.6 Limitations

Several limitations in this thesis needs special attention. Some issues are already mentioned above (4.6 & 4.7), but a brief overview is needed.

There is limited research on ISO 9001 certification practices in healthcare in Norway, and this thesis is a novel work in these perspectives. The thesis is therefore explorative in nature. Despite the explorative nature, the thesis has applied several theoretical foundations in order to guide the study and analysis. There is a risk that the theoretical perspectives chosen in such novel work do not capture important elements of the certification practices that it intended to do. E.g. theory driven categories adopted form regulation theory were used to analyze the certification body's and auditors' conduct in certification processes and the normative standards as guidance for certification.

The narrative in case 1 constructed retrospectively of the certification process in an emergency department was a story but not necessarily the whole story or the real story in an objectivist sense. The narrative may have discriminated the complexity of multiple, simultaneous and various narratives and sensemaking processes that were worked out within the organization, or captured internal elements that were not caused by the process under study [118, 213]. The meaning making processes were studied within a single emergency department in a single hospital in Norway. The sample size is a limitation for generalizations from this study.

Further, as discussed above (4.6), the number of informants included in each case study are small, and only one certification body is included. Even though the information power [232] is strengthen due to the highly specific

characterizations of the participants and context, consideration should be taken when generalizing from this thesis.

This thesis has not studied how the specific clauses in the ISO 9001 standard were assessed and translated by auditors and the auditees during the certification processes. Neither does the study include the specific changes or outcomes in the hospitals from the different certification processes observed, besides that all the hospital organizations were certified. Cautions must be taken of the relationship between the certification approaches and process and the actual outcomes in the organizations.

7 Conclusion

I will conclude by revisiting the research questions and their contributions to the aim of the thesis. Moreover, I propose possible directions for future research.

The first aim was to develop knowledge about external drivers and internal processes in hospital certification. Answers to research questions i and ii improve our understanding of how cues provided by external pressure and institutional structures, meet the micro-level change processes in organizations involved in adoption of ISO 9001 certification.

i. How do external environments contribute to an adoption of ISO 9001 certification in an emergency department?

This thesis identified two situationally specific triggers and two institutional triggers in the external environment that contributed to an adoption of ISO 9001 certification. The two situationally specific triggers were: 1) that nonconformities during a national supervision, mirrored known challenges in the emergency department, prompting a search for change by the management; and 2) an external offer to take part in a pilot project for ISO 9001 certification became a quick and plausible option for the emergency department. The two institutional triggers were the current regulation for quality management (internal control regulation) in healthcare and the ISO 9001 standard and certification process. These stable institutional structures were perceived as ambiguous and provided cues that enabled the emergency management's sense making processes and their own search for control.

ii. How does local management make sense of the certification process?

By combining sensemaking theory with institutional theory, this thesis demonstrated that the ambiguous institutional structures inherent in health care regulations and the ISO 9001 standard set in motion important sensemaking processes around continuity and change. Preferably, ISO 9001 certification processes, unlike health care regulations, involved predictable external auditing that integrated direct feedback to the ambiguous change processes. This was

acknowledged by the emergency department as important and useful for improvement.

The second aim of this thesis was to develop knowledge about the scope, understanding and practice of certification processes. Answers to research questions iii – vi added to this knowledge by demonstrating that the international ISO 9001 certification regime stressed consistency and objectivity while opening for flexible and context-specific audit approaches. Further answers contributed to the identification of adaptable auditing styles involved in hospital certifications and showed that a certification body included both assessment and guidance to their understanding and practice of ISO 9001 certification processes in hospitals. The thesis also extends the application of the theoretical auditor style framework.

iii. What styles do auditors apply in hospital certification processes?

By adopting an auditor typology framework, this thesis identified auditor styles characterized by their preference for an opportunistic and less structured type of interview practice during ISO 9001 certification in hospitals. Guidance and stimulation for improvement were also incorporated into the auditors' assessment style. Further, this thesis identified that the auditors used group interviews, instead of individual interviews as defined by the auditor typology framework that was applied. Therefore, an additional dimension of group interview practices was proposed, to refine the auditor style typology.

iv. How do auditors perceive their role in hospital certification processes?

This thesis identified that the auditors perceived their auditing role in coherence in terms of how they practiced their audit style. They all perceived both assessment of conformity to the ISO 9001 standard and guidance for improvement as embedded parts of their auditing role.

v. What auditing approach for certification bodies is embedded in standards and guidance notes for ISO 9001 certification?

This thesis shows that the international standards and guidance for ISO 9001 certification expected certification bodies to have structures and systems in place to ensure consistent and objective certification processes. At the same

time, they gave auditors the latitude to adopt a flexible and context-specific audit approach, in order to add value during certification processes.

vi. How do managers and auditors of a certification body perceive and practice the certifications?

The members of a certification body explored in this thesis acknowledged and navigated their sharp end certification approach holistically, integrating both assessment and guidance. They also perceived their own formal structures and management system for ISO 9001 certification as important for reliable certifications, and to be formalized to a greater extent than the sharp end practices of certification auditing.

The third aim of this thesis was to develop knowledge about possible contributions to performance improvement. By exploring characteristics of ISO 9001 certification approaches in hospitals, this thesis identified flexible and adaptable certification processes that may support and nurture resilient performance of healthcare organizations undergoing certification processes.

In addition, this thesis proposes a model of the accredited ISO 9001 certification regime that may be helpful in future studies and development of ISO 9001 certification practices in hospitals.

7.1 Further research

Following this thesis, futures studies are suggested to increase the knowledge of the role, application and effects of certification programs in hospitals. Especially in Norway, where quality system certification has a novel history, further research should be welcomed.

In-depth studies of certification bodies over time to identify variations in work practice and style, together with comparative studies of different certification bodies should be encouraged. Further, studies of the certification bodies' work practices should, like this thesis, include the role and conduct of the auditors to further explore the interactional element between the auditors and auditee. An appliance of the auditor typology framework used in this thesis can help refine and extend the framework further and judge whether all of the proposed styles actually exists in current auditing practices. These studies would benefit from

including how the specific requirements in the ISO 9001 standard are emphasized and operationalized by auditors during certifications.

Studies should explore further internal and external elements that trigger and motivates hospitals to adopt and continue ISO 9001 certification programs, and, likewise, elements that affect hospitals to quit ongoing certification programs. There is specially a need to explore the different stakeholders view on certification, such as patients, healthcare professionals and policymakers.

Studies should further explore how ISO 9001 certification and the standards requirements relates (support or hamper) the regulatory mechanisms in health care in Norway, and how the standard's requirements are operationalized in hospitals in relations to the current healthcare regulations. Studies should further include explorations of certification practice's impact on knowledge transfer and learning across hospitals and other healthcare organizations.

Controlled studies are missing and should be enhanced to study certification processes and its effect on performance and outcomes in hospitals, especially if certification is adopted on a wider scale in Norwegian hospitals. Studies should also include the economic implications. There is also a need for studies on the certification's long-term effects on change and performance in hospitals. These studies should explicitly study the external assessments' impact on continuity of change and improvement in hospitals. The impact from different forms and frequencies of external assessments should be included in these studies.

Studies should adopt recognized framework and methodologies to strengthen comparison to previous studies and certification programs in other countries. A further application of the resilience perspectives to studies of certification programs in hospitals seems to be a promising direction.

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PART 2

Article I

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Safety in Health

RESEARCH ARTICLE Open Access

Why adopt ISO 9001 certification in hospitals? A case study of external triggers and sensemaking in an emergency department in Norway

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Abstract

Background: Certification and accreditation are widely used to achieve quality and safety in health care but are also questioned regarding their assumed effects. This is a challenge for policymakers and managers, since adoption of these regimes can have a circumstantial impact upon organizations. This study's aim was to explore how external conditions catalyzed and triggered organizational change and internal sensemaking processes as part of an ISO 9001 certification process.

Methods: The study applied an explanatory single-case design, using a narrative approach, to retrospectively follow a sensemaking process in an emergency department in a Norwegian hospital undergoing ISO 9001 certification. The certification process was a pilot initiated by a Regional Health Authority, which ran from autumn 2008 until spring 2012. Nine semi-structured, qualitative interviews were conducted, and documents in the form of minutes and reports were collected. The data was analyzed according to an organized sensemaking framework.

Results: The adoption of the ISO 9001 certification did not follow a comprehensive decision-making process. Our study shows two external situational triggers that initiated adoption. First, a countrywide supervision conducted by the Norwegian Board of Health Supervision concluded that inadequate management and leadership negatively affected the day-to-day running of Norwegian emergency departments. This external disruption visualized longstanding organizational challenges that threatened the managers' shared identity. A search for meaning became prominent. Second, an occasional, externally initiated certification project was a plausible solution that would lead to an immediate action that would reduce uncertainty. Institutional requirements and concepts in the international ISO 9001 standard and in the national health regulations were unfamiliar and ambiguous for the project group involved in the certification. These issues became the institutional external triggers for intra-organizational sensemaking processes that made ISO certification possible. External assessments were acknowledged as useful for making improvements.

Conclusions: By combining institutional theory with sensemaking theory, this case study contributes to a better understanding of how external pressure meets micro-level change processes. These understandings are important because environments give rise to adoption of different management tools, such as certification, but organizations adopting new management tools seldom abandon others. This can lead to even more complex health care.

Keywords: Certification, Accreditation, ISO, Quality improvement, Sensemaking, Organizing, Change, Institutional theory, Narrative analysis

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Background

Accreditation and certification programs in health care are used internationally to ensure, regulate and drive quality improvement and safety initiatives. Starting as a professional self-regulatory standardization and control initiative in the early years of the twenty-first century, the number of programs globally has grown tremendously in the last 25 years. In Norway such programs have no clear history other than some small ad hoc initiatives. At a national level, nationwide certification and accreditation programs have been debated [1, 2] and were recommended by the Government in 2015 [3]. Claims about a limited evidence base and rigorous study designs of the effects upon recognized quality measures have been put forward in several international publications, especially in relation to how many resources are allocated to accreditation and certification systems internationally [4–6]. Recently, two updated systematic reviews about the effects of certification and accreditation [5] or external inspections [7] upon process or clinical outcomes only found respectively one and two studies that met their inclusion criteria. The authors found no strong evidence to conclude about the effectiveness of certification or accreditation. Earlier reviews, with broader inclusion criteria report in general inconsistent findings on the relationships between certification and accreditation programs and clinical performance and outcomes, a positive trend about the programs ability to stimulate improvement work and promote organizational and cultural change and change in professional practice concerned with quality of care, and contrasting views among professionals towards accreditation [8–10]. Studies of 89 European hospitals indicate that accreditation and International Organization for Standardization (ISO) 9001 certification are positively associated with some quality and safety structures and hospital outputs such as hospital management, clinical practice, safety, patient-centeredness and cross-border patient-centeredness. These studies demonstrated that accreditation has slightly more impact than ISO certification, but either system is better than no external assessment [11, 12]. The recent EU project DUQUE with data from 73 European hospitals studied the relationship between ISO 9000 certification, healthcare accreditation, and quality management. The researchers concluded that accreditation and certification were positively associated with clinical leadership, systems for patient safety, and clinical review, but not with clinical practice [13]. In a Danish nationwide population-based study the researchers reported a lower 30-day mortality risk for admissions at fully accredited hospitals compared to admissions at partially accredited hospitals [14]. Using an interrupted times series analysis following one hospital in Abu Dhabi over 3 years, the researchers showed that the positive impact of healthcare accreditation on hospital quality measures to some degree was maintained during the 3 years accreditation cycle, but concluded that more focus on continuous improvement methods to sustain the positive impact form accreditation was needed, for instance, frequently self-assessment or unannounced external reviews [15]. The use of unannounced external reviews was recently studied in a nationwide cluster-randomized controlled trial [16]. No difference between announced and unannounced surveys in detecting non-compliance with accreditation standards in hospitals was found.

The uncertain relationship between adaption of different accreditation or certification programs and quality and safety objectives poses a challenge for policymakers and managers. Despite these challenges, hospital certification and accreditation are widely used and differ extensively in their purpose and organization [10, 17]. Certification and accreditation can therefore be considered as a legitimate and institutionalized means of regulation of quality and safety in hospitals, and in complex organizations they reflect contemporary tendencies of *means–ends decoupling* [18]. In means–ends decoupling, we see that the adoption of new policies or formal structures has a real impact upon change of organizational activities and cultures, but there is limited evidence linking these changes to organizational effectiveness and outcomes (see Fig. 1).

Figure 1 presents the questions about why complex organizations allocate resources to practices that have a scarce or diffuse known relationship to organizational objectives. In hospitals, such objectives are most often linked to better outcomes of patient care. This case study takes these questions into a hospital context in Norway, and investigates why and how an emergency department (ED) adopted and was certified in the *ISO 9001:2008 Quality management systems – Requirements* standard.

ISO 9001 certification—what is it?

ISO 9001 certification can be seen as an external conformity assessment or control mechanism to assure and regulate quality and safety in health care. It is often compared to or described interchangeably within the "family" of external assessment strategies for health care organizations, and especially accreditation [19, 20]. The common purpose of these external assessment programs is to provide information and evidence that the organizational system and performance conform to a specific standard, and both certification and accreditation programs award the assessed organization with a certificate on successful conformity. Certification bodies and auditors should strive to build confidence and trust through a practice rooted in impartiality, competent assessments, and decisions based on objective evidence [21]. The ISO 9001 standard does not prescribe performance requirements.

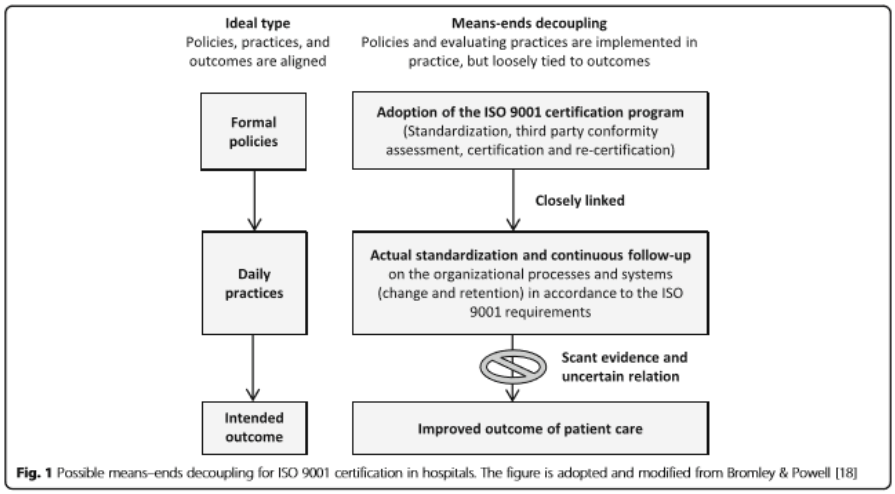

Fig. 1 Possible means–ends decoupling for ISO 9001 certification in hospitals. The figure is adopted and modified from Bromley & Powell [18]

Rather, it proposes generic requirements for structures and systems that enable organizations to formalize production or service processes into a series of procedures, and to continuously monitor, document and improve its efficiency upon customer (patients) requirements and legal regulations [22, 23]. An audit program has a 3-year audit cycle: the initial certification process, two shorter "surveillance audits" over the next 2 years, and then re-certification in the third year.

Aim and research question

The aim of this case study is to explore external conditions that may catalyze and trigger organizational change [24–27], and internal sensemaking processes in the local ED management [24] that led to the continuity and change in favor of ISO 9001 certification. The following research questions guided the study:

- How do external environments contribute to an adoption of ISO 9001 certification in an emergency department?
- How does the local management make sense of the certification process?

This paper reports on the sensemaking processes in an emergency department in a Norwegian hospital undergoing ISO certification. By combining institutional theory with sensemaking theory, the paper contributes to a better understanding of how external pressure meets a local conceptualization of quality management processes in ISO certification.

Theoretical approach

The rise in certification and accreditation practices in healthcare [17] reflects the shifting mode in regulation (often a reduction in "hard laws" and directives), spread and diffusion of modern management tools, and demands for accountability and transparency in our contemporary society. In this case study, we treat the interplay between the enforced internal control regulations and voluntary ISO certification from the perspective of re-regulation [28] or decentered or plural regulation [29]. Typical of such regulation is the transformation into modes of governance[1]; with or without governments, often transnational in structure, and represented by non-binding "soft" rules and regulations. Such soft regulations are often diffuse and lead organizations to search for other means and control mechanism [28, 30].

To study the interplay between mandatory regulatory demands in healthcare and the voluntary adoption of ISO certification in a Norwegian hospital context, we draw on the contributions of institutional and sensemaking theory.

Institutional trigger

The present study emphasizes how macro institutional elements shape, trigger, or become situated by organizations and individuals, but with less influence over the continuing intra-organizational sensemaking processes [25, 27, 31]. People act and then use institutional structures to give meaning to their actions. This perspective breaks with more traditional perspectives where institutional environments

place cognitive constraints upon organizations and intra-organizational processes by preclusion of other alternatives. According to Weber and Glynn [25], there are three mechanisms in addition to traditional cognitive constrains whereby institutional context affects sensemaking: *priming*, *editing* and *triggering*. Institutional contexts, in their view, refer to both the external institutional environment and institutionalized structures or scripts within organizations. People acting in situations extract cues to activate sensemaking processes. In this case study, we follow the triggering mechanisms [25] which relate to how contradictions, ambiguities, and gaps inherent in stable institutional structures create puzzles that require people to search for meaning. For example, the Norwegian healthcare regulation and the international ISO 9001 certification system represent different institutional structures that when adopted are supposed to constrain action. They also carry different legitimacy mechanisms that when adopted in different organizational contexts have the potential to be ambiguous, diffuse, or incomprehensible.

Sensemaking, turbulence, and change

The sensemaking perspective [24, 31, 32] helps to see the micro processes that enfold when managers adopt popular quality and safety programs, such as total quality management, six sigma, and LEAN management. Adoption processes do not follow rational, instrumental decision-making processes, rather they are filled with constantly changing sensemaking processes in order to give meaning to changing situations and outcomes [31, 33]. Sensemaking is most evident when the world is perceived to be different from its expected state or when there are surprises [31]. Such diversity is described as triggers or a discrepant set of "cues" [24] enacted by individuals. Cues can be small bits of information, events or simple familiar structures, and people turn to earlier scripts, schemes, or frames to ascribe meaning to cues and decipher the situation. In other words, people are guided by institutional constraints, organizational premises, plans, expectations, acceptable justification, and traditions inherited from predecessors [31]. Weick [24] explains the sensemaking mechanisms that foster these organizational processes as thoughts, feelings, and intentions, the "intrasubjective meanings", being merged into "intersubjective meanings" through conversations. In times of stability, individuals draw on common scripts and frames to make sense of situations. But, in times of turbulence and change, these "old" scripts no longer work. A gap needs to be filled and an intersubjective or collective sensemaking process again becomes prominent. People look for reasons to continue or resume their work. In the search for reasons, sensemaking is about the interplay of action and interpretation rather than the influence of evaluation on choice [31]. It is not about accuracy and truth, but about plausibility. People continually redraft their stories in their search for meaning, so the stories become more comprehensive and resilient to criticism, and richer in data. Important in our case study was how a local project group constructed a story that we regard as collective shared meanings. *Shared meanings* is a core theme for both crisis sensemaking and change sensemaking [26].

Methods

In this section we will describe the regulatory context of Norwegian hospitals. Then we continue with design and data collection and present our analytical framework.

Context and internal control regulation in Norway

The Ministry of Health and Care Services has the overall responsibility for the specialized health care services in Norway. Public hospitals are owned by the Government and organized in four Regional Health Authorities (RHA).

The regulation of quality and safety for health service providers in Norway is based on a functional legislation, outlined as enforced self-regulation [34], where different regulatory requirements are based on an internal control system [35]. Hospitals have in this perspective a great deal of latitude to make decisions and set priorities about their organization and services [36].

All hospitals, their service and health personnel, are subject to supervision by the Norwegian Board of Health Supervision (NBHS), through the 18 Offices of the County Governors. The main supervision of hospitals is performed as system audits, whose aim is to ensure and control whether health services are complying with national acts and regulations. In practice it involves auditing the health service's internal control system.

In 2005, a RHA voluntarily adopted the ISO 9001 as a guide for all its hospitals, in order to operationalize the internal control system requirements [37]. It was argued that an identified lack of follow-up on the internal control system could be connected with difficult conceptualizations, vague demands, and uncertainties about overall quality management systems and its advantages [38].

Design

The present study is designed as an explanatory single-case study [39]. For explanation building, we used a narrative approach [40–45] and storytelling [46] to retrospectively follow sensemaking during the local ISO 9001 certification process of an ED in a hospital trust in Norway. The process ran from autumn 2008 until spring 2012.

An overall story or narrative was produced during the research process. It illustrates how those involved in a local project group collectively made sense of the

practices and experiences that unfolded during the certification process. The stories and meanings that the informants provide about past experiences can in itself be seen as a sensemaking process, as the nature of sensemaking builds upon frames that continuously change as the informant act and acquires experience [24]. The narrative can as such be seen as a co-construction between the informants and the author (the researcher), in addition to stories from documents (artefacts), and are constructs through which events are made sense of rather than just representations of these processes [40].

Sample and data collection

The case study relies on data produced from qualitative interviews and documents [39, 47]. An initial exploratory interview was conducted in June 2011. Then documents and informants were selected for further study. Data derived from documents took the form of minutes of meetings and reports that were made available by informants and official websites (Table 1). The main data collection was performed during spring and autumn 2012.

Twelve informants were firstly purposefully selected. All were managers and key personnel in the ED, head of clinical and service departments, key personnel in the certification process, and the project management in the Regional Health Authority. After conducting eight interviews (Table 2), a distinct picture of the key local project management for the certification process could be drawn. The eight interviews revealed a distinct local organizing and sensemaking process, especially that of the local project management (and the local ED management, since managers were represented in the project management).

Semi-structured interviews were conducted in June and August 2012, according to an interview guide and centered upon three themes: (1) the subjects' role, the organization, and aspects concerning quality and safety work; (2) the certification process and its results; and (3) how ISO 9001 standard and certification was understood in relation to formal quality and safety regulations and management tools. Open questions were generally used, often followed by either preplanned or ad hoc probing questions, in order to help subjects to recall and tell more detailed stories about the ISO certification process and their experiences.

Analytical framework and process

Organized sensemaking is primarily a process theory. When conceptualized organized sensemaking can be treated as a sequence of "ecological change—enactment—selection [and]—retention [31]". *Ecological changes* in this context are treated as both intra- and inter-organizational environments. In the organizing process of *enactment*, people are shaped by environments and sense anomalies that are "…triggered by discrepancies and equivocality in ongoing projects, [and] *begin* to change the flux of circumstances into the orderliness of situations" [31]. *Selection* is a process of narrative reduction where possible meanings are reduced and generate a tentative and plausible story. In *retention* the plausible story is connected to past experience and fit with identity, and such makes a new script or cognitive frame that feeds back to the prior processes. In this case study we have applied the following analytical categories, modified, and adopted from Steyer et al. [48], that aims to emphasize the key elements in organized sensemaking processes [24, 31, 49] (See Fig. 2):

Frame (retention): Involves cognitive frames (retained plausible stories, such as acquired from work, training or life experiences) and formal frames (e.g., categories, plans, procedures, organizational structures, and artefacts). Frames are sources of guidance for interpretation and action.

Cue: Information or event extracted from the environment by actors. People ascribe meaning to cues by relating them to frames.

Table 1 Data sources—documents

Data source	Type of document	Year	Document title
Norwegian Board of Health Supervision - Office of the County Governor	Report	2007	Report from supervision of adequacy and quality in the emergency department in somatic specialist health service in xxx hospital
Norwegian Board of Health Supervision	Report	2008	"While we are waiting…."—do patients receive adequate treatment in accident and emergency units?
Regional Health Authority and Norwegian Accreditation	Project description	2008	Accreditation in emergency departments "… for good and equal health services"
Norwegian Accreditation Sector committee P14 Emergency departments	Report	2010	Report from the Norwegian Accreditation Sector Committee P-14 Emergency Departments
Norwegian Accreditation	Guidelines (including special or extended scope of requirements)	2010	NA Doc. 59 Guidelines of ISO 9001:2008 for Emergency Departments
Emergency Department	Minute	2010	Evaluation meeting about ISO certification of the emergency department 08.02.10.

Table 2 Data sources—interview subject profiles

Formal position	Role in the certification project	Formal education
Head of Department, ED	Leader of the local project group, and the local pilot projects (EDs) representative in the overall regional project organization	Intensive care nurse, Master of Management
Head of Section, ED	Member of the local project group	Intensive care nurse, Master of Management
Head of Unit-1, ED	Member of the local project group	Nurse, Ongoing (2012) Master of Management
Head of Unit-2, ED	Member of the local project group	Emergency care nurse
Quality Advisor, Quality and research department	Member of the local project group	Nurse, Master of Management, Quality studies
Project Leader, Regional Health Authority	Project leader in the overall regional project and focal point for the local pilot project in the emergency department	Nurse, Master of Health Administration, Quality studies
Head of quality and research department	Allocated personnel to the local certification project group	Unknown
Head of doctors, Department of internal medicine	Managed doctors working in the Department of internal medicine	Nurse

Discrepancy: Equivocality and discrepancies between cues, and between cues and frames. It gives an occasion to search for and reconsider a meaning. It is related to the question "same or different" [31]. When a situation feels different, it activates a search for meaning.

Concern: A tentative plausible story (e.g., an opportunity, problem, perceived uncertainty, issue, or controversy) that the individual or group pay attention to.

Action: Through action, people produce parts of their environment and are "making" what is sensed [24]. People also enact what has been made sense of back into the world. In this study the main actions are identified, while acknowledging the challenge of simultaneously identifying both action and cognition [48].

Our analytical process follows the principle of "narrative analysis" proposed by Polkinghorne [50], incorporating analytical features from Boje's [45] causality analysis in an antenarrative perspective. Our narrative follows the characteristics of a narrated plot [42, 45, 50], where beginning, middle, and ends of the story come into being. Such retrospective reconstruction often starts with the outcome as a starting point for *how* this event came about. In this case

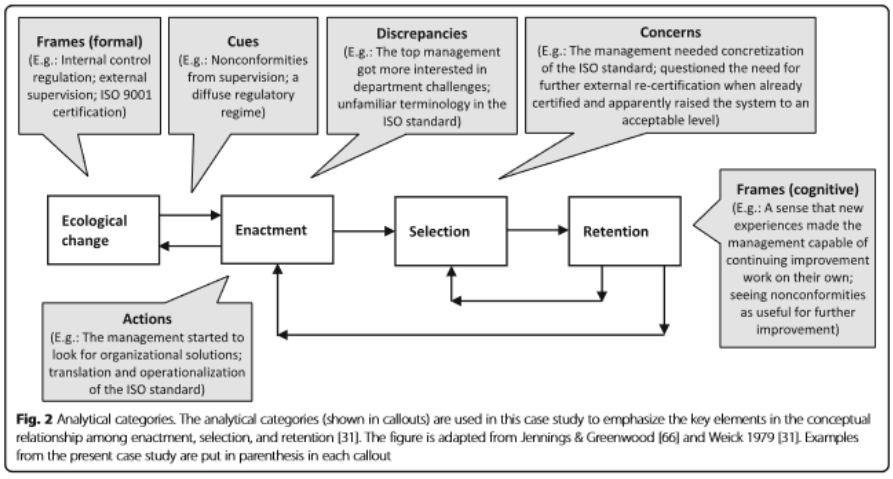

Fig. 2 Analytical categories. The analytical categories (shown in callouts) are used in this case study to emphasize the key elements in the conceptual relationship among enactment, selection, and retention [31]. The figure is adapted from Jennings & Greenwood [66] and Weick 1979 [31]. Examples from the present case study are put in parenthesis in each callout

study the guiding outcome was the ED's adoption of ISO 9001 certification. Our first analytical step was to arrange the data elements chronologically and construct a baseline story. The baseline story was modified in an ongoing process along with a repeated reading of the interviews. In our next step we identified elements that are contributors to action and outcome [50]. Here the baseline story was categories into our analytical framework (Fig. 2). Our final analytical step was an ongoing construction (writing, categorizing, and rewriting) of the narrative into a *temporally patterned whole* [50]. We have visualized in brackets the categorization in the final narrative presented in this paper, to make the analytical process more transparent. To ensure trustworthiness, the narrative, with its analytical categories, was sent by e-mail to six of the informants, who confirmed the narrative. Only slight changes in the narrative were done after the informants' responses.

Results

The story of change

The following story is presented in two stages. The first outlines the initial establishment of the external project that initiated the pilot process in the ED. The second narrates the intra-organizational sensemaking that contributed to continuity and change in favor of ISO 9001 certification.

Following up on unacceptable conditions in emergency departments

In 2007 the Norwegian Board of Health Supervision (NBHS) carried out a countrywide supervision of 27 out of 54 hospital emergency departments in Norway, and concluded that in general, there was a lack of management responsibility for ensuring that daily tasks were planned, organized, carried out, and improved in accordance with legislative requirements [51]. The NBHS described the situation as unacceptable and required the management to take action.

As a direct follow-up of this report the Norwegian Accreditation (NA)[2] and one Regional Health Authority (RHA) initiated a collaborative project. Its objective was to set a standard that EDs could use to ensure and improve internal control and management systems, and for accreditation or certification purposes [52]. A sector committee[3] including an administrative project organization, the regional project group (RPG), was established in the spring of 2008.

The sector committee was composed of representatives from all the RHA, NBHS, and other professional experts, and their work took place from August 2008 until March 2010. The new accreditation standard for EDs was supposed to concretize the generic requirements in the legal internal control regulation. The committee considered different management standards to build upon or implement, and decided on the *ISO 9001:2008 Quality Management System - requirements* standard, with its additional guidelines for use in health services [23]. The main reason was that the ISO 9001 was in compliance with the current Norwegian internal control regulation. Two ED was chosen as pilots for the project, in order to (1) identify core processes and risk areas to specify new requirements for EDs and (2) become ISO 9001 certified and meet the new requirements. One of the EDs ended the process before becoming certified, and the other, whose story is told in the next section, became certified in 2010 [53].

The initial phase

The ED had struggled for years with a heavy and challenging patient flow, and worked to improve the system without acceptable results [frame]. During this time there had been a change towards more attention to quality improvement and control, both through central, regional, and local initiatives. The RHA had become more explicit on requirements about, among others, waiting time for patients, patient safety, and prevention of infections [frame]. The ED was also in the middle of a rebuilding and merging process to take over the emergency functions from another hospital. The volume of patients was high, they were kept waiting, and there was not enough beds [concern].

The ED got two nonconformities from the countrywide supervision that required managerial follow-up. The first nonconformity pertained to the accumulation of patients that could lead to failure of treatment; the second was related to the examination conditions in the ED, which did not ensure adequate protection of confidentiality, patient integrity, and information exchange [cue]. The challenges in the ED were once again highlighted [cue] and the hospital top management became more involved in resolving these challenges [discrepancy]. The ED once again started to look for solutions and make efforts to improve patient flow [action].

Some months after the report from the NBHS, the hospital trusts in the RHA were asked to participate in the pilot project. The ED was then asked by their hospital CEO [cue]. The Head of Department had a quick consultation with middle managers in the ED, and the response was "Yes, let us jump on it" (Informant Y). They immediately decided to participate in the pilot [action]. Their expectation was to get the assistance to work systematically to resolve the challenges in the ED [concern].

The process in the ED started in autumn 2008. The first meeting was represented by people from the hospital who delivered services to the ED (e.g., physicians and the X-ray department) in addition to people from

the regional project group. The intention was to anchor the project with concern to those departments that delivered services to the ED, and not just the ED in isolation [concern]. Especially, the integration of physicians was considered important [concern]. The head of department was the hospitals representative in the RPG and was highly involved in the development of the new requirement for EDs during spring 2009. She also became a key actor and a primer for the local pilot throughout the project.

During spring 2009, the ED established a local project group (LPG) led by the head of department and three middle managers [action]. At that time they did not know what to expect, other than they would be assessing and describing processes, identification of system vulnerabilities, and implementation of relevant actions in the ED [discrepancy]. In any case, they immediately threw themselves into the work, starting to describe processes and identify vulnerabilities [action]. After a while they were made aware of [cue] that the pilot project would involve the use of the ISO 9001 standard [discrepancy]. Then they realized their need for local assistance about developing quality management systems [concern]. A quality adviser from the Quality and Research Department integrated in the LPG [action]. The main work on ISO 9001 certification began in the summer of 2009.

The standardization and certification phase: summer–autumn 2009

The LPG worked enthusiastically and intensively, especially in July and August 2009. Most of the group members worked extra to complete the work [action]. The rest of the employees in the ED were less involved, limiting their participation to some ad hoc working groups, such as those to establish and revise procedures. Even though the LPG had agreed that the main intention for the ED was to review their management systems [frame], there seemed to be a clear awareness among the LPG members that the hard work on standardization consisted of taking steps towards certification [concern]. They had an opportunity for external help with improvement work, and this extra focus [cue] seemed to generate actions and a desire to demonstrate that they now were able to succeed [concern].

> [I]t was a combination of several things. […] When the crisis is big, it's even more important to get things done. It's a motivation in itself to do something—that was important. We were selected from the Regional Health Authority to accomplish this—that was an important element. […] It turned out just like a competitive element, just like: 'This is something we can master'. Clearly, much was done before the certification body came in. We had been working very much; however, they did the last part in order to push us all the way to the end. (Informant Z)

None of the LPG members had experiences [frame] with ISO 9001 standardization and certification processes [discrepancy], except for one member of the quality department, who became an important "translator" [cue] of the ISO standard during the pilot project. The standard needed contextual adaptations to be legitimated in the ED [concern]. Terms like risk assessments, measuring, monitoring, and recording are obvious concepts and parts of an ISO quality management systems, but it was an unfamiliar terminology for the LPG [discrepancy]. The additional ED requirements developed during the project became important concretizations of the ISO 9001 standard and the internal control regulations. It generated a contextual translation [cue] of rather general requirements [discrepancy] and so ordinated a meaningful operationalization in the ED [action]. As "newcomers" [frame], the LPG needed concretization [concern].

The LPG referred favorably to the certification body. In the first phase of preparing the ED for the initial onsite document review, there was a large amount of e-mail between the ED and the certification body. The hospital received much advice and help on how to improve the organization [cue]. The auditors were considered very detailed, sometimes almost too much [discrepancy], especially during document reviews and the certification audit. At the same time the auditors created confidence with their detailed knowledge and ability to identify salient points and ask questions about the documents and systems [cue]. They also transferred experiences from other organizations and brought expert knowledge on systems and change processes. The LPG experienced the certification process more as guidance than as control [discrepancy].

It was a turning point for the LPG when they received feedback from the certification body and gained experience from the standardization process itself [cue] that changed their understanding of systems that they had considered well-functioning: "things that we took for granted" (Informant Y), but were not good enough [discrepancy]. They started working differently with their systems [action] which generated an improved overview of their organization and tasks [cue], the number of procedures was reduced considerably [cue], and explicit objectives for improvement was created [cue]. The latter was a shift from describing objectives in general concerns, like "we should be better at…" to develop measurable objectives that could be monitored. The entire improvement and certification process [action] was considered as an important help [frame].

The initial countrywide supervision pinpointed the responsibility of other professions, especially physicians, to hold them accountable for the challenges in the ED [cue]. The emphasis on creating descriptions and visualization of core processes in the ED [action] made the department more visible and the process was considered a key to the shared understanding and commitment among leaders in other departments [cue]. The certification body drove this accountability concern further, and mutual contracts with "service" departments (including physicians) was a requirement for certification [cue]. "A milestone could be seen when agreements with other heads of departments became evident" (Informant X).

There were some worries among the employees in the ED about the perceived absence of management [cue], but the LPG did not enact any significant opposition either inside or outside the ED [cue]. The fact that the ED was a part of the pilot project and was supposed to [frame] organize for and deliver a service that was certifiable [discrepancy] was regarded as an important driver, not just for the LPG but also for other professions outside the ED that participated in working groups. It seemed that "no one" would contribute to the failure of a certification status, especially since it was decided at the top of the organization and as a direct follow-up of the external supervision [concern].

> [T]he symbolic perspective of certification is just as prominent as the rational. I believe that, and that's my conclusion. Much of the things that we initiate are like that. Symbolic perspectives should not be underestimated (Informant Z).

After following up on the nonconformities that were given during the certification audit, the ED finally received its first ISO 9001 certificate in January 2010.

The time after: winter 2010–summer 2012

According to the managers and the LPG, the ISO certification process generated improvement of the management system; however, a direct impact on patient treatment was hard to demonstrate [frame]. ISO 9001 was considered as a managerial tool [frame]. When the revised management system was contrasted with the situation before certification, it illustrated both positive practical implications and improved daily organizing of the ED [frame]. The ED management started talking differently about quality improvement, and used terms and explanations that had originated from the standardization and certification process [action]. They were proud of their achievement and gladly shared their material and experiences. The ISO standard and the additional requirements for EDs were not considered the optimum way of organizing, but it was treated as one way, among many others, that generated system improvement [frame]:

> [T]he fact that we are ISO-certified—as I say: We have put some things in place; it is easier to find, easier to breathe, you don't need to doubt, you don't have to look; it is helping to create those secure frames. So that those who work within these frames are given the opportunity to flourish in the face of the patient. (Informant W)

Even though the LPG considered the certification process to imply system improvement [frame], they did not expect that the employees would perceive quality improvements, or associate system changes with the ISO certification [concern], since the certification process did not really affect the daily operations and patient treatment. At least two other quality improvement initiatives (triage and nurses' continuing education) were initiated in parallel with the certification process, and these were considered to have more positive association with improved treatment quality compared to the ISO certification [cue].

The ED underwent two yearly surveillance audits[4] conducted by the certification body after the initial certification audit. These external assessments were considered important for sustainability of quality improvement [cue], even though the management understood that quality improvement should be part of everyday practice [discrepancy]. Whether these audits needed to be performed by a third-party certification body was not considered of major importance, and neither was the importance of the certificate in itself [Frame].

The ED management started to question the need for further use of an external certification body [concern]. These concerns were based on (1) negative experiences from the latest surveillance audit, where a new team from the certification body conducted the audit [discrepancy], (2) the costs and resources spent [frame], and (3) having brought their quality management system to an acceptable level. The ED management had generated knowledge that enabled the ED to perform ongoing system improvements on its own [frame]. However, some sort of external audit was considered necessary [concern]. Internal audits performed by the quality department in the hospital was in theory considered equal with external audits, but in practice the external audits (e.g., by a certification body, NBHS, or the RHA) had stronger impact and triggered more managerial action than internal audits [discrepancy]. Managers from the LPG changed their perspective on audits, from seeing them as a way of controlling organizations to something useful for sustainable improvement [frame]. They started

asking for internal audits and acknowledged the possibility of letting someone outside the department assess their systems and give feedback [action]. Nonconformities were used as means for further improvement [frame].

> [F]or the last couple of years we have requested audits, when there are things we are questioning. [...] It's not so frightening anymore, and we see that it's very useful for us. That I think is a result of the process. We are not so afraid of getting nonconformities, and see that these [nonconformities] are things that we can work on. (Informant V)

Discussion

As a result of the countrywide supervision, the Norwegian EDs were turned inside out in ways that made it obvious to ask whether it was safe to be a patient there. The turbulence did not lead to additional formal national inquiries or major policy changes that we have seen from turbulence or health care crises in other countries [54], but it was thoughtless disruption or turbulence that was a powerful occasion for organizational change [26]. The story of the adoption of an unfamiliar set of organizational requirements (ISO 9001), that had a quite circumstantial influence on the local ED management, fits at first glance into the picture of sensemaking, where action and interpretation rather than evaluation on choice were present in the first face of the adoption process. A quick decision to become part of the pilot project was taken in the face of longstanding challenges in the ED related to patient flow and management systems. These challenges had become a frame of reference for the management, and different initiatives to resolve them had become discrepancies between what had been expected and the reality. It was not a surprise or a shock that prompted sensemaking, but ongoing discrepancies as circumstances great enough to expect people to ask for what is going on, and what should they do next. This situation challenged the management's social and shared identity [24, 26, 31], as they were responsible for the quality and safe running of the ED. Such an internal turbulent environment can in itself be treated as a trigger for managers' engagement in sensemaking towards that specific challenge or threat [55]. The importance here is how the external environment triggered sensemaking processes that initiated the adoption, continuation, and change in favor of ISO 9001 certification and additional standards. Four external triggers are identified. The first two external triggers (nonconformities and regional certification project participation) were situational-specific and present initially in the process. The last two triggers are institutional in nature [25], derived from perceived ambiguities in relative stable institutional structures (the current internal control regulation and the ISO 9001 certification). These ambiguities triggered sensemaking processes around continuity and change (the organizing processes) towards internal control systems and certification.

Situational triggers

The first trigger relates to the nonconformities from the countrywide ED supervision. For the ED management, the nonconformities did not cause disruption, but rather verification of known challenges. What they now perceived as different from earlier (a discrepancy), was the increased focus upon these known challenges and turbulence from the hospital's top management. Treated institutionally, such an increased focus can be explained by demands to follow up on nonconformities through institutional coercion [56, 57] or regulatory enforcement [58]. But in the sense that these onsite supervisions are ad hoc initiatives, most often with years in between, they also have the potential to cause careless disruption or surprises for organizations that can offer strong occasions for sensemaking. Basically, it can be an interruption produced by new and unexpected circumstances [24]. This seems to be true in this case study, where the received nonconformities made known challenges "visible" [59] for other parts of the organization and especially the top management, and so triggered further actions for control and accountability.

The second trigger relates to the way in which external possibilities for assistance and support led to "quick" action and interpretation. The ED management's uncertainty about proper solutions threatened their social identity. The external possibilities for support prompted almost immediate action. Organizational uncertainty can be seen as a form of ignorance or an inability to extrapolate current actions and therefore foresee future consequences [24]. Such occasions lead people to construct processes of sensemaking to reduce that ignorance. Plausibility and belief about current action, rather than accuracy about the future, are salient in such sensemaking processes. Early available sources and information that gave some sort of plausible directions for the ED, replaced uncertainty about the future, with more certainty about the present, and as such made it possible to continue. The shared belief among the ED management prompt action, rather than change resistance, that often are seen in organizational change when identity is challenged due to identity replacement, updating, or transformation [26, 55].

Institutional triggers

The third trigger relates to institutional structures in the current internal control regulation. Adoption of internal

control system has shown to be a challenging task in health care [60], and the ED did not have a system that was clearly built up around a fulfillment of these regulatory requirements. Finding solutions to operationalize these requirements was inherent in the pilot project. The LPG's work on concretizing the requirements and developing additional requirements for EDs set in motion important sensemaking processes about the internal control regulation. The internal control system is founded in a functional legislation [34, 61] with a wide scope and possibilities for organizations to choose among a variety of tools for quality and safety work [62]. It is a form of soft regulation that can be (too) diffuse and therefore trigger organizations' search for control [28, 30]. It becomes a question of transparency and accountability [59], not just in the eyes of external actors, but for the organizations themselves. Because making things transparent is not just about documenting and open the "curtains" for direct insight, it is also about adopting new technologies that make organizational performance visible [59]. The process of concretizing the requirements in the internal control regulation that the LPG performed was such a necessary visualization that gave meaning to their own system and processes [32]. When analyzed from the perspective of Weber and Glynn's [25] institutional trigger mechanism, we see that the stable institutional structure inherent in the regulatory system became ambiguous for the LPG and trigged further sensemaking that made organizing possible. These findings support other research arguing that a lack of competence on developing internal control systems makes it difficult to adapt to the internal control regulation in Norway [60].

The fourth trigger relates to the institution of ISO 9001 certification. The present case study shows that the ISO 9001 standard consisted of general and unfamiliar concepts and systems that triggered the LPG to find ways to translate and contextualize these ambiguities, in their efforts to make sense of the standard. Seeing the ISO standard as a trigger relates to the same institutional triggering mechanism as for the third trigger. What is different about the institution of ISO 9001 certification is that it involves auditing process performed by external auditors, and therefore integrates direct feedback mechanisms that are interlinked with sensegiving perspectives [31, 63] or mechanisms on how institutions edit sensemaking [25]. Auditors control, negotiate, and guide during their interactions with the organizations, and those tasks give auditors room for different interpretations and conducts of their same auditing role. Concerns about interaction are important, because research on accreditation shows that when health professionals are given the opportunity to participate in assessment contexts that are collaborative and supportive, it can self-reinforce a collaborative quality and safety culture [64]. These considerations on the auditor–auditee encounter may also underpin our present findings where there was a perceived discrepancy between the conduct of the first audit team (performing both the initial certification audit and the first surveillance audit the first year) and the conduct of the last surveillance audit team the second year. The first team was perceived by the LPG to have real impact upon the standardization and improvement work in the ED. The conduct of the second team was so different that it made the ED management question the reliability of the certification process and the meaning of renewing their certificate.

A recent study [65] on stakeholder perspectives identified four factors that seemed important to increase the likelihood of a successful implementation of accreditation: (1) the program is collaborative and valid and uses relevant standards; (2) that accreditation is favorably received by health professionals; (3) that healthcare organizations are capable of embracing accreditation; (4) and that accreditation is appropriately aligned with other regulatory initiatives and supported by incentives. These findings highlight external regulatory structures and intra-organizational factors that seem to be in line with findings on triggers and organizing perspectives related to certification in our study.

Limitations

This single-case study is limited to meaning making processes within a single emergency department in a single hospital in Norway. The small sample is a clear limitation of generalization from this study.

Conclusions

Certification and accreditation are widely used for quality and safety in health care but also questioned in respect to their assumed effects. This is a challenge for policymakers since these regimes can have a circumstantial impact upon different parts of the organization. The present case study shows that the adoption of the ISO 9001 certification in an emergency department was not led by a comprehensive decision-making process. It shows that an exogenous disruption visualized long-standing organizational challenges that threatened the managements shared identity. Again a search for meaning became prominent. The occasional possibility for help through an external standardization and certification project was a plausible solution that led to immediate action, and reduced uncertainty. Further, the case study shows that the relative stable institutional requirements that are inherent in the internal control regulation and the certification standard were unfamiliar and ambiguous and therefore triggered local sensemaking processes for a contextualization of these regulations

and standards, which made the continuation and change possible. It also led to the acknowledgment of external assessments or audits in general as useful for improvement work.

When considering implications for further theory development, we see that the institutional trigger mechanism in Weber and Glyns' [25] framework contributes to explaining the occasion for sensemaking. There is a need for more research that can refine this institutional mechanism (in addition to institutional constraints) and inform explanations of why some regulatory institutions give rise to (trigger) adoption of different modern management tools (e.g., certification or accreditation). These considerations are important, because when organizations adopt new management tools, they seldom abandon others. This can lead to even more complex health care.

Endnotes

[1]Governance in this perspective refers more to the neoliberal approaches inspired by rational choice theories and governance as networks within the institutional tradition, than to a decentered theory of governance underpinned by postfoundational philosophy and democratic stands [67].

[2]Norwegian Accreditation (NA) is the Norwegian body for accreditation of laboratories and sampling organizations, certification bodies, inspection bodies, and environmental verifiers. NA represents Norway on three European and international bodies—the European cooperation for Accreditation, the International Laboratory Accreditation Cooperation and the International Accreditation Forum. NA is also the Norwegian monitoring body for Good Laboratory Practice (GLP) inspections, according to OECD's GLP principles (http://www.akkreditert.no/en/om-oss/, accessed 12. February 2014).

[3]Norwegian Accreditation establishes different sector committees, often broadly represented, when the aim is to establish a new standard on a new domain or sector.

[4]Surveillance audit is a yearly onsite audit so that the certification body can maintain confidence that the certified management system continues to fulfill requirements between (re-)certification and re-certification [21].

Abbreviations

ED: Emergency department; ISO: International Organization for Standardization; LPG: Local project group; NBHS: Norwegian Board of Health Supervision; RHA: Regional Health Authorities; RPG: Regional project group

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Availability of data and materials

The data generated and analyzed during this study are not publicly available due to concerns about confidentiality regarding a small sample size and the sensitive nature of the interviews. Instead, quotations and analytical categories are included in the text. We are happy to discuss the findings or the analysis if any questions should arise.

Authors' contributions

DTSJ was responsible for the conception and design of the study and undertook acquisition of data as well as analysis and interpretation of data. SW was consulted during the analysis, and interpretation process. DTSJ led the drafting of the manuscript. DTSJ and SW were both involved in critically revising the manuscript for important intellectual content and both read and approved the final manuscript.

Ethics approval and consent to participate

The research was performed with the ethical approval of the Norwegian Social Science Data Services (December 16, 2011, Ref. 27543). A clearance for staff interviews was obtained from the hospital prior to data collection. Informants first got a written invitation to participate at its inception and then a written and oral invitation prior to the commencement of recording. The invitation explained that the interview was part of a research project, that the results would be used anonymously for analysis and publication, and that participation was voluntary and could be terminated at any time. All informants provided oral consent.

Consent for publication

Our manuscript does not contain any individually identifiable person's data. All informants have got the opportunity to read and respond to a late draft of the manuscript, including quotes, before submission.

Competing interests

The authors declare that they have no competing interests.

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Article II

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Exploring hospital certification processes from the certification body's perspective - a qualitative study

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Abstract

Background: Hospital certification is an external assessment mechanism to assure quality and safety systems. Auditors representing the certification body play a key role in certification processes, as they perform the assessment activities and interact with the involved healthcare organizations. There is limited knowledge about the approaches and methods that auditors use, such as role repertoire, conduct, and assessment practice. The purpose of this study was to explore auditors' practice in hospital certification processes, guided by the following research questions: What styles do auditors apply in hospital certification processes, and how do auditors perceive their role in hospital certification processes?

Methods: The study was performed in two stages. In the first stage, non-participant observations (59 h) were conducted, to explore the professional practice of three lead auditors in certification processes of Norwegian hospitals. In the second stage, semi-structured interviews were conducted with these three observed lead auditors. The role repertoires and conducts identified were analyzed by using a deductive approach according to a surveyor (equivalent with auditor) styles typology framework.

Results: Two distinct auditor styles ("explorer" and "discusser") were identified among the three studied auditors. Both styles were characterized by their preference for an opportunistic and less structured type of interview practice during certification audits. All three auditors embedded a guiding approach (reflections about findings, stimulate improvements, experience transfer from other industries) to their perception and practice of certification audits, interacting with the auditees. The use of group interviews instead of individual interviews during certification audits, was the rule of their professional practice.

Conclusion: The auditors' perceptions and styles demonstrated a multifaceted certification reality, in contrast to what is often presumed as consistent, stringent and independent practices. These findings may have implications for reliability judgements when developing hospital certification programs, and for the refinement of the current framework used here to study the different auditing practices.

Keywords: Certification, ISO 9001, Auditor, Surveyor, External assessment

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Background

ISO (International Organization for Standardization) 9001 Certification is used for external assessment of quality and safety systems in health care. It is often associated with accreditation and other external assessment programs for health care organizations [1–6]. In these programs, external assessment bodies collect evidence to assess whether organizational systems and performances are following recognized standards and most often provide a certificate on successful compliance with the standard. In addition, many programs intend to add value and support improvement in organizations. Auditors, equivalent with surveyors, inspectors, assessors, evaluators, or visitors in other programs [6–8], are key to certification, as they perform the assessments and interact with the involved healthcare organizations. In ISO 9001 certification, auditors assess conformity to requirements for quality management systems, and as with most other external assessment strategies their main methods to collect information include interaction with the certified organization through interviews, observations, and review of documentation and records [9, 10].

Concerns have been raised related to arguments of scarce evidence of the benefits from external assessment programs, and the wide use and amount of resources that healthcare services allocate to these programs [11–14]. There are contrasting views about accreditation programs among health care professionals. Some view these programs as effective for development of organizational processes and patient safety, while others have concerns about the bureaucratic burden, the financial and human resources that are required, and the efforts to meet a large number of standards [15]. There is scarce evidence of the impact of care outcome measures [13, 16]. However, previous research has documented how accreditation has potential impact on organizational processes, changes in professional practice, and cultural change concerned with quality of care [17–19] and that certification and accreditation may be better than no external assessment when associated to hospital outputs and quality and safety structures [3, 20]. Furthermore, previous research has demonstrated that hospital accreditation and ISO 9001 certification were not significantly associated with evidence-based clinical care, but had significant benefits to patient safety systems and processes, such as clinical leadership and clinical review [21]. Other studies showed how admission to a fully accredited hospitals can be associated with a lower 30-day mortality risk compared to admission at partially accredited hospitals [22] and that a frequent accreditation cycle may have positive impact on maintaining hospital quality [23].

Despite growing evidence of the effects from certification and accreditation in healthcare, little is known about practices and mechanisms involved in the interactional processes between assessment bodies and healthcare organizations in external assessments. In external assessments systems, such as ISO certification, the auditors' experience, selection of auditors, training, support and motivation may influence the performance, style, and reliability of the auditing (assessment) practices [6, 8, 24–26]. The approach and methods that auditors use in their assessments and verification processes, such as role repertoire, auditor's conduct (e.g., inspection or guidance) and assessment practice need further exploration [15, 25, 27–29]. Exploring these matters may identify elements that can be beneficial for training, development and consistency of certification programs both within and between certification bodies, and for further research. For healthcare organizations and policy makers it may benefit from the transparency and insight into these widely used means, often involving for-profit certification bodies, to monitor, assure and improve performance in healthcare. Transparency and insight make it possible to better judge for what grounds certification decisions are made, and for fairness, and reliability. Insight into auditing practices is also important in order to meet requests for more flexible and context dependent external evaluation programs that are relevant for future changes in healthcare and to meet demands for user involvement [30].

The purpose of this study was to explore the audit practice as perceived and performed by auditors in one certification body involved in hospital certification processes in Norway. The following two research questions guided this study: (i) What styles do auditors apply in hospital certification processes, and (ii) how do auditors perceive their role in hospital certification processes?

By exploring the ways in which auditors perceive and perform their role in three hospital certification processes this study contributes with valuable insights into the practices and approaches of a for-profit certification body that often can be challenging to get access to. The exploration reveals different role repertoires and professional conduct among the auditors from the certification body. We discuss how this influences further research and development of future certification processes, and highlight the implications for policy makers.

ISO 9001 certification: the normative framework and the certification process

ISO 9001 quality management system certification is a third-party conformity assessment (audit) against requirements in the international standard ISO 9001 *Quality Management Standard – Requirements* [31, 32]. In health care, ISO 9001 certification is applied to entire organizations and to their individual departments. The requirements for certification bodies and their auditors are stipulated in the international standard ISO/IEC 17021 *Conformity assessment -- Requirements for bodies*

providing audits and certification of management systems [9, 33, 34]. The standard intends to ensure that certification bodies operate management system certification in a competent, consistent and impartial manner, and "the overall aim of certification is to give confidence to all parties that a management system fulfills specified requirements" [34]. The standard emphasizes consistency both in audit program processes and in the reporting of results, and certification decisions should be based on objective evidence. Impartiality is described as a necessity for certifications that instills confidence [34, 35], and the management and control of impartiality are required for certification bodies. The normative standard for third-party conformity assessments is underpinned by the guiding principles in the generic guidelines for auditing management systems [36].

An audit program has a three-year audit cycle: initial certification, surveillance audits in the first and second years, and re-certification in the third. The on-site audit activities include an opening meeting to introduce the audit team, confirm the audit plan and scope, and to verify the procedures and communication that are used during the audit. The next phase is to collect and verify information pertinent to the audit objectives, scope and criteria and prepare audit conclusions. Methods of collecting information include interviews, observation of processes and activities, and review of documentation and records. The ISO standards presents interviews as one of the main methods to collect information, but do not describe the method in detail or explicitly refer to one respondent interviews or suggest group interviews [9, 10, 34, 36]; nor do the guidelines that recommend good practices for all elements of conformity assessment [37]. Finally, the audit team holds a closing meeting to present and discuss conclusions and non-conformities and agree on follow-up actions.

Auditor typology framework

Several typologies explain regulatory institutional practice in the regulator-regulatee encounter, like characteristics of the regulated organizations [38]; regulator's perception [39]; inspector's inconsistency [40]; and types of relational signals [41]. In this study, we apply a typology framework developed from research on auditors in health care accreditation in Australia [24] to explore and analyze the styles that auditors in ISO certification apply. The framework was developed from observations on how a team of three auditors undertook their auditing practice in a small health organization providing general and specialist medical and surgical services [24]. The researchers' observations focused on assessing against the standard, education for improvement, and learning for transfer of knowledge to others. Based on the observed differences in the auditors' interview practice, three distinct styles were identified: *interrogator*, *explorer* and *discusser*, and one hypothesized style: *questioner*. These styles were categorized within two dimensions (see Fig. 1): questioning (structured vs. opportunistic), and recording (explicit: written vs. implicit: memory).

The interrogator

The auditor conducts interviews in a formal and structured question-and-answer manner, and the answers are systematically recorded as she/he proceeds. Questions may be prepared in advance based on the standard. The interrogator had sporadically short periods of opportunistic questioning as approached by *explorer*.

The explorer

The explorer conducts a more opportunistic interview. The explorer begins with open-ended questions, and takes unstructured notes. This auditor typically comments about what she/he has learnt and can use elsewhere. The explorer is less inclined to engage in the educational component of audits.

The discusser

The discusser prefers a more interactive interview that is like a discussion. All the three elements -- assessment, education, and learning -- are implicitly a part of the discussion. The discusser took unstructured notes, like the *explorer*, after the interviews.

The hypothesized questioner

The questioner conducts a structured interview. The recordings are conducted implicitly, making this kind of interview seem less formal than the interrogator's.

Methods

Design

The study was a qualitative explorative single case study [42] of a certification body interacting in certification processes in hospitals in Norway. The case study had three embedded units of analysis consisting of three lead auditors from the same certification body that performed certification audits in three different hospital organizations. We explored how the auditors conducted and perceived their certification processes.

Data sources and collection

Data collection was performed in two stages (see Table 1) from autumn 2012 until spring 2013. First, we explored the different role repertoires and professional conduct among three lead auditors from the same certification body by conducting non-participant observations in third-party conformity assessments (certification audit) and then semi-structured interviews were conducted with the same lead auditors. The three auditors were

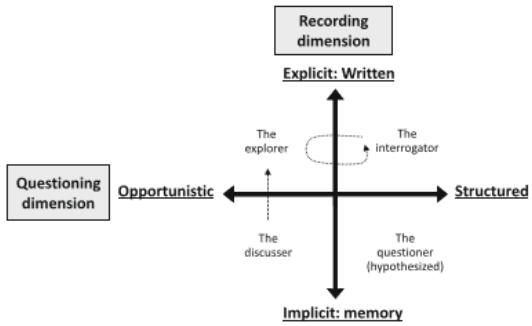

Fig. 1 Auditor style typology adopted from Greenfield, Braithwaite & Pawsey [24] with permission. The arrows show that the interrogator sporadically used opportunistic questioning, and that the discusser took unstructured notes after the interviews

purposefully selected from one certification body in Norway. The certification body was one of four certification bodies in Norway that were approved by accreditation[1] to perform external third-party conformity assessments and certifications of hospitals according to the ISO 9001:2008 standard.

Stage 1: The first author conducted about 59 h of non-participant observation in three separate certification processes according to the *ISO 9001:2008 Quality management systems – requirements* revision of the standard. The first author followed three audit teams, all from the same certification body. The certification body received a written and oral invitation to participate in the study prior to observations and interviews. The certification body further identified the three auditors and was the first to ask them to participate in the study. The first author followed the lead auditors through all on-site audits, and usually sat at the table with those involved in the audit during the audit interviews. All notes were taken openly, and the observations focused on the conduct of the lead auditors (team leaders) during their interviews and conversations (review process) with representatives from the organization under certification. The two dimensions in the auditor style typology -- questioning and recording -- guided the observations and note taking. The observations did not focus on the auditors' on-site walk-arounds, where they had informal talks with different hospital staff and reviewed physical processes and activities in the hospital.

Stage 2: Some weeks later, semi-structured interviews [43] were conducted with all three lead auditors who had been observed. The first author conducted the interviews. Each interview lasted from 45 to 75 min. The interview guide centered around three main issues: First, the interview subjects' role and the certification body's approach to ISO 9001 certification; second, the certification processes; and third, ISO 9001 certification and its relationship to the health care regulation. Open questions were generally used, followed by either preplanned or ad hoc probing questions, in order to help interview subjects to recall and tell more detailed stories. All interviews were tape recorded and transcribed verbatim.

Setting and participants for observations

The first and second observations took place in organizations that were changing certification body and were therefore undergoing a full review in order to become re-certified. Hence, it was the first time for the lead auditors to survey these organizations. The first survey was performed in a clinic for internal service. The second survey took place in a hospital where the objective was to certify the whole hospital. Many of the departments within this hospital were already ISO 9001 certified by another certification body, and were included in the overall certification process. The survey was performed as an on-site document review, whose objective was to review the management system documents and records, and their adequacy in terms of the requirements in the ISO standard. This assessment differed from the others in our study as it did not include an on-site observation of activities and the work environment. On-site observation was planned at a later stage. The third survey was conducted in an emergency department with a three-year certification history, and was now part of a re-certification process.

Personnel from the organizations present during the interviews were managers, management representatives,

[1]By the national recognized accreditation body Norsk Akkreditering, which verified the certification body's independence and competence to carry out the certification process.

Table 1 Data Collection and Sources

	Data collection	Auditors	Location/ organization	Duration
1. stage	Non-participant observations of three separate conformity assessments (ISO 9001:2008 certifications)	Auditor 1: lead auditor (in training)	Clinic for internal service	2 days (about 15 h.)
		Auditor 2: lead auditor (5–10 years auditor experience)	Full hospital	3 days (about 22 h.)
		Auditor 3: lead auditor (independent subcontractor, > 20 years auditor experience)	Emergency department	3 days (about 22 h.)
2. stage	Semi-structured interviews	Auditors 1, 2 and 3	Auditors 1 and 3: The central office of the certification body Auditor 2: By telephone	45–75 min per interview

and staff responsible for following up the organizations' management systems. Technical expert auditors were present for the assessments of specialized departments, such as those responsible for technical equipment, cleaning or medical specialties.

Analysis

All of the data material from the observational field notes and the transcribed interviews was subjected to theoretical (deductive) thematic analysis [44, 45] of each of the three auditors. The two dimensions in the auditor style typology [24] – questioning ((a) structured vs. (b) opportunistic), and recording ((c) explicit: written vs. (d) implicit: memory)– were employed as predefined themes to categories data from the observations, in order to identify the auditors' conduct that matched or contradicted with the auditor styles in the framework. Further, data from the observations were explored according to the predefined themes related to the opposites between (e) assessing conformity against requirements, focusing on retrospective auditing practices (inspect, control), and/or (f) quality improvement work, focusing on prospective auditing practices (guidance, educate, transfer experiences, give advice). The same themes were used to analyze data from interviews in order to reveal the auditors perception of their auditing approach. NVivo 10 was used to explore and thematically analyze the interview data. Data from the interviews were then related to data from the observations, and compared in a reflexive manner to explore whether the auditing style and conduct as observed were concurrent with the auditors perceived approach. The analysis was conducted for each auditor, in order to highlight the identified auditing styles and the themes emphasized in perceptions and practices, before we compared the themes in the analytical framework across auditors to illustrate commonalities and differences.

To ensure trustworthiness in the analysis we conducted member checks by sending a draft of the paper to all three auditors. The auditors were able to comment if they recognized the description of themselves, the use of data and clarify misinterpretations of facts and figures. One auditor gave her response by phone, another responded both by phone and e-mail, and the last by e-mail. Only minor changes to the draft was made after the member check.

Results

In the following section, findings from the three auditors are presented. For each auditor, we present his or her perception of how he or she approached the audit interview situation; then we present the observation findings from the audit interview; further, we present what the auditors perceived as their main tasks according to the dimensions of assessing conformity or stimulating improvement; and finally, summarize and compare the auditors' style and perceived auditing approach.

The explorer: auditor 1

The auditor cited dialogue in her auditor-auditee encounter as an important means of collecting information and for stimulating and guiding improvement. As part of that audit dialogue, she asked deeper questions to collect additional information:

> It's part of that dialogue. First you check out: "How do you do it?" Get a clear view of that. Then you ask if they actually experience that their approach is appropriate. What actually do work, the way they do it, and what do not. And based on that you will say: I have seen others who have a slightly different approach, so perhaps we can adjust a little bit. [...] [T] hey follow the book since they fulfill the minimum requirements, but should they, when they have those [the requirements] in place, consider

whether they can get more out of that arena. (Auditor 1).

During the on-site assessment in the clinic for internal services, the auditor performed all her interviews with groups of staff from the different departments. The groups never had fewer than four people. The respondents were usually a manager or middle manager, the hospital's contact person/quality manager, and one or two others "relevant personnel" (the term used in the agenda) from the departments under assessment. All interviews were held in the same room. The auditor used a template to highlight the main requirements in the ISO 9001 standard against which she assessed conformity, and to structure the progress during the interview. The auditor recorded what was said, either in her notebook or on the template sheet. A projector was used in most of the interviews to review and discuss documents and recordings, like policies, objectives, plans and procedures. The auditor usually started with an open-ended question, such as "Can you tell me about the management system?" She invited a conversation about the topic, or had the respondents explain documents on the screen. If the respondents mentioned something that caught her interest, she either asked for verification or a probing question. An example was observed when the auditor asked the auditee about the control of errors and non-conformities. A vague answer from the respondents led her to ask for more explicit documentation, and to see examples of how they correct errors and non-conformities. She directed most of her questions to all the respondents in the room, and was usually answered by the manager (often a middle manager) who was responsible for that topic. The others (often one or two employees from the department and the hospital's contact person/quality manager) followed up if the manager seemed to have left something out of the answer.

According to Auditor 1's perception her main task was to bring added value to the organization. This was not just related to the general understanding of the expected added value from third-party certification (e.g., increased legitimacy), but also to organizational development as part of the certification process. Again, the auditor opened a dialogue.

> When we are out, they want us to create added value for the customer, and help the customer to become better at managing risks in relation to their core areas. […] Moreover, in my decision-making process I will then review and ask, in a dialogue with the customer: "What do you see as challenging?"; "Where do you think the problems lie?"; That's just as important …, that dialogue is very important. (Auditor 1).

The perception of improvement was emphasized when auditor 1 described her approach within the inspection-guidance axis. She perceived concern over the balance of not adopting a consultancy approach.

> You largely control, but at the same time you're also a guide. I do not think it is possible to see them isolated. So, you control in the sense that you can kind of check out if things are in place - yes or no. However, since improvement is as central as it is, then together with the customer, in that dialogue, it is to identify things where one in advantage might take small steps to raise oneself further ahead. That becomes the guidance role. I think they go like hand in glove. At the same time, it is important in that guidance role, that you do not give very clear recipes on how things should be done. (Auditor 1).

The explorer: auditor 2

The next auditor stressed the importance of asking questions to elicit information that was needed for the audit. She also perceived her manner of asking questions as an explorative encounter, where the intention was to foster self-reflection.

> The most important tool is to ask question, and then to be shown what you have requested. Maybe they do have it, maybe they don't. And then use what comes to the table in the best possible manner. We may not always follow the preplanned agenda, because one sees that there are strengths in some areas, or weaknesses in other areas where you need to go in-depth. Because, that's what gives results, getting to the core, and perhaps especially the way one asks questions, so that they themselves see it. It should be themselves who sees it- those are the best audits. When they get a wake-up-call that make them see that this is useful, and they see where they can get better. (Auditor 2).

In her interview strategy, auditor 2 perceived it as important that the respondents were informed, knew the purpose of the session, and felt safe during the audit interview:

> Moreover, it is often appropriate that they are not alone, but that there are two, three of them, so they can ask each other. […] If there are several findings of nonconformity they can feel unfortunate, and think that if someone else had answered maybe it would have been different. They try to represent the

> organization and they want to be good. That's what we all want to. (Auditor 2).

During her three-day document review of the hospital's quality management system, the auditor always performed the interview with at least two people from each department, often a manager and a staff member who was involved in quality development in the department. Observations showed that she used a template to guide the interview, but unlike the first auditor she sporadically recorded what she heard and observed. She used a projector during the interviews to review and discuss documents and recordings, like policies, objectives, plans and procedures. Like the first auditor she also often started with an open question when shifting to a new topic. A significant difference from the first auditor was that the second auditor often raised questions about solutions and self-reflection, especially when she observed potential improvements or non-conformities, like "What is a challenge here?" "How and where would a nurse look for this procedure?" If respondents asked for feedback or suggestions about their management systems, the response was often "What is useful for you?" These answers encouraged reflections instead of giving direct suggestions or advice, and also indicated the importance of quality systems as useful and not for the systems in itself. When interviewing the top management, the auditor seemed to base her arguments upon the logic of the quality management standard, as when she was interviewing the top management, represented by the managing director, the vice managing director and the management representative. The observations showed that vice managing director entered in a hurry and asked if it was necessary for him to participate. He agreed to "take part in the beginning" after getting a very short explanation of the objectives for the meeting. The auditor went through the organization's quality policy, quality objectives, management review and the like in a dialogue-based approach with the respondents, often referring to, and explaining requirements in the ISO standard. The vice managing director turned out to be the most engaged in the whole meeting, and stated that the ISO 9001 management system approach visualized challenges that clearly had improvement potential.

The auditor perceived verification to be her most important task, which entailed to assess if there was consistency between the systems organizations have and the practices they perform, and to look for improvement and what works well. Her focus on improvement and the certification process was also perceived as valuable from her perspective:

> Then it's about getting a review of the system. What we are talking about …; I can see that awareness, learning, and systematic improvement is helpful for them, because they use their own material to understand these aspects within a context. This is what I may experience is of greatest value, because the report [they receive from us] is short. The process that it entails is perhaps just as important for those involved, so that they over time constantly strive to understand more of the system, systematics, improvement opportunities, in their own organization. (Auditor 2).

Observations and interviews showed that improvement was a central theme of her audit practice. It was embedded in a focus upon motivational factors to bring about organizational improvement. She expressed respect for the limited possibility of her getting a total picture of the organization during a couple of days, and kept in mind that she was not there to tell the organization how things should be done or give advices, but to a great extent provide support for good practice and identify opportunities by giving examples from best practices elsewhere. She perceived that the control dimension was about 30% of her auditing practice. Auditor 2 stated that there might be some differences in the way she performed audits in hospitals than in other sectors, and suggested that underdeveloped management systems might have been a reason for her motivational approach rather than verification.

The discusser: auditor 3

When auditor 3 conducted her interviews, she wanted the participants to be engaged and to contribute to the discussions. Both revision and sharing of experiences were embedded in her dialogue strategy. She strategically used her interview to communicate requirements and meet key personnel in daily practice. As she expressed:

> [T] he way I've started now, because of what I have experienced in the health sector, where they have placed very much on the quality managers. So, when I put management processes on the [audit] agenda, […] I then ask if all the persons who participates in the management review [from the organization] can participate. Then, it is not just the head of department, or director of administration, or... So, when we assess the minutes from meetings and things like that, all participants should have a possibility to participate – and for me to be able to ask them about their expectations of the system and to get to know them, and so on. So, there's a direct auditor role. But they have to think themselves to speak. They have to make their, their contributions then -- more active. (Auditor 3).

Auditor 3 started her three-day recertification of an emergency department by claiming in the opening meeting that she preferred an audit that was based on open dialogue. She often repeated this at the start of every interview. She emphasized that she wanted no surprises in the closing meeting, and that everything should be clarified during the assessment. The audit was arranged so that all the interviews were held in locations where the personnel did their daily work. She said that she wanted to talk to people while they were closest to where they worked. In one audit interview, observations showed that the auditor spoke with only one respondent at some times, but in all others, there were at least two or more other people present. She usually began the interview with a short introduction about the intention for the assessment. She then asked for a description of how things were done in relation to the matter to be discussed. She encouraged the staff to talk about their system, and welcomed dialogue or conversation. One respondent thought she was supposed to be asked questions, and said she had not prepared for an open or "formal" presentation about how "we do things around here." Auditor 3 often asked direct questions about an issue that had arisen during the conversation, and was then clearly steering the interview. She alternated direct questioning with dialogue. Her point of departure was based on documents or procedures that she had read beforehand in relation to the standard, but never used the standard openly during the interview. Sometimes she drew analogies to her professional background in the process industry, and discussed good practices that she had observed elsewhere. She did not record her interviews, but occasionally took notes when there seemed to be findings related to conformities or nonconformities.

Auditor 3 perceived that the certification body expected her to add value when she performed her assessment practice. The practice of adding value seemed to be related to a guidance role. At first, auditor 3 seemed a bit reluctant to focus upon a guiding role or to give advice:

> [...] because I've always kept that one should be objective and not give advice and so forth, but it's a balancing act when you see that the customers are not completely familiar with the extent of the requirements in the standard. (Auditor 3).

When responding to the inspection-guidance axis she expressed an organizational reality that asked for reflexivity towards the maturity of the organization's competence on what the ISO 9001 standard actually mean for their own management system. She stated that it is not enough "to sit in school and learn the standard" (Auditor 3), the organizations have to translate the content to their own management system as well. Auditor 3 cited examples of how the audits and certification processes drove development and change in hospitals, even though her formal role during certification was assessing the organization. For example, there were often many other control mechanisms that hospitals needed to conform to, and therefore the regular certification activities could become an arena for organizations to seek advice. The auditor perceived that sharing experiences from elsewhere was the best way to avoid giving advices and to balance the audit practice between inspection and guidance.

Summary of themes in the findings

Overall, our findings showed that all three auditors adopted an opportunistic questioning approach, but auditor 3 was more likely to turn to a more direct and closed type of questioning than the others. The first two auditors used a template to guide their interview related to the normative standard, but none used structured pre-planned questions. There were significant differences in how the auditors recorded the interview results. The first two auditors took detailed notes during the interview - the first more frequently than the second. This showed that they were oriented towards the written side of the recording dimension. The third auditor only jotted down a few words occasionally. She was more oriented to the opposite side of the recording dimension: implicit note taking. The two first auditors adopted the conduct of the explorer, while the third adopted the conduct of the discusser. All the auditors perceived both assessment of conformity to the ISO 9001 standard and guidance for improvement as embedded parts of certification audits. They were all concerned about not giving the certified organizations specific advises on how to improve but were familiar with transfer of experiences from elsewhere and giving general guidances. Auditor 2 and 3 were also more concerned with encouraging the certified organizations own reflections of their quality management system, in order to nurture improvement. In the next section, we will discuss this in further detail.

Discussion

In this paper, we explored auditors' role in hospital certification. By ways of non-participant observation of audit interviews and qualitative interviews with the lead auditors, we have explored different auditor styles and how the auditors perceive their role in hospital certification processes in Norway. In the following we will discuss the findings according to the auditor typology framework [24].

Auditors role repertoires and professional conduct – mediating opportunities for assessment and improvement

According to the normative standards, certification relies upon objectivity and consistency among auditors [27, 46]. Consistency is also a key to the reliability of certification

and accreditation programs [25]. However, the normative guidelines [37] state that ISO 9001 must not be considered as a "tick-off" scheme, because the detailed requirements are only means to ensure the most important focus, which is the customers' (or patients') requirements. The normative frame of reference (ISO standards) takes into account that auditors get only a snapshot of what is going on in the organizations. Hospital organizations and healthcare services are complex, and the auditors should be able to comprehend that complexity in these systems during the assessments. Auditors need information to "diagnose" the management system [47] and our study demonstrated how the auditors used the standard to help gather the information that they need. Our auditors, however, took different approaches in their search for this information. All used open questions, but auditors 1 and 2 relied on structuring interviews according to the standard, while auditor 3 emphasized more an open dialog approach. Auditor 2 and 3 were more concerned with encouraging reflection and hence a higher degree of learning within the organization during the audit interview.

In a study of stakeholders' views and experiences on accreditation survey reliability [25] the authors found that the reliability of accreditation is embedded in its technology and enacted in audit practice. Technologies like the accreditation programs themselves, workforce management and documentation have a greater influence on reliability than the conduct of auditors and the dynamics in the auditor-organization encounter. Technological factors can narrow the potential expectations and conduct and therefore also assume more consistencies, but only to a certain degree. A consistent regime within which certification auditors act, helps auditors to meet a level of reliability in complex and shifting contexts such as hospitals, but the dynamic variations are determined by the auditors' different self-governing systems. In our study, we found that the auditors conducted their role according to the standards and expectations of their role. However, they also sometimes used their competence and experience to add value to the hospital under certification. Our results are in line with the literature on certification and accreditation programs showing an increased focus on holistic processes [12, 48] in terms of organizational development, where auditors are more involved in the improvement activities, sharing experiences, educating and giving advice. It is not just the verification itself, but a mutual process and understanding between the certification body and the hospital. These institutional changes can shape the expectations and legitimacy concerns in auditor-auditee relationships.

The auditors in this study expressed concern about giving advice, since organizational follow-up on such advices may imply that auditors will audit their own solutions (advices) at a later stage. The normative standards describe consultancy work, like advice and education, as threats to confidence in the process. The three auditors seem familiar (numbers 1 and 2 even more so than 3) with giving suggestions (not "advices" in their opinion) for improvement and transfer experiences from other hospitals, even though it may blur the strict consistency tied to the certification norms. Our results are similar to what is found in studies of regulatory models that seem to be deterrence-oriented in the first place, but more compliance-oriented at the sharp end (auditors, regulatory staff) [41, 49]. This seems to be because of the realities of "street-level" interaction where services improvement can be reached by some degree of advice or experience transfer from other sectors that are more advanced in their organizing of quality. This knowledge is important for policy makers and certification bodies, as their adaptive capacity in these roles play a key function in translating hospital certification into sound learning processes. This appears equally important to the auditors, as the certificate itself.

Auditor styles within the surveyor style typology

Our findings show that the auditors approached and perceived their role both as assessors of compliance, while educating and stimulating improvement. The pre-planned audit agenda was guided by topics from the ISO 9001 standard and directions during interviews was embedded in the requirements among all the auditors. These findings show that the structured certification program contributes to consistency, despite the differences in surveying style, and are in line with findings in other studies [24, 25].

A central proposition in the surveyor style typology is the assumption that auditors perform the same role in different ways. Gaining knowledge about the auditors' perception of their audit role is therefore important to understand why auditors perform their role differently, especially if we are to follow the suggestions of Greenfield, Braithwaite, and Pawsey [24] about using the typology framework as a tool for training, development and assessment of auditors. Our study has explored some factors that might assist in understanding why auditors perform the same role in different ways. Greenfield, Braithwaite, and Pawsey [24] also suggest using the typology in allocation processes to ensure survey teams with either similar or mixed styles, targeting different organizational contexts. This allocation approach presumes knowledge about the effects of different audit styles upon the organization. There is no consensus on the effects of different styles in auditor-auditee encounter. Similar questions about styles have been at the heart of theoretical development in regulation theory [49–51]. According to the conformity assessment standard [34]

the auditors may identify and record opportunities for improvement but refrain from suggesting the cause of nonconformities or their solutions. The auditors in this study claimed that hospitals rarely have the same comprehensive management systems that other sectors do. They perceived themselves as balancing verification with inspection, and between guidance and advice. It is difficult to see if there is a clear boundary between these two extremes, but what might seem apparent is that none of the auditors perceive or approach their role in a "highly inspectoral" manner.

Systems audits as performed in ISO 9001 certification are similar to the methods used by inspectors in the Norwegian Board of Health Supervision, who performs system audits founded in the ISO standard for audit practice [36]. The main difference is the possibilities for enforcement and the power balance. Certification bodies do not have the same possibility of escalating enforcement strategies that regulatory authorities can, and therefore have a different pressure for taking part in voluntary system improvement than what inspectors have. These aspects are often linked to independence challenges. Organizational independence is most often described as the challenge in third-party audits, but operational independence might influence the street-level practice of auditors [47]. As noted earlier, auditors depend on information. A solution to the information asymmetry between the auditors and the auditee is a more interactive and collaborative style, as adopted by the auditors in our study. Another aspect in operational independence is the epistemic dimension [47]. It is expected that clear standards imply more inspection-oriented role performance than assessment against generic standards, which is the case in ISO 9001 certification where the standard is more generic.

Implications for the surveyor style typology and suggestions for further framework development

The auditor practice showed a considerable use of group interviews. Two auditors explained it as a strategic choice, because of respondents' uncertainty during the assessment, an opportunity to target people who are involved in daily practice, and possibilities for reflections and awareness through discussions. Even though it seems a well-known practice, we have not been able to find suggestions about group interviews in the audit standards [33, 34, 36] that underpin the auditors' review practice. Even individual interviews are hardly mentioned, in comparison with the amount of literature on research and evaluation methodology, where interviews are subject to rigorous scrutiny about how they are able to give or produce evidence [52–55]. We propose the use of group interviews as an additional dimension for the auditor style typology, since the empirical evidence that underpins the model does not give any information as to whether they are based on individual or group interviews. In the methodology literature, group interviews or focus groups have been distinguished from individual interviews in qualitative inquiries and evaluation [56–58]. The interactional construction of knowledge highlights the shift from an asymmetric power balance during the interview process, to the empowerment of the respondents. It is a shift from the operating principle of control, to collaboration between the interview participants [57], which could also be reflected upon in the ISO standards or guidelines. Concerns about interaction are important, because when health professionals participate in assessment contexts that are collaborative and supportive, it can self-reinforce a collaborative quality and safety culture [59]. Greenfield, Pawsey, and Braithwaite [59] also showed that auditors' use of group interviews had positive effects for successful participation and collaboration with staff in accreditation. We suggest further qualitative explorative research to investigate into the role of the interactional element and how this influence both the certification processes and improvement efforts, as this is still an important area for knowledge generation. Methods wise we encourage in-depth studies of several certification bodies over time to identify variation in auditor work practice and style, and how their practices are considered from auditors and the certified bodies' perspective. This may also help to further refine and extend the typology framework and judge whether all of the proposed styles actually exists in current auditing practices.

Strength and limitations

The strengths of the study are the combination of observations and interviews behind the curtains of a certification body. The ability of follow auditors during certification processes and follow up with interviews provide a rich data set on their performance as observed and their perceived experiences. This is an approach lacking in the literature. This is an exploratory study, and the limitations of the study are first, a small sample size with three lead auditors in one certification body. However, choosing one certification body, allows for more details and adds to the knowledge about the practice of auditors representing one organization that may increase the information power [60] in the results. In addition, it is a challenge to involve additional certification bodies in a Norwegian context, due to the low number of certification bodies and thus a high transparency in this sector implying a risk of identifying participants. Second, a thematic analysis based on deductive approach could imply missing some of the inductive results. However, the framework we used in the deductive analysis contributed to guide the analysis and we were able to

suggest further refinement of the typology which is often missing when using theory to guide research [61].

Conclusions

Auditors from a certification body demonstrated a polymorphic certification reality in which guidance and stimulation for improvement were incorporated in the auditors' styles and perceptions of ISO 9001 certification processes. This contrasts to what is often presumed as consistent, stringent and independent audit practices. A difficulty with the analytical auditor typology framework [24] is its lack of sensitivity to the different auditor styles. The originators of the typology suggest the need for more research to identify additional dimensions associated with the identified styles, like differences between the use of closed and open questions or examining the content and detail of note taking [24]. Our study suggests adding the distinctions between performing individual or group interviews during assessments, because these differences may influence the asymmetric power balances in the auditor-auditee encounter. However, there is a need for further research to understand and explore different auditor styles in different contextual settings and provide more knowledge on how auditor approaches affect the audit process and outcome in the organization under certification.

Abbreviation

ISO: International Organization for Standardization

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Authors' contributions

DTSJ was responsible for the conception and design of the study and undertook the acquisition, analysis, and interpretation of data. SW was consulted during the analysis and interpretation process. DTSJ led the drafting of the manuscript. DTSJ and SW were both involved in critically revising the manuscript for important intellectual content. Both authors read and approved the final manuscript.

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Availability of data and materials

The data generated and analyzed during this study are not publicly available due to concerns about confidentiality regarding a small sample size and the sensitive nature of the interviews. Instead, quotations and analytical categories are included in the text. We are happy to discuss the findings or the analysis if any questions arise.

Ethics approval and consent to participate

The research and the procedure for obtaining oral consent to participate were conducted with the ethical approval of the Norwegian Social Science Data Services (December 16, 2011, Ref. 27543). A clearance for observation and interviews with the auditors was obtained from the certification body prior to data collection. The three auditors received an individual written invitation to participate, and all three responded per e-mail with their consent to participate. Written and oral information were given prior to the commencement of observation and interview recording, and all three auditors provided oral consent.

A clearance for observations during the review process in the hospitals was obtained from the hospital prior to data collection. Written information about the observation was sent to the hospital and given to the hospital staff taking part during the review process. Before every new review meeting, oral information about the observation and data collection was given. All the persons from the hospitals that took part in the certification meetings provided oral consent. All written and oral information to auditors from the certification body and meeting participants from the hospitals explained that observations and interviews were part of a research project, that the results would be used anonymously for analysis and publication, and that participation was voluntary and could be terminated at any time.

Consent for publication

Not applicable.

Competing interests

Author Siri Wiig is associate editor for BMC Health Services Research.
The authors declare that they have no competing interests.

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Article III

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RESEARCH ARTICLE Open Access

Certification as support for resilience? Behind the curtains of a certification body — a qualitative study

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Abstract

Background: Certification in healthcare often involves independent private sector bodies performing legally required or voluntary external assurance activities. These certification practices are embedded in international standards founded in traditional beliefs about rational and predictable processes for quality and safety improvement. Certification can affect organizational and cultural changes, support collaboration and encourage improvement that may be conducive to resilient performance. This study explores whether ISO 9001 quality management system certification can support resilience in healthcare, by looking at characteristics in the objectives, methods, and practice of certification from a certification body's perspective.

Methods: One of Norway's four certification bodies in healthcare was studied, using an explorative embedded single-case design. The study relies on document analysis of the international standards and associated guidances for the performance of certification bodies and thematic analyses of data from 60 h of observations of auditors in three certification processes and nine qualitative interviews with managers and personnel from the certification body. Results from the analyses were compared to identify discrepancies between the written and perceived certification approach and practice.

Results: Standards and guidances for certification embed an elasticity between formal and consistent assessments of nonconformities in organizations and emphasize holistic approaches that brings added value. Auditors were then left with the latitude to navigate their auditing strategy during interaction with the auditees. Members of the certification body perceived and practiced a holistic and flexible auditing approach using opportunities to share knowledge, empower and make guidance for improvement.

Conclusions: ISO certification expects structures and systems to ensure consistent and objective certification processes. At the same time, it embodies a latitude to adopt flexible and context-specific certification approaches, as demonstrated by a certification body in this study, to give added value to the certified organizations. Such an ISO 9001 certification approach may support resilient performance in healthcare by nurturing the potential to respond and learn. These results are important for further development of methods that certification bodies use in the auditing encounter.

Keywords: Certification, External assessment, Regulation, ISO, ISO 9001, Resilience

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Background

External assessment programs, such as certification, accreditation, peer reviews and inspections are widely used as a regulatory means of assurance, accountability and performance improvement in healthcare [1–5]. Originating in voluntary self-regulation, certification and accreditation programs are increasingly becoming statutory regulatory mechanisms in healthcare [2, 6]. In Norway there are no legally required certification programs in healthcare, but several organizations have voluntarily become ISO (International Organization for Standardization) 9001 Quality Management System certified.

There have been several claims about limited evidence from external assurance mechanisms of the effects upon recognized quality measures in healthcare [7–9]. Two systematic reviews have found no strong effects upon clinical outcomes from certification and accreditation [10] or external inspections [11] in healthcare. Other reviews have shown that accreditation in healthcare might have organizational impact and foster change and instill professional values, stimulate improvement work, and promote organizational and cultural change concerned with quality of care and change in professional practice [4, 12, 13]. Moreover, studies show a positive association with quality and safety structures and hospital outputs such as hospital management and clinical leadership, systems for safety and patient-centeredness [14–16]; and to be effective for organizational change, developing relationships, cooperation and nurturing links between healthcare organizations and other stakeholders [17]. Benefits from accreditation seems to be linked to the motivation for the activities involved in the process [18]. Recent research from Australian hospitals has demonstrated that accreditation supports continuous and systematic quality improvement [19]. However, little is known in healthcare about the approach and methods that external assessment bodies use in their assessment and verification processes, such as auditor's role repertoire, auditor's conduct (e.g., inspection or guidance) and assessment practice [4, 20–22].

Theoretical approach and ISO 9001 certification

We now present our theoretical approach, using resilience to understand ISO certification processes.

The concept of resilience has, in recent years, been applied to healthcare [23–25]. Resilience is defined as "[...] an expression of how people, alone or together, cope with everyday situations – large or small – by adjusting their performance to the condition. An organization's performance is resilient if it can function as required under expected and unexpected conditions alike (changes/disturbances/opportunities)" [26]. The resilience literature focuses on the difference between (a) work as prescribed and expected in regulations, guidances, standards, work planning and design, and (b) the work that actually occurs. The former is Work-as-Imagined (WAI) and the latter Work-as-Done (WAD). Supporters of resilience in healthcare emphasize the development of flexible and adaptable local systems, where local knowledge and professionals' judgments are at the heart of everyday performance [24, 27]. Resilience in healthcare builds upon four potentials — Respond, Monitor, Anticipate, Learn — which need to be managed and supported to bring about resilient performance [26]. The first potential is the ability to *respond* to the situation and know what to do. It is associated with the ability to respond to regular and irregular changes and opportunities, and initiate prepared actions, adjust activities or creating new ways of doing things. The second potential, *monitor,* is knowing what to look for that can improve or diminish organizational performance. *Anticipate* means knowing what to expect and when conditions change. The final potential, *learn,* addresses the factual by knowing what has happened and being able to learn from it. Learning can be specific or institutional [26].

The ISO 9001 standard [28, 29] is a generic norm for quality management systems. It is intended for adaptation to all organizations, from the manufacturing industry to service organizations, such as most healthcare organizations. Organizations can be assessed by an external third-party organization for ISO 9001 certification [30], meaning that it has been recognized for the fulfillment of requirements in the standard. These external assessments are termed *third-party conformity assessment* or *certification audits* and are performed by certification bodies in accordance with the normative standard *ISO/IEC 17021* [31].

The certification regime involves three essential control components or methods used to affect behavior, and directed at those persons or institutions that seek to be influenced or controlled: *direction* (standard setting) *detection* (information gathering), and *enforcement* (behavior modification) [1, 32, 33]. In ISO 9001 certification, certification bodies use the ISO 9001 standard to *direct* and assess organizations for certification, but the certification bodies themselves have no direct influence on the development of the standard. The certification bodies are themselves *directed* by the international ISO/IEC 17021 standard and related guidances which require certification bodies to manage and keep control of the prescribed and practiced approach to *detection* and *enforcement* in certification auditing processes. The distinction relates to the resilience perspective of Work-as-Imagined and Work-as-Done [27], where WAI includes both the ISO/IEC normative standards for certification processes and the certification bodies' own prescriptions

and perceptions of certification processes. WAD, in contrast, describes the practices that unfold in certification encounters. Figure 1 (explained in the methods section) illustrates this perspective.

The main assessment activities, detection and enforcement in ISO 9001 certification are processed by auditors interacting with the certified organizations in on-site certification audits. A classical distinction used to describe the detection and enforcement styles in regulatory encounters, is the one between compliance or deterrence [1, 5, 33–35]. Compliance is prospective, and focused on preventing harm, forming closer relationships, cooperation, support, education, improvement work, and the use of formal sanctions only as the last resort. Deterrence is more retrospective, focused on detecting violation, distant relationships, formal processes, noncompliance, and extensive use of formal sanctions. There is no general agreement on what approach or style to external assessment in certification serves the certified organizations the best [1].

Different certification approaches may support resilience in healthcare organizations in different ways. No studies to our knowledge have previously explored the relation between certification and resilience and how certification processes can support resilience in healthcare.

Aim and research question

External assessment in healthcare affects organizational and cultural changes, support, collaboration and encourages improvement. Such effects may be fruitful in terms of resilience. This study explores the characteristics of approaches to ISO certification and discusses whether these approaches can support resilience in healthcare. The following research questions guided the study.

1. What auditing approach for certification bodies is embedded in standards and guidance notes for ISO 9001 certification?
2. How do managers and auditors of a certification body perceive and practice the certifications?

The study reports on approaches to certification processes and practices expressed in international ISO certification standards and as seen by auditors and managers in a Norwegian certification body. The paper contributes to our knowledge of the characteristics and flexibility in external reviews that might be important in further development of the ISO certification and external assurance mechanisms.

Methods

Design

This study uses an explorative embedded single-case design using several sources of evidence [36, 37]. The case study is based on certification processes implemented by one of the four certification bodies accredited to perform ISO 9001 certification of healthcare organizations in Norway.

Sources, recruitment, and data collection

The study relies on data collected from document analysis of international standards and guidance notes related to ISO 9001 certification, and qualitative

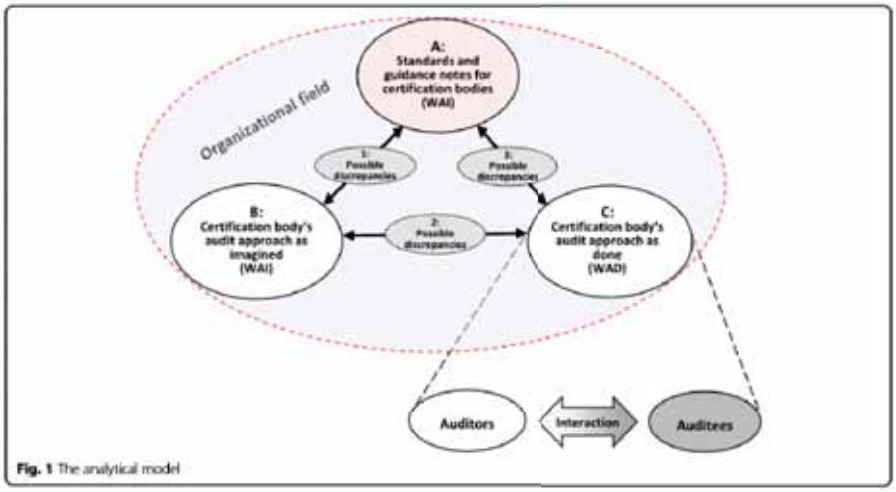

Fig. 1 The analytical model

Table 1 Data Sources and Collection

System level	Data sources	Data collection	Location	Duration
International/national (Norway)	6 ISO/IEC standards 55 AAPG and APG guidelines	Document analysis		
Certification body Organizational/individual	3 lead auditors in 3 separate conformity assessments	Nonparticipant observation	1 Hospital 1 Clinic for internal service 1 Emergency department	3 days 2 days 3 days (About 60 h)
Certification body Organizational	5 lead auditors 4 leaders/administrative personnel	Semistructured interviews	Certification body, central office	45–75 min per interview

semistructured interviews and observations related to the certification body's approach to certification (Table 1). The certification body identified managers and certification teams as bases for data collection by interviews and observations. Hospitals collaborating with the certification body were contacted by the author DTSJ. The standards were obtained through ISO's electronic distribution platform, and the guidance notes were openly available and downloaded from the ISO's web page.

Data collection took place in three stages. In the first stage, we collected data from the international normative standards and guidance notes for bodies providing ISO 9001 certification. The standards include the ISO/IEC 17021:2011 standard for certification bodies performing ISO 9001 certification and its related standards relevant for this study (Table 2). We also collected data from 55 guidance notes from two international auditing practice groups, constituted as informal groups of experts and practitioners active in the development of the official auditing standards. These were the ISO 9001 Auditing Practices Group (APG)[1] and the Accreditation Auditing Practices Group (AAPG).[2]

In the second stage, we explored certification practice by conducting nonparticipant observations of three lead auditors in three third-party conformity assessments (certification audits) in two hospitals. The first observation was in a clinic for internal service. The second was in a hospital where the objective was to certify the total management system and delivery of specialized health services of a hospital. The third observation was conducted in an emergency department.

The first author followed the lead auditors during onsite audits for 60 h. The observations followed an observation guide focusing on the conduct of the lead auditors during their interviews and conversations (assessment process) with members of the certified organization. Topics covered were interaction and communication, methods of interview and personal style. All observation notes were taken openly and guided by an auditor typology framework [38]. The auditor styles observed were presented in a separate article [39].

In the third stage, nine semistructured interviews (Table 1) were conducted with the lead auditors (five people), and managers and administrative personnel (four people, who were also lead auditors) from the certification body. The interviews lasted 45–75 min and were conducted at the informants' workplace. The interviews centered upon three themes in the interview guides (see Additional files 1 and 2): 1) the informants' role, the organization and their approach to ISO 9001 certification; 2) the certification process and regime; and 3) ISO 9001 certification and regulation in healthcare. Open questions were used to make the informants recall and tell detailed stories about the topics addressed. Questions were often followed by either scripted or ad hoc probing questions. All interviews were audiotaped and transcribed verbatim.

Analytical framework and data analysis

Our analytical framework represents central elements in the certification process and the involved organizations in the healthcare setting (certification body and the certified hospitals). The purpose of the framework is to guide the analytical process by assessing the relationship between the auditing approach embedded in formal standards and guidances (research question 1) and how managers and auditors perceive and experience and practice the certification (research question 2). Figure 1 presents the framing.

In Fig. 1, the objectives and methods for certification as defined in standards (normative references) and guidance notes (A) gives scope of opportunities for certification practices and are perceived and translated by certification bodies (B). Certification bodies also perform the certification activities (C) where auditors access and interact with the certified healthcare organization in the

[1] with quality management system (QMS) experts, auditors and practitioners drawn from the ISO Technical Committee 176 Quality Management and Quality Assurance (ISO/TC 176) and the International Accreditation Forum (IAF)

[2] with accreditation experts, auditors and practitioners, drawn from the ISO Policy Committee for Conformity Assessment (ISO/CASCO), the ISO Technical Committee 176 Quality Management and Quality Assurance (ISO/TC 176) and the International Accreditation Forum (IAF).

Table 2 Standards and Normative References Included in this Study

ISO/IEC 17021:2011	Conformity assessment: Requirements for bodies providing audit and certification of management systems
ISO/IEC 17000:2004	Conformity assessment: Vocabulary and general principles
ISO 19011: 2011	Guidelines for auditing management systems
ISO/IEC Guide 60	Conformity assessment: Code of good practice

auditing encounter. Ideally, elements A, B and C are harmonized. Numbers 1,2 and 3 in Fig. 1 represent possible discrepancies among the elements. The model assumes that the certified organization also assesses, from an internal perspective, its own documented quality management system and its consistency with the ISO 9001 standard. The two assessments are then matched, discussed and negotiated in the interaction between auditors and the auditee to identify nonconformities or areas in need of improvement.

To explore characteristics in approaches to ISO certification, and be able to compare elements A, B and C in the analytical model the data related to each element was subject to theoretical (deductive) thematic analysis [40, 41]. Two broad a priori themes were applied underpinned by the theoretical opposites of deterrence and compliance approaches to regulatory enforcement [1, 34]. This was operationalized as: (a) *assessing conformity against requirements*, focusing on retrospective auditing practices (detect noncompliance, control, provide formal processes and distant relationships) and (b) *quality improvement work*, focusing on prospective auditing practices (offer guidance, educate, transfer experiences and give advice). The two a priori themes were applied to the thematic analyses described in the next two sections.

To analyze the data according to research question 1, the auditing approach embedded in certification standards and guidance notes, a document analysis was performed by an iterative process combining content analysis and thematic analysis [42]. The analytical process included a superficial examination (skimming and summative content analysis), followed by thorough examination (reading and rereading, reading concepts in context and thematize) and finally interpretation. The qualitative research software NVivo 10 were used for a summative content analysis [43] of the guidance notes. This analysis first included a word frequency query of all words with a minimum of four letters grouped with stemmed words; this led to 1800 words being identified. Second, the results were reviewed and words that were prospective and related to development work were used for a text query within all the guidance notes. These words were *guide*, *utilize*, *encourage*, *stimulate*, *instruct*, *recommend*, *suggest*, *propose*, *warn*, *consult*, *assist*, *advice*, *support*, *give*, and *help*. Finally, the query was spread to a broad context within the guidances, and the contents of the text were then subjected to thematic analysis combined with the content of the ISO/IEC 17021:2011 standard and its related standards. The document analyses identified "work as imagined" in standards and guidances for certification.

To analyze the data according to research question 2, how managers and auditors experience and practice certification, all the data material from the observational field notes and interviews was subjected to thematic analyses [40–42] using the a priori themes. NVivo 10 was used to explore and thematize the interview data. A reflexive approach was used for the analyses, drawing attention to the narratives (stories) [41] that contoured an auditing orientation towards either strict retrospective assessments of conformity to requirements or prospective quality improvement approaches. These analyses identified "work as imagined" by managers and auditors and "work-as-done" in certification practices.

Finally, to compare findings that addressed research question 1 and research question 2, the results from all analyses were reflexively compared to spot discrepancies [37] among A, B and C in the analytical model (Fig. 1). To ensure trustworthiness, we conducted a member check with the certification body.

Results

In this section we first present the results related to research question 1, the certification auditing approach embedded in standards and guidance notes for certification bodies (WAI) which relates to element A in the analytical model (Fig. 1). We then apply the results to research question 2. First, we explain how managers and auditors of the certification body perceive certification processes (WAI), which relates to element B in the analytical model. We then turn to the practice of certification audits (WAD), associated with element C in the analytical model.

Element a: approach to certification in standards and guidance notes for certification bodies (WAI)

The standard ISO/IEC 17000 outlining the vocabulary and general principle for conformity assessments in general, defined three functions for conformity assessments: *selection*, *determination*, and *review and attestation*. *Selection* consists of planning, preparation and specifying the requirements and audit criteria for certification. *Determination* is the development and collection of information regarding fulfilment of specific requirements,

such as audit activities. *Review and attestation* are the final stage of checking evidence of conformity before deciding on certification. These functions were recognizable in the ISO/IEC 17021 standard, regulating specific certification processes, which defined the overall objective for certification as "[...] to give confidence to all parties that a management system fulfils specified requirements."

The ISO/IEC 17021 emphasized that certification bodies and auditors should build confidence and trust through a practice rooted in impartiality, consistency, competent assessments, and decisions based on objective evidence. For certification bodies to do this, the ISO/IEC 17021 detailed requirements for the certification bodies' organizational structures and their management of impartiality, resources, competence, information and the specific certification processes. Related to formal stages of certification auditing programs and processes, the ISO/IEC 17021 referenced the generic ISO 19011 standard for auditing management systems. Both standards emphasized a consistent audit approach that focused on retrospectively assessing and detecting noncompliance with the requirements of a management system. For example, the standards include almost identical formal clauses with requirements for the stages in on-site (the location of the certified organization) audits such as *conducting the opening meeting, communication during the audit,* [assigning roles and responsibilities of] *observers and guides, collecting and verifying information, identifying and recording audit findings, preparing audit conclusions and conducting the closing meeting.*

Processes that involve human interaction between auditors and auditees in on-site audits, such as interviews and observation to collect and verify information, were described in short terms or became implicit in the formal stages of the audit processes, such as when confirming, reporting, explaining, introducing and presenting. Interactive activities between auditors and auditees were briefly and explicitly mentioned to *discuss* and *resolve* audit finding and conclusions. An annex in the ISO 19011 gave some informative guidance about conducting formal individual interviews during on-site audits.

In general, the ISO/IEC 17021 and the ISO 19011 standard had a retrospective approach where assessment of the certified organization's management system activities, processes and products or services, and the extent of conformity to certification requirements were the main subject. Descriptions of prospective auditing approaches, such as support, transfer of experiences or giving advice were almost absent in the standards. According to the ISO/IEC 17021, "The audit team may identify opportunities for improvement but shall not recommend specific solutions." The standard reiterated the threats to impartiality for certification bodies involved in certification processes. Such threats may come from certification bodies doing management system consultancy work to the certified organization, such as giving advice, describing causes of nonconformities or being involved in improvement work, or when certification bodies are being too familiar with or trusting of auditees instead of seeking audit evidence.

Comparing the guidance notes for certification with the certification standards, we found a more prospective orientation in the notes as described in the next section.

Guidance notes on ISO 9001 certification

Guidance notes from the Auditing Practice Group (APG) and Accreditation Auditing Practice Group (AAPG) communicated, in principle, that all audits should add value or be useful to the auditee. To do this, APG suggested "[...] a 'holistic' approach to evidence gathering throughout the audit, instead of focusing on individual clauses of ISO 9001" (ISO & IAF, 2009, How to add value during the audit process).

It was emphasized that the requirements in the ISO 9001 standard must not be considered a "tick-off" scheme, either by the auditor or the auditee. The auditors should look not only at compliance but also at the effectiveness and benefits of the implemented management system.

> Instead of simply looking for formal compliance with the requirements of the standard, auditors should look at the real effectiveness of the management system and identify the benefits that the adoption of the system give to the organization and to its clients. [ISO & IAF, 2008, Added value certification audit versus consultancy)

According to the guidance notes, auditors should furthermore be process- and result oriented, instead of stressing procedures and records, to maximize the possible added value. Adding value was related to making the ISO 9001-based quality management system more useful for the organization. As a further means of adding value, certification audits should provide "[...] information to top management regarding the organization's ability to meet strategic objectives; by identifying problems which, if resolved, will enhance performance; [and] by identifying improvement opportunities and possible areas of risk" (ISO & IAF, 2009, How to add value during the audit process). This meant that auditors should acquire some understanding and be sensitive to the maturity of the quality management system and the quality culture in the certified organization, in order to modify the auditing approach and reporting of audit findings.

The guidance notes did not include much advice on performing formal interviews or observations, although

it did encourage interactive processes in auditing practices.

> [...] open discussions with people who are primarily responsible for management of the organization could allow the effective use of audit resources and time and may provide major benefits for the organization. (ISO & IAF, 2008, Added value certification audit versus consultancy)

The guidance notes focused upon prospective approaches in which the improvement of the management system was central to audit practices. Auditors were not to act as consultants by giving advice or explaining "how to solve a nonconformity" situation. However, stimulating improvement should be encouraged:

> [A] correct approach to the handling of nonconformances is for auditors to encourage the auditees to find their own solution, by raising questions and stimulating understanding and awareness, but not providing direct advice as to how problems should be solved. (ISO & IAF, 2008, Added value certification audit versus consultancy)

According to the guidance notes, the audit reports should, if possible, go beyond descriptions of mere compliance of audit requirements and identify opportunities for performance improvement but without offering specific solutions.

Element B: certification body's audit approach as imagined

The certification audit approach perceived by managers and auditors in the certification body was largely oriented towards a prospective auditing approach.

The informants from the certification body focused on certification as an ongoing process. The certificate in itself should not be the main objective, but the process should bring added value and inspire internal improvement processes in healthcare organizations. The informants used terms like "driver for change," "added value," "improvement," "review the system" and "to have satisfied customers (or patients)" when describing the objectives of the certification processes. They also reported that the certified organizations seldom focused on the certificate but were more concerned with improving their system.

> What I'm saying is that the certificate itself is not so important to us, but it's more for you. It's proof that someone has conducted a review and shared their experiences of the journey with you. And now you have the foundation in place. (– 67)

Most informants considered the ISO 9001 standard suitable for the healthcare context, while others described it as one of many suitable standards. There was a consensus that the auditors should focus on the healthcare organizations' own processes, and less on prescriptions and detailed requirements. An experience among the informants was that the quality management systems in healthcare were often novel, lacking familiarity with management concepts mentioned in the ISO 9001. As a consequence, audit activities had to prioritize achieving "minimum certification standards" and identify significant risks at the expense of facilitating continuous improvement processes. Another concern was that the auditors often needed to do guidance on integrating daily practices into the quality management system.

> I constantly try to find out what they are good at and how they can improve, by using what they have in a better way. Simply, cleaning up their own house. It's too much of everything, and maybe they lack what's important — missing the overall perspective many times. (–72)

A general view among the auditors was that the certification process was capable of nurturing local processes in healthcare organizations by enhancing awareness for improvement of processes. One effect often mentioned was the certification processes' contribution to reducing the number of procedures, or to making the procedures more functional. Some of the informants complained that there was a misconception that the ISO standard was overly complicated and required many procedures. As one informant explained:

> It is simply process thinking. But soon you [the hospitals] spend a lot of time looking at paper and bureaucracy, and take the focus away from patients, in order to build a [quality] system. It is a great challenge for us that it [the standard] is known in many countries as: "ISO 9000 - It's just paperwork." (–76)

Descriptions of the auditing process as purely a collecting of evidence of conformity to requirements in ISO 9001, or performance as in standardized observations and interviews, were almost absent in our interview results. The informants focused on improvement work with the purpose of bringing the organization to an acceptable level of compliance with internal and external requirements, and to becoming certified. Focusing on the minimum level of conformity during certification practice did not match the preferences of the informants. It was clear that they preferred (and considered it their job) to persuade organizations to improve their

management system beyond the minimum level of requirements. The informants also emphasized the importance of continuous follow-up from audits, the yearly surveillance audits, and re-certifications every third year to nurture improvement.

The auditors described their position along a continuum from a proactive role, facilitating organizational development towards a reactive role of "compliance with rules." They were clear about not giving advice, because they might come back later and audit their own solutions. In this context, advice means suggesting specific solutions to problems. Giving examples from other organizations, transfer experiences, or offering solutions that might be fruitful for the organization to discuss or choose from, was not considered "advice." The informants often experienced such information as what the organizations mostly valued, and they often discussed different solutions. Even good experiences from other sectors were considered valuable for transferring into healthcare organizations.

The certification body had an internal management system consisting of the procedures, checklists and templates for the management of certifications, which intended to meet the requirements in the conformity assessment standard ISO/IEC 17021 for certification bodies. This system was considered important for the reliability and consistency of the certification process. The informants emphasized three key elements to ensure reliability in their approach to certification: the certification body's internal written routines, templates and checklists for the different stages of certification; the internal control routines that were independent of the respective auditor; and the internal program for competence and regular calibration of auditors. To gain consistency, the certification body's internal routines and prescriptions defined structures for the certification processes before and after the on-site audits, but they were less concerned with prescriptions for the on-site audit activities.

> Many people think that it's the standard we are auditing according to, but if we take an audit, it's a very small... We do not walk around with the standard [...] So in that way the standard's requirements are used much less than you might think. (–73)

When considering reliability issues in the auditor-auditee encounter, the informants highlighted the importance of the competence and experience that the individual auditor brought with them and stressed the importance of having auditors with knowledge of the healthcare field in the audit team. Differences in performance among auditors were acknowledged and not seen as a threat to the certification practice. It could even be worthwhile for the auditee to change auditors for several reasons: because a relation over a longer period may threaten the independence of the certification body; because human relations may not always fit; or because one auditor sometimes see opportunities or nonconformities in organizations that another does not. It was pointed out that an audit is only a snapshot of an organization, based on sample controls on parts of the management system.

> It has happened - but not very often - that an auditor has been to a place and not seen anything, and then the next auditor comes in and sees a lot of noncompliance and many shortcomings. (–74)

There were differences in the way that auditors approached audit findings and communicated them to the auditee. Defining "observations" or nonconformities was expressed as an important formal part of the certification practice. An observation could lead to a nonconformity if allowed to continue, or a condition without enough evidence to confirm that it constituted a nonconformity. At the same time, most of the informants seemed willing to adapt to organizational circumstances and negotiation when they considered different forms of responses to audit findings. Improvement seemed to be a bearing principle to such considerations. Responses could be to reduce the number of nonconformities by merging "small" nonconformities into larger ones. As one informant described:

> Counting nonconformities is never a good indicator. I merged 20 and made two [...] Two big ones can be much more serious than ten small ones. (–70)

Another strategy could be to strengthen the response by giving an observation as a "wake-up call" to motivate the auditees to stretch themselves. According to one informant:

> What we often do is try to increase the level a little all the time. Perhaps giving them an observation. Shake things up by giving them an observation and saying: "Assess, then you'll get even better." (–73)

Element C: certification body's audit approach as practiced

Observation of the certification practices identified that the auditors were largely oriented towards a prospective auditing approach. The assessments of conformity to the ISO 9001 standards were interwoven in dialogues and interactions with the auditees.

During the opening meeting in all three on-site certification audits observed, the lead auditors systematically

explained how the assessment activities would be carried out. During the meetings it was also emphasized that the audit process was not only an assessment of conformity to the ISO 9001 standard, but also a process intended to encourage improvement of their quality management systems. They all mentioned the importance of the certification process bringing an added value to the hospitals.

We found some differences in the way the lead auditors used pre-planned templates to guide the audit process during dialogues and interviews with the auditee. Two of the lead auditors used a template to highlight topics from the ISO 9001 standard, and to keep track of the conversations with the auditee. The template was also used for systematic or sporadic recordings of the audit findings. The third lead auditor who was observed did not use a template during interviews and dialogues with the auditees. None of the lead auditors used the ISO 9001 standard as a tick-off scheme or referred to specific requirements in the standard. The standard was hardly mentioned during the audits observed, and most often only if the auditees asked for references to relevant requirements in the ISO 9001 for the issues at hand. The lead auditors did not use structured pre-planned questions in their interviews with the auditees, but rather opened for dialogue and discussions. They often used open-ended questions to stimulate self-reflection on the issues at hand. There was always more than one person from the certified organization represented during the planned interviews and dialogues with the auditors. Only some short ad hoc individual conversations between auditors and auditees were observed in some of the on-site walkarounds in the certified organizations.

Our results showed that nurturing local processes was important for promoting improvement and efficiency and for raising awareness. Only a few of the many challenging issues about the hospitals' quality management system, raised in the conversations between auditors and auditees, were considered as nonconformities. The following three examples show how local awareness of improvement possibilities becomes inherent in conversations between auditors and the auditees about issues related to the hospitals' quality management system. None of the issues in the examples were reviewed as nonconformities to the ISO 9001.

In the first example, the auditor asked how the handbook communicated laws and regulations, and followed up with a rhetorical question: "How and where would a nurse in a department find or try to find these [laws and regulations]? – [you should] think from the bottom up." Then, two departments presented examples from their procedures. The first department received positive feedback from the auditor because it had operationalized only the parts of regulations that pertained to the procedure. The second department had provided a long list of references to many laws and regulations in their procedure, but not operationalized it into practical useful information to the employees using the handbook. The auditor responded by repeating, "Think from the bottom up. What is relevant for the employees?"

In the second example, an auditor praised an orthopedic department's internal annual report as one of the best the auditor had ever seen. The manager (who was also the chief physician) had on his own initiative, for years, systematically registered data from their activities, analyzed it and generated annual internal reports. The report was shown during the audit almost by coincidence, because the manager did not see it as part of the organization's quality management system, and therefore thought it was not valid for the quality management certification audit. The department's annual reports were considered more useful for departmental activities, than most of the data collected for the hospital official reports. The auditor responded by emphasizing the importance of the annual internal report, both because it was expected by the ISO 9001 for the department to give inputs to the hospital management, but mostly for organizational control and learning and as a model for other departments. The auditor made certain he would express to the hospital's top management their responsibility to ensure that they received the best accessible inputs to their management review. The top management review is a requirement in the ISO 9001. The manager was delighted but was not sure if the internal report would be considered legitimate by the hospital management, since it was not part of the mandatory performance report.

In the third example, the auditor was performing a re-certification audit of a hospital's emergency department. Part of the agenda was to review if the written agreements between the emergency department and the internal support departments had been followed up by both parties since the last surveillance audit (the yearly audits between the three years full certification and re-certification cycle). When visiting the technical department, the auditor asked questions related to the department's use and implementation of the documented risk assessment. The manager admitted that risk assessments were often carried out and used to receive funding for improvement. "What about revision of the risk assessment when actions have been taken?" the auditor asked. The manager answered that the risk assessments were seldom revised when different risk related actions had been taken. By the end of the auditor's visit, the department manager concluded, "I have learnt one thing today: we should make the risk assessments more 'alive.'"

When the same auditor visited the department for purchasing and supply, one of the topics discussed was how the department ensured that external goods meant to be delivered to the emergency department actually arrived as required. The auditor and the auditees discussed how far and by what means the department should evaluate their external suppliers, especially since the ISO 9001 certificate was addressed only to the emergency department and since the organizational internal structure would probably change. The auditor then finally stated for the auditees, "Now listen. I'm not supposed to be didactic – But, you will always be changing and the [quality management] system will need to change too."

Harmonizing the audit approach as imagined and done in standard and guidances, perceptions, and practices

Overall, a comparison between the standard and guidances for ISO 9001 certification processes, the certification body's perceptions of the process and their practices showed an alignment towards characteristics of a prospective auditing approach in the auditing encounter. This meant an auditing approach enabling the recognition of opportunities for improvement, the provision of generic solutions, and the sharing of best practices.

Discussion

In the following section we discuss the identified approaches to certification processes, and how these processes may support and nurture resilient performance in healthcare organizations undergoing certification.

Certification as support for resilient performance

External assessment programs in healthcare can affect organizational and cultural changes, enhance support, collaboration and encourage improvement [4, 12–17], which may be fruitful in terms of resilience. However, the external assessment approaches that may support these changes are not well studied in healthcare. The standards and guidances for ISO 9001 certification audits explored in this study proposed an elasticity between consistent audits to identify possible nonconformities and audits that enhanced added value (e.g. recognizing support, education and improvement work). The certification regime left certification bodies, and hence auditors, with a latitude to navigate their auditing conduct towards the respective hospital context. The perceived and practiced auditing approaches were characterized by the auditors' adaptation to the certification context. This included their interaction, negotiation, and dynamic communication with the auditees. These auditing characteristics seem to be in line with creation of reflexive spaces and responsiveness in the auditor – auditee encounter, that are important for creating conditions that nurture abilities for resilience in healthcare. Such reflexive spaces are characterized by trust, dialogue, respect and psychologically safe atmospheres [44].

The dynamic auditing approaches are possible since the ISO 9001 standard builds on generic requirements [28] that expands the auditor's latitude to "translate" the requirements to specific organizational contexts. This means that auditors have a latitude that they can take advantage of. Auditors can adapt their performance to their perception of the maturity of the auditees' quality management system and work. Such adaptation was emphasized by the certification auditing guidances. Generic requirements do also give the certified hospitals room to choose between different quality management tools that from their perspective meet the requirements the best. This means that when auditors try to communicate organizational challenges and requirements, such as managing risks, audit conclusions need to be constructed based on interactions, negotiation and dynamic communication practices with the auditees [45]. The certification body's auditing approaches emphasized interactional audit processes. Further, the auditing practices inside hospital departments showed examples of the possibilities the auditors had to uncover challenges or opportunities for improvement of daily activity. Such practices can give surprises or external disruptions leading hospitals to trigger resilience by activating internal collective sensemaking processes and purposeful reorganizing [46–48].

As our theoretical approach we have presented four potentials proposed to be necessary for resilient performance; to *respond*, *monitor*, *learn* and *anticipate* [26]. These potentials are interdependent, and it can be challenging to operationalize them and keep them apart in healthcare research [49, 50]. E.g. when the auditors in this study performed audits in hospitals, they were monitoring the certified organization's quality management system. But, such monitoring activity (the audit) does not necessarily mean that the hospital's potential to monitor its own performance have been strengthened.

In our study we have identified characteristics of the organizations and their involvement in the certification supporting features of at least two of the four resilience potentials: the organization's potential to respond and its potential to learn. Further explorations should be done related to all the potentials, here we will discuss more in depth the two most prominent in our study.

The potential to respond

Healthcare organizations are often assumed to desire standardization and procedures [25]. To revisit and revise organizational action plans and procedures are important for diagnosing and improving the potential to respond, but not necessarily by including more detailed prescriptions or increasing the number of procedures

[26]. There seems to be a general understanding of ISO certification as mostly concerned with formal prescriptions and procedures (often uncoupled from the organization's own practices) [51, 52]. Our study revealed quite the opposite. The main concern of the certification body has been the complexity and high number of procedures in healthcare. Their effort has been on helping to reduce the extent of procedures, having focus on the functionality, appropriateness and availability of procedure for those working in the sharp end. Too many detailed checklists or procedures might undermine the discretion and autonomy of the health professionals working in hospitals [53, 54]. Procedures that support flexibility and adjustment, rather than constraining action and forcing people to make trade-offs, are important for resilient performance [54–57]. Similar results have been seen in previous research in hospitals [53], where a balance between structure and flexibility in standardization and employees' discretion may improve performance and reduce errors.

It is noteworthy to see that the number of mandatory documented procedures required for a quality manual set out in the 2008 version of the ISO 9001 standard (included in this study) was reduced from six to none in the 2015 version. Now it emphasizes flexibility for the use of documented information required for the quality management system [58], and it stresses that ISO 9001 requires a "documented quality management system," not a "system of documents" [59]. We recommend further studies of how this revised version can be conceptualized in a resilience perspective both from the certification body's and the certified organization's points of view. Also, studies from the patient's and next of kin's perspective could be of key value [60–62].

The potential to learn

Two characteristics of ISO 9001 certification in our study are important for an organization's potential to learn: the auditors' opportunities and practices to affect learning during certification processes within organizations; and learning within or between organizational fields. Our assessment of the certification process describes a holistic approach to auditing in which the auditors used their scope of opportunities within the certification regime to share knowledge and make guidance for improvement part of their audits. We also found that auditors empowered local improvement initiatives at the sharp end. A holistic approach to auditing has been shown to be important for internal motivation and commitment to auditing practice and improvement work [18, 48]. The potential to learn is also exposed when auditors take initiatives to transfer experiences and good practices from one auditee to another, within or between organizational fields. That can be between different healthcare organizations and/or between the healthcare organizations and organizations in other sectors that undergo ISO 9001. Bringing these aspects into the certification process may create reflexive spaces where learning processes can take place between the certification body and the certified organization. In other studies, these reflexive spaces have been identified as keys in leveraging resilience into healthcare regulation and management [44].

The centralization of the knowledge that certification bodies provide may be important for resilient performance across an entire healthcare system [54]. Such centralized knowledge might be rules-of-thumb, but they could also be important lessons (challenges or opportunities) transmitted from one healthcare organization to another. In countries with widespread certification, certification bodies might be important mechanisms for spreading local information through their certification processes. The centralized knowledge bases that certification bodies serve and their influence on resilient performance remains to be studied in greater depth.

Limitations

This study explores approaches to certification and discusses how these approaches might affect organizations. We have not studied how all the clauses in the ISO 9001 standard were assessed and translated during the auditing processes. Nor have we included the outcomes of different certification processes. Caution must therefore be taken about the relationship between the certification approach and process and the actual outcomes for the organizations.

According to the logic of representation and generalizability, the number of informants is small. Norway has only four certification bodies, and only a few lead auditors who perform ISO 9001 certifications in healthcare. The characteristics of the strategic participants are highly specific, and therefore strengthen the information power in the study [63]. To make theoretical generalizations from an in-depth case study, a theoretical sampling [36, 37] of a single institution (a certification body) was chosen instead of participants from several institutions.

Our study does not include the views from healthcare professionals and patients. This could add interesting insights to the certification research in a resilience perspective and should be further investigated.

Conclusions

There is no simple way to manage and control quality improvement in healthcare. This study has shown that the auditing approach embedded in ISO 9001 certification expects certification bodies to have structures and systems in place to ensure consistent and objective

certification processes. At the same time the normative references and guidance for auditors give a great deal of latitude for auditors to tailor their audits to context-specific problems, in order to add value to the auditees during certification audits. The members of a certification body perceived and practiced a flexible auditing approach in which both assessment and guidance were interwoven during certification audits. We argue that the ISO 9001 auditing approach described in this study supports resilient performance in healthcare through nurturing, especially the potential to respond and learn. We encourage further research to explore how certification processes contribute to the resilience potentials of anticipation and monitoring.

To date, certification has been questioned in Norway [64]. However, seen from a Norwegian context, there are key aspects from our study to highlight if one would like to scale up and implement a quality management certification in healthcare practice. Since it is not mandatory for a healthcare organization to be quality management certified, the benefits from a flexible approach, where organizations are supported to strengthen the already ongoing quality improvement work, should be emphasized. Moreover, focus on certification as one way of learning, monitoring and transferring experiences should also be highlighted as added value. In addition, the possible ability for certification processes to create reflexive spaces, discussions, and support to keep systems updated, could also contribute to motivating and supporting an upscaling of certification. An upscaling of certification programs needs to follow a thorough review and communication of research evidence on quality improvement processes and outcome from other countries and levels.

Supplementary information

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Additional file 1. Interview guide: Certification body – Lead auditors.

Additional file 2. Interview guide: Certification body – Managers and administrative personnel.

Abbreviations

AAPG: Accreditation Auditing Practice Group; APG: Auditing Practice Group; ISO: International Organization for Standardization; WAI: Work as Imagined; WAD: Work as Done

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Authors' contributions

DTSJ was responsible for the conception and design of the study and undertook acquisition of data as well as analysis and interpretation of data. DTSJ drafted the manuscript. SW and PHL contributed to study design and discussion during data analysis and gave substantial input to the drafting and revision of the manuscript. All authors have approved the final manuscript.

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Availability of data and materials

The data generated and analyzed during this study are not publicly available due to concerns about confidentiality regarding a small sample size and the sensitive nature of the interviews and the certification body. Instead, quotations are included in the text. We will be happy to discuss the findings or the analysis if any questions should arise.

Ethics approval and consent to participate

The research and the procedure for obtaining verbal consent to participate were conducted with the ethical approval of the Norwegian Social Science Data Services (December 16, 2011, Ref. 27543). Clearance for interviews and observations was obtained from the certification body prior to data collection. Interview participants first received an individual written invitation to participate followed by a written and verbal information prior to and at the commencement of recording. All participants provided verbal consent that were documented at the beginning of the recording. The three auditors observed received an individual written information and invitation to participate, and all three responded per e-mail with their consent to participate. Written and verbal information were also given prior to the commencement of observation and all three auditors provided verbal consent. A clearance for observations during the assessment process in the hospitals was obtained from the hospital prior to data collection. Written information about the observation was sent to the hospital and given to the hospital staff taking part during the review process. Before every new review meeting, verbal information about the observation and data collection was given. All the persons from the hospitals that took part in the certification meetings provided verbal consent. All written and verbal information to participants from the certification body and certification participants from the hospitals explained that observations and interviews were part of a research project, that the results would be used anonymously for analysis and publication, and that participation was voluntary and could be terminated at any time.

Consent for publication

Not applicable.

Competing interests

Author Siri Wiig is associate editor for BMC Health Services Research. The authors declare that they have no competing interests.

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Publisher's Note

Appendices

Appendix 1 – Norwegian Social Science Data Services (NSD) – Project approval

Norsk samfunnsvitenskapelig datatjeneste AS
NORWEGIAN SOCIAL SCIENCE DATA SERVICES

NSD

Dag Tomas Sagen Johannesen
Institutt for medie-, kultur- og samfunnsfag
Universitetet i Stavanger
Postboks 8002 Posterminalen
4068 STAVANGER

Vår dato: 16.12.2011 Vår ref: 27543 / 3 / AH Deres dato: Deres ref:

KVITTERING PÅ MELDING OM BEHANDLING AV PERSONOPPLYSNINGER

Vi viser til melding om behandling av personopplysninger, mottatt 01.07.2011. All nødvendig informasjon om prosjektet forelå i sin helhet 14.12.2011. Meldingen gjelder prosjektet:

27543	*Sertifisering og akkreditering i spesialisthelsetjenesten*
Behandlingsansvarlig	*Universitetet i Stavanger, ved institusjonens øverste leder*
Daglig ansvarlig	*Dag Tomas Sagen Johannesen*

Personvernombudet har vurdert prosjektet og finner at behandlingen av personopplysninger er meldepliktig i henhold til personopplysningsloven § 31. Behandlingen tilfredsstiller kravene i personopplysningsloven.

Personvernombudets vurdering forutsetter at prosjektet gjennomføres i tråd med opplysningene gitt i meldeskjemaet, korrespondanse med ombudet, eventuelle kommentarer samt personopplysningsloven/-helseregisterloven med forskrifter. Behandlingen av personopplysninger kan settes i gang.

Det gjøres oppmerksom på at det skal gis ny melding dersom behandlingen endres i forhold til de opplysninger som ligger til grunn for personvernombudets vurdering. Endringsmeldinger gis via et eget skjema, http://www.nsd.uib.no/personvern/forsk_stud/skjema.html. Det skal også gis melding etter tre år dersom prosjektet fortsatt pågår. Meldinger skal skje skriftlig til ombudet.

Personvernombudet har lagt ut opplysninger om prosjektet i en offentlig database, http://www.nsd.uib.no/personvern/prosjektoversikt.jsp.

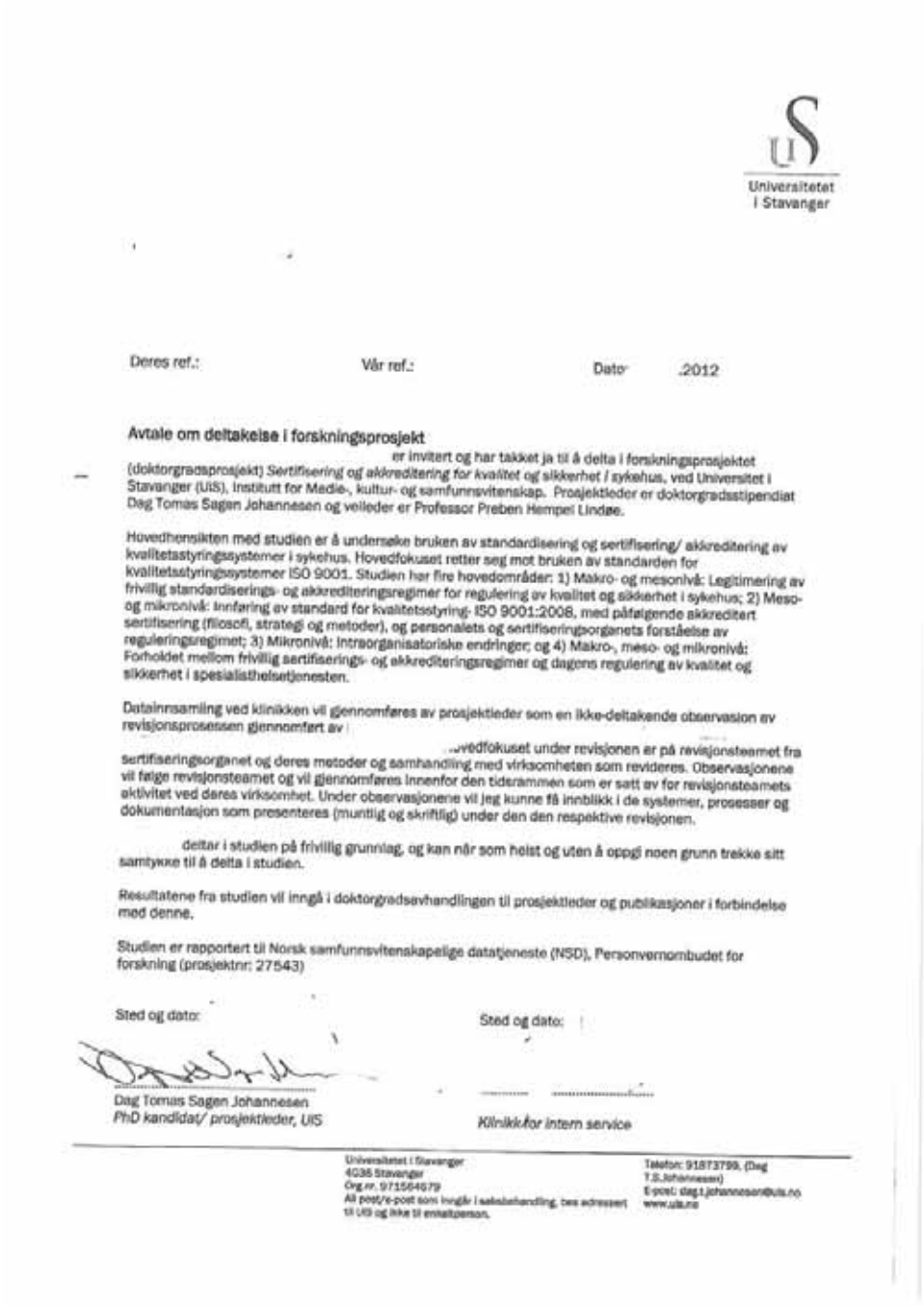
Personvernombudet vil ved prosjektets avslutning, 30.06.2014, rette en henvendelse angående status for behandlingen av personopplysninger.

Vennlig hilsen

Vigdis Namtvedt Kvalheim Åsne Halskau

Kontaktperson: Åsne Halskau tlf: 55 58 89 26
Vedlegg: Prosjektvurdering

Appendix 2 – Example of agreement with organizations



Universitetet
i Stavanger

Deres ref.: Vår ref.: Dato: .2012

Avtale om deltakelse i forskningsprosjekt

er invitert og har takket ja til å delta i forskningsprosjektet (doktorgradsprosjekt) *Sertifisering og akkreditering for kvalitet og sikkerhet i sykehus*, ved Universitet i Stavanger (UiS), Institutt for Medie-, kultur- og samfunnsvitenskap. Prosjektleder er doktorgradsstipendiat Dag Tomas Sagen Johannesen og veileder er Professor Preben Hempel Lindøe.

Hovedhensikten med studien er å undersøke bruken av standardisering og sertifisering/ akkreditering av kvalitetsstyringssystemer i sykehus. Hovedfokuset retter seg mot bruken av standarden for kvalitetsstyringssystemer ISO 9001. Studien har fire hovedområder: 1) Makro- og mesonivå: Legitimering av frivillig standardiserings- og akkrediteringsregimer for regulering av kvalitet og sikkerhet i sykehus; 2) Meso- og mikronivå: Innføring av standard for kvalitetsstyring- ISO 9001:2008, med påfølgende akkreditert sertifisering (filosofi, strategi og metoder), og personalets og sertifiseringsorganets forståelse av reguleringsregimet; 3) Mikronivå: Intraorganisatoriske endringer; og 4) Makro-, meso- og mikronivå: Forholdet mellom frivillig sertifiserings- og akkrediteringsregimer og dagens regulering av kvalitet og sikkerhet i spesialisthelsetjenesten.

Datainnsamling ved klinikken vil gjennomføres av prosjektleder som en ikke-deltakende observasjon av revisjonsprosessen gjennomført av

...vedfokuset under revisjonen er på revisjonsteamet fra sertifiseringsorganet og deres metoder og samhandling med virksomheten som revideres. Observasjonene vil følge revisjonsteamet og vil gjennomføres innenfor den tidsrammen som er satt av for revisjonsteamets aktivitet ved deres virksomhet. Under observasjonene vil jeg kunne få innblikk i de systemer, prosesser og dokumentasjon som presenteres (muntlig og skriftlig) under den den respektive revisjonen.

deltar i studien på frivillig grunnlag, og kan når som helst og uten å oppgi noen grunn trekke sitt samtykke til å delta i studien.

Resultatene fra studien vil inngå i doktorgradsavhandlingen til prosjektleder og publikasjoner i forbindelse med denne.

Studien er rapportert til Norsk samfunnsvitenskapelige datatjeneste (NSD), Personvernombudet for forskning (prosjektnr: 27543)

Sted og dato: Sted og dato:

Dag Tomas Sagen Johannesen
PhD kandidat/ prosjektleder, UiS

Klinikkfor intern service

Universitetet i Stavanger
4036 Stavanger
Org.nr. 971564579
All post/e-post som inngår i saksbehandling, bes adressert til UiS og ikke til enkeltperson.

Telefon: 91873799. (Dag T.S.Johannesen)
E-post: dag.t.johannesen@uis.no
www.uis.no

Appendix 3 – Invitation to participate: Participants

Universitetet i Stavanger

Til potensielle informanter

Deres ref.: Vår ref.: Dag T.S. Johannesen Dato: Des. 2012

Forespørsel om å delta i forskningsprosjektet "Sertifisering og akkreditering for kvalitet og sikkerhet i sykehus"

Dette er et spørsmål til deg om å delta i en doktorgradsstudie ved Universitetet i Stavanger. Målsettingen med studien er å bidra til mer kunnskap om hvordan sertifisering og akkrediteringsordninger i sykehus brukes og forstås i arbeidet med kvalitet og sikkerhet i sykehus.

Bakgrunn og hensikt
Sykehus er institusjoner med store og komplekse organiseringer og systemer. Det er derfor helt avgjørende at den daglige organiseringen og driften blir utført og styrt med fokus på faglig forsvarlighet, kvalitet og sikkerhet. For å holde kontroll med at kravene til en forsvarlig tjeneste blir ivaretatt, er det i Norge etablert en lovpålagt internkontrollsystem. Det vil si at sykehusene selv i stor grad er pålagt å føre kontroll med egen organisering og virksomhet. Innholdet i internkontrollen blir i denne sammenheng er verktøy for å sikre systematisk planlegging, organisering, utførelse og vedlikehold av aktivitetene i henhold til gjeldende lover og forskrifter.

I Norge har flere sykehus og avdelinger frivillig tatt i bruk internasjonalt anerkjente standarder i arbeidet med kvalitet og sikkerhet. ISO 9001:2008, er et eksempel på en slik standard. Et sentralt argument for bruken av denne standarden har blant annet vært for å iverksette og implementere kravene i internkontrollen. De fleste av disse prosessene følges opp ved at en ekstern aktør kontrollerer at virksomheten tilfredsstiller kravene i standarden. Hvis virksomheten tilfredsstiller kravene, bevitnes dette ved at virksomheten tildeles et sertifikat (bevis). En slik godkjennelse er tidsbegrenset, og det vil være behov resertifisering hvis virksomheten vil opprettholde sertifikatet.

Internasjonalt er sertifisering og akkreditering i sykehus utbredt, og i enkelte land lovpålagt. Sertifisering og akkreditering er systemer som har til hensikt å påvirke til bedre kvalitet og sikkerhet. Ulike forståelse og implementering av standardene kan føre til ulike effekter i virksomheten. Studien har et perspektiv knyttet til hvordan verdier og normer i samfunnet påvirker sykehusene og andre aktører i deres arbeid for å sikre og kontrollere kvalitet og sikkerhet. Sykehusenes ulike praksiser vil igjen kunne påvirke de ulike aktørene i virksomheten og enkeltpersoners meninger og mulighet til å handle. Denne studien følger blant annet bruken av ISO 9001:2008 i sykehus.

Hensikten med studien:
- Vurdere hvordan og hvorfor sertifisering og akkreditering er forankret i sykehus.
- Studere forståelsen av sertifisering og akkreditering.
- Studere hvordan sertifisering og akkreditering møter dagens krav om kontroll.
- Bidra til å forklare ulike aspekter som kan ha betydning for sertifiserings- og akkrediteringssystemer.

Det samfunnsvitenskapelige fakultet
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Studien retter seg mot sentrale myndigheter og aktører som kan påvirke og kontrollere praksisen ved de ulike sykehusene. Videre vil ledere og personale som er eller har vært involvert i sertifiseringsprosesser inkluderes. Studien vil også inkludere private virksomheter og konsulenter som bidrar i utviklingen av standardene og/eller som utøver kontroll med sykehusene (sertifiserer og/ eller akkrediterer).

Hva innebærer studien
Din forståelse og erfaring med sertifiserings- eller akkrediteringssystemer er viktige, både i forhold til din rolle og i forhold til institusjonen du er en del av. Det er derfor ønskelig med et individuelt intervju. Intervjuet vil hovedsakelig være mellom 45 min og halvannen time. Det er ønskelig at intervjuene gjennomføres på eller i nær tilknytning til din arbeidsplass. Intervjuet vil tas opp på en digital lydopptaker og det er kun undertegnede som vil være tilstede. Det er også mulig at det vil bli aktuelt å gjennomføre en oppfølgingsundersøkelse innenfor prosjektperioden. Du vil da bli kontaktet på nytt ved en senere anledning.

Prosjektslutt er berammet til juni 2014.

Hva skjer med informasjonen om deg
Datamaterialet oppbevares konfidensielt. Navneliste oppbevares trygt og separat fra intervjutranskripsjoner og lydopptak. Det er ingen andre enn min veileder, professor Preben Hempel Lindøe, og jeg som vil få tilgang til de personidentifiserbare opplysningene. Det vil bli benyttet elektronisk bearbeidingen og analyse av de innsamlede data. Ved prosjektslutt vil alle navnelister, lydopptak (digitale lydfiler) og intervjutranskripsjoner bli slettet, og alle øvrige data vil anonymiseres. Publikasjoner fra denne studien vil være anonymiserte.

Frivillig deltakelse
Det er frivillig å delta i studien. Du kan når som helst og uten å oppgi noen grunn trekke ditt samtykke til å delta i studien. Hvis du sier ja til å delta i studien, har du rett til å få innsyn i hvilke opplysninger som er registrert om deg. Du har videre rett til å få korrigert eventuelle feil i de opplysningene vi har registrert. Dersom du senere ønsker å trekke deg fra studien kan du når som helst kontakte undertegnede.

Forskningsprosjektet er meldt til Personvernombudet for forskning, Norsk samfunnsvitenskapelig datatjeneste A/S. Prosjektet er finansiert av Forskningsrådet gjennom den ordinære tildelingen til Universitetet i Stavanger.

Ta gjerne kontakt hvis du har spørsmål eller ønsker å bli informert om resultatene fra undersøkelsen når disse foreligger.

Med vennlig hilsen

Dag Tomas Sagen Johannesen
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Samtykkeerklæring:
Jeg har mottatt skriftlig informasjon og er villig til å delta i studien.

Signatur ..... Telefonnummer .....

Appendix 4 – Interview: Information to participants

Intervjuguide – Informasjon om prosjektet

"Sertifisering og akkreditering for kvalitet og sikkerhet i sykehus"

Bakgrunn og hensikt
Sykehus er institusjoner med store og komplekse organiseringer og systemer. Det er derfor helt avgjørende at den daglige organiseringen og driften blir utført og styrt med fokus på faglig forsvarlighet, kvalitet og sikkerhet. For å holde kontroll med at kravene til en forsvarlig tjeneste blir ivaretatt, er det i Norge etablert en lovpålagt internkontrollsystem (Forskrift om internkontroll).

Internasjonalt er sertifisering og akkreditering i sykehus utbredt, og i enkelte land lovpålagt. Sertifisering og akkreditering er systemer som har til hensikt å påvirke til bedre kvalitet og sikkerhet, og er basert på anerkjente standarder. Et eksempel på dette er ISO 9001:2008, som er en internasjonal standard for kvalitetsstyring. I Norge har flere sykehus og avdelinger frivillig tatt i bruk denne. Ulike forståelse og implementering av standarden kan føre til ulike effekter i virksomheten.

Hensikten med studien:

- Vurdere hvordan sertifisering og akkreditering er forankret i sykehus
- Hvordan sertifisering og akkreditering møter dagens krav om kontroll.
- Studere forståelsen av sertifisering og akkreditering.
- Bidra til å forklare ulike aspekter som kan ha betydning sertifisering og akkrediteringssystemer.

Studien retter seg mot sentrale myndigheter og aktører som kan påvirke og kontrollere praksisen ved de ulike sykehusene. Videre vil ledere og personale som er eller har vært involvert i sertifiseringsprosesser inkluderes. Studien vil også inkludere private virksomheter og konsulenter som bidrar i utviklingen av standardene og/eller som utøver kontroll med sykehusene (sertifiserer og/ eller akkrediterer).

Veileder professor Preben Hempel Lindøe

Hva innebærer studien
Din forståelse og erfaring med sertifiserings- eller akkrediteringssystemer er viktige, både i forhold til din rolle og i forhold til institusjonen du er en del av. Intervjuet vil hovedsakelig vare mellom en og halvannen time. Intervjuet vil tas opp på en digital lydopptaker. Det er også mulig at det vil bli aktuelt å gjennomføre en

oppfølgingsundersøkelse innenfor prosjektperioden. Du vil da bli kontaktet på nytt ved en senere anledning. Prosjektslutt er berammet til juni 2014.

Hva skjer med informasjonen om deg
Datamaterialet oppbevares konfidensielt. Navneliste oppbevares trygt og separat fra intervjutranskripsjoner og lydopptak. Det er ingen andre enn min veileder, professor Preben Hempel Lindøe, og jeg som vil få tilgang til de personidentifiserbare opplysningene. Det vil bli benyttet elektronisk bearbeidingen og analyse av de innsamlede data. Ved prosjektslutt vil alle navnelister, lydopptak (digitale lydfiler) og intervjutranskripsjoner bli slettet, og alle øvrige data vil anonymiseres. Publikasjoner fra denne studien vil være anonymiserte.

Frivillig deltakelse
Det er frivillig å delta i studien. Du kan når som helst og uten å oppgi noen grunn trekke ditt samtykke til å delta i studien. Hvis du sier ja til å delta i studien, har du rett til å få innsyn i hvilke opplysninger som er registrert om deg. Du har videre rett til å få korrigert eventuelle feil i de opplysningene vi har registrert. Dersom du senere ønsker å trekke deg fra studien kan du når som helst kontakte undertegnede.

Forskningsprosjektet er meldt til Personvernombudet for forskning, Norsk samfunnsvitenskapelig datatjeneste A/S. Prosjektet er finansiert av Forskningsrådet gjennom den ordinære tildelingen til Universitetet i Stavanger.

Appendix 5 – Interview guide: Hospital personnel

Intervju helseforetak: Ledere, mellomledere, kvalitetsrådgivere
Del 1: Om informanten og organisasjonen og deres tilnærming til systemer for styring av kvalitet og sikkerhet
Informanten Stilling/ rolle Bakgrunn og tidligere erfaring **Organisasjon / avdeling** Organisering Generelle oppgaver, ansvar, mandat **Kan du fortelle om organisasjonens / avdelingens arbeid og ansvar i forhold til kvalitets og sikkerhetssystemer?** Hva er organisasjonens / avdelingens ansvar i forhold til kvalitet og sikkerhet? Hva oppfatter du at organisasjonen legger i kvalitet og sikkerhet? Hvordan tilnærmer organisasjonen seg arbeidet med kvalitet og sikkerhet? Hva er de viktigste tiltakene dere har for å sikre kvalitet og sikkerhet? **Kan du fortelle om din rolle og ditt ansvar i forhold til kvalitet og sikkerhet i organisasjonen?** Hva legger du i kvalitet og sikkerhet relatert til sykehus? Hva er din tilnærming til kvalitet og sikkerhet i sykehus? Hvilke forventninger stilles til din rolle i kvalitets og sikkerhetsarbeidet?
Del 2: Om sertifiseringsprosessen og/ eller vurdering og utvikling av sertifiserings- / akkrediteringsregimer
Kan du tenke tilbake på da dere begynte å snakke om sertifisering av kvalitetssystemer, og fortelle om dette? Hvem var det som først introduserte ideen? Hvorfor ønsket man ISO standardisering og sertifisering? Hvem var involvert og pådrivere i prosessen? Hva syntes du om tanken på å sertifiseres? Kjente du til ISO standarder eller sertifisering fra før? Hvorfor tror du at nettopp ISO standarden ble valgt? Hva er hovedhensikten med ISO standarden? Hvilke forventninger hadde du da dere startet med sertifiseringsprosessen? Hva oppfattet du at var andres forventninger til sertifiseringen? **Hva skjedde videre i sertifiseringsprosessen?** Hvordan gikk dere fram?

Intervju helseforetak: Ledere, mellomledere, kvalitetsrådgivere

Hvordan tok dere i bruk standarden?
Hvem var involvert og hvordan forankret dere prosessen?
- Internt (toppledelsen, mellomledelse, kvalitetsavdeling, profesjoner, kollegaer…)
- Eksternt (sertifiseringsorgan, regionalt helseforetak…)

Hvordan var du involvert?
Hvem oppfatter du at har vært nøkkelaktører i prosessen?
Hva var den viktigste kompetansen dere måtte ha i prosessen?
Var det noen viktige vendepunkt?
Var det noen overraskelser?
Møtte dere noe motstand i prosessen?
Møtte dere andre problemer og utfordringer?
Hvordan håndterte dere motstand og utfordringer?
Hva kunne dere evt. ha gjort annerledes for å unngå dette?
Hvis dere skulle ha gjort hele prosessen om igjen, hva ville du ha lagt vekt på?

Kan du fortelle litt om sertifiseringsorganets rolle og metode og deres forhold til disse?

Hvem gjennomførte revisjoner?
Hvordan var teamet satt sammen?
Hvordan ble revisjonene gjennomført?
Hvilke metoder brukte de for å kommunisere kravene i standarden?
Hvordan gikk de frem for å vurdere/ måle organisasjonen etter kravene i standarden?
Hvordan ble godkjenningen gitt?
Hvordan oppfatter du at revisjonsteamet så på sin oppgave og rolle?
- Kontroll, veiledning, læring…

Hvordan ser en helt vanlig dag ut for deg?

Hvis du tenker tilbake på en av disse "vanlige" dagene i tiden før standardiserings og sertifiseringsarbeidet startet, hva er eventuelt annerledes i dag?
Hvordan oppfatter du at standardiseringen eventuelt har hatt innvirkning på ditt arbeid?
Hvordan oppfatter du at standardiseringen eventuelt har hatt innvirkning på organisasjonen?
På hvilke områder har det eventuelt ført til endringer?

Kan du fortelle litt om hva dere har oppnådd og hvordan dere vil følge dette opp videre?

Hva er det viktigste dere har oppnådd med standardiserings og sertifiseringsprosessen?

Intervju helseforetak: Ledere, mellomledere, kvalitetsrådgivere
Er det noen tydelige fordeler og ulemper ved at dere nå er sertifisert? - økonomisk, legitimitet, synliggjøring av kvalitetssystemer… Hvordan tror du at andre oppfatter organisasjonen etter sertifiseringen? Hvis du skulle ha gitt noen råd til noen som ønsket å starte med sertifiseringsprosesser, hva ville du ha lagt vekt på da?
Del 3: Om standardisering, sertifisering og akkreditering, og regulering av kvalitet og sikkerhet i sykehus
Kan du fortelle litt om hva du tenker og forstår med sertifiserings og/ eller akkrediteringssystemer i sykehus? - Tredjepartskontroll - Reguleringsregime - Kontroll, revisjon, evaluering - Veiledning - Læring, utvikling - Aktører, Roller, funksjoner, personer - Ledelses- og styringsverktøy Hvis du skulle ha beskrevet for en avdeling i et sykehus hensikten med sertifisering av kvalitetssyringssystemer, hva ville du ha lagt vekt på? Hva oppfatter du at er de viktigste argumentene for etablering av sertifiseringsregimer? Hva oppfatter du at er de viktigste argumentene mot etablering av sertifiseringsregimer? **Hvordan oppfatter du at sertifiseringsordning for kvalitetsstyring forholder seg til dagens regulering og kontroll av kvalitet og sikkerhet i sykehus?** - Internkontroll - Krav i lov og forskrifter - Fokuset på faglig forsvarlighet - Fokuset på kvalitet og sikkerhetsarbeid **Hvordan oppfatter du sertifisering som en måte å regulere kvalitet og sikkerhet på i fremtiden?**
Vi har nå snakket om kvalitet og sikkerhet relatert til standardisering, sertifisering og sertifiseringsprosessen, er det noe mer du vil legge til om dette som du ikke har fått sagt? Har du noen forslag til personer i deres organisasjon som du tror er viktige og sentrale at jeg snakker med videre i studien?

Appendix 6 – Interview guide: Certification body - lead auditors

Interview guide: Certification body – Lead auditors

Part 1: About the informant and the organization and their approach to certification in hospitals according to ISO 9001

The informant

Position

Background and previous experience

Experience from audit work

What is your role and responsibilities related to hospital certification?

What do you believe the certification body consider as your most important tasks when it comes to certification?

Can you very briefly explain what certification according to ISO 9001 is?

Think back to your last audit in a hospital (health institution).

What do you see as your most important tasks during the audit?

Control, guidance, learning

What do you perceive as your most crucial background and basis that enables you to carry out audits in hospitals?

- Professional background
- Another background
- Personal characteristics
- The standard
- Auditing system

Can you tell about how you are followed up by the certification body to be able to carry out your tasks as a lead auditor?

Imagine an axis where each extreme represents a different approach to auditing practice. One outer edge represents control, and the other represents guidance/advice. In what direction do you mainly feel that your auditing practice is going?

Can you tell more about what you think and understand about hospital certification?

- Third party control
- Regulatory Regime
- Control, audit, evaluation
- Guidance

Interview guide: Certification body – Lead auditors

- Learning, development
- Actors, Roles, functions, persons
- Management and management tools

(If you worked for the organization then) Can you think back to when you started talking about certification of quality systems in hospitals, and tell about that?

Who first introduced the idea?
Why was hospital certification considered?
Who was involved and drivers in the process?
What did you think about the idea of certification/accreditation in the health sector?

What do you think is the reason why the certification body conducts hospital certification?

Part 2: About the certification process and/or assessment and development of certification regimes

Think back on one of your latest certification audits in a hospital. Can you tell about how you planned and conducted the audit and what you emphasized during the process?

How were you involved?
How was the team put together?
How did you proceed / what methods did you use?
What methods do you use to communicate the requirements of the standard?
When you talked about certification in the opening meeting, what did you emphasize?
Whom do you perceive to be key players in the certification process?
What was the most crucial skill you needed in the process?
Were there any surprises / turning points?
Did you meet any resistance during the process?
Did you face other problems or challenges?
How did you handle resistance or challenges?
What could you possibly have done differently to avoid this?
If you were to do the whole process again, what would you have emphasized?

Can you tell about what you think the hospital has achieved through the certification process?

What are the most important achievements for the hospital from the standardization and certification process?
Are there any clear advantages and disadvantages for the certified hospital?
economic, legitimacy, visibility of quality systems...

Interview guide: Certification body – Lead auditors
How do you think others perceive the hospital after the certification? **Can you tell about something that has surprised you after you started with hospital certification?** **If you were to give some advice to someone who wants to start with certification processes, what would you have emphasized then?**
Part 3: On certification and regulation of quality and safety in hospitals
When you perform certification audits in hospitals and are asked the question "what is the purpose of certification?", What do you answer then? What do you think are the most important arguments for hospital certification? What do you think are the most important arguments against hospital certification? **A common argument for ISO 9001 certification is that the certificate itself is not an important matter, but that a certification process is a tool for continuous quality improvement and for operationalizing the requirements in the internal control regulation. Can you comment on this argument?** **How do you perceive that ISO 9001 certification relates to the current regulation on quality and safety in hospitals?** - Internal control regulation - Requirements in law and regulations - The focus on professional soundness - The focus on quality and safety work **It has been considered whether some form of certification or accreditation of hospitals should be required by law in Norway. How do you think that your ISO 9001 certification activities may be suitable in this context?** How do you understand certification as a way to regulate quality and safety in hospitals in the future? **How do you understand the Certification body's role and responsibilities if adverse events occur at a hospital/ward that you have certified?** How do you think you would understand this responsibility if the certifications you conducted were required by law? **If you should highlight some essential improvement points for hospitals certification practices, what would you emphasize?**

Interview guide: Certification body – Lead auditors
If you should propose any changes to the ISO 9001 standard related to the health service, what would you emphasize?
We have now talked about quality and safety related to certification and the certification process, is there anything more you want to add that you have not told?

Appendix 7 – Interview guide: Certification body – managers and administrative personnel

Interview guide: Certification body – Managers and administrative personnel

Part 1: About the informant and the organization and their approach to certification in hospitals according to ISO 9001

The informant
Position
Background and previous experience
Experience from audit work

What is your role and responsibilities related to system certification?

Can you very briefly explain what certification according ISO 9001 is?
Does xxx have a specific definition of certification, and do you know this?
What do you think is the most important thing about the ISO 9001 standard?

Imagine an ordinary revision according to ISO 9001...
Can you tell about the most important tasks for a lead auditor in relation to certification?
Control, guidance, learning...
What do you perceive as your most crucial background and basis that enables you to carry out audits in hospitals?

- Professional background
- Another background
- Personal characteristics
- The standard
- Auditing system

Can you tell about what xxx does for lead auditors and technicians to be able to carry out the best possible certifications?

Imagine an axis where each extreme represents a different approach to auditing practice. One outer edge represents control, and the other represents guidance/advice. In what direction do you mainly feel that your auditing practice is going?

Can you tell more about what you think and understand about hospital certification?

- Third party control
- Regulatory regime

Interview guide: Certification body – Managers and administrative personnel

- Control, audit, evaluation
- Guidance
- Learning, development
- Actors, Roles, functions, persons
- Management and management tool

(If you worked for the organization then) Can you think back to when you started talking about certification of quality systems in hospitals, and tell about that?

Who first introduced the idea?
Why was hospital certification considered?
Who was involved and drivers in the process?
What did you think about the idea of certification/accreditation in the health sector?
What did you perceive to be the health sector's expectations for certification?

What do you think is the reason why the certification body conducts hospital certification?

Part 2: About the certification process and / or assessment of certification regimes

Think of an ordinary certification/audit process according to ISO 9001, preferably one you have been involved in. Can you tell about the steps in the process?

Are you usually involved in the process?
How is the team put together?
What methods do you use / how do you proceed?
What methods do you use to communicate the requirements of the standard?
Whom do you perceive to be key players in the certification work?
What is the most important competence you need in the process?
Do you know of any typical surprises/turning points?
If you encounter resistance, what are its characteristics?
Do you often face other problems and challenges?

Can you tell us a bit about what makes your ISO 9001 certification processes reliable?

What do you think the hospitals see as important for certifications to be reliable?

Can you tell about what you think hospitals/companies achieve through certification?

What do you think are the most important achievements?

Interview guide: Certification body – Managers and administrative personnel

Are there any clear advantages and disadvantages for hospitals/companies being certified?
economic, legitimacy, visibility of quality systems…
How do you think others perceive hospitals/companies after the certification?

Can you tell about something that has surprised you after you started with hospital certification?
What do you think is special about certification in hospitals in relation to other sectors?

If you were to give some advice to someone who wants to start with certification processes, what would you have emphasized then?

Part 3: On certification and regulation of quality and safety in hospitals

When you are on an assignment for xxx and are asked the question "what is the purpose of certification?", What do you answer then?
What do you think are the most important arguments for hospital certification?
What do you think are the most important arguments against hospital certification?

A common argument for ISO 9001 certification is that the certificate itself is not an important matter, but that a certification process is a tool for continuous quality improvement and for operationalizing the requirements in the internal control regulation. Can you comment on this argument?

How do you perceive that certification (according to ISO 9001) relates to the current regulation and control of quality and safety in hospitals?

- Internal control regulation
- Requirements in law and regulations
- The focus on risk management
- The focus on professional soundness
- The focus on quality and safety work

It has been considered whether some form of certification or accreditation of hospitals should be required by law in Norway. How do you think that your ISO 9001 certification activities may be suitable in this context?
How do you understand certification as a way to regulate quality and safety in hospitals in the future?

How do you understand the Certification body's role and responsibilities if adverse events occur at a hospital/ward that you have certified?

Interview guide: Certification body – Managers and administrative personnel
How do you think you would understand this responsibility if the certifications you conducted were required by law? **It is often pointed out that there is a lack of research that shows that certification affects quality in the health sector. Can you comment on this argument?** **If you should highlight some essential improvement points for hospitals certification practices, what would you emphasize?**
We have now talked about quality and safety related to certification and the certification process, is there anything more you want to add that you have not told?

Appendix 8 – Observation: Information to hospital personnel participating in certification audits

Universitetet
i Stavanger

Til deltakere ved revisjon
– 2012.

Deres ref.: Vår ref.: Dag T.S. Johannesen Dato: 2012

Informasjon om observasjonsstudie (forskningsprosjekt) i forbindelse med revisjon ved i

I forbindelse med revisjonen som gjennomføres i vil det foregå en uavhengig observasjon av planleggings- og revisjonsprosessen. Observasjonen er en del av doktorgradsprosjektet "Sertifisering og akkreditering for kvalitet og sikkerhet i sykehus", og er godkjent av ledelsen ved sykehuset. Du kan når som helst før og under revisjonen reservere deg fra å delta i studien ved å ta kontakt med meg, Dag Tomas Sagen Johannesen, eller din nærmeste leder. Jeg vil også informere om studien ved oppstart av revisjonen.

Hovedmålsettingen med studien er økt kunnskap om hvordan sertifisering og akkrediteringsordninger i sykehus etableres og brukes i arbeidet med kvalitet og sikkerhet.

Bakgrunn og hensikt med studien
Sykehus er institusjoner med store og komplekse organiseringer og systemer. Det er derfor helt avgjørende at den daglige organiseringen og driften blir utført og styrt med fokus på faglig forsvarlighet, kvalitet og sikkerhet. For å holde kontroll med at kravene til en forsvarlig tjeneste blir ivaretatt, er det i Norge etablert en lovpålagt internkontrollsystem (Forskrift om internkontroll). Det vil si at sykehusene selv i stor grad er pålagt å føre kontroll med egen organisering og virksomhet. Det finnes flere ulike internasjonalt anerkjente standarder for kvalitetsstyring, som i hovedsak innbefatter mange av de samme kravene som internkontrollen. Implementeringen av standardene følges gjerne opp ved at en ekstern aktør kontrollerer, gjennom en sertifiserings- eller akkrediteringsprosess, at virksomheten tilfredsstiller kravene i standarden.

Internasjonalt er sertifisering og akkreditering for regulering av sykehus anerkjent, og i enkelte land lovpålagt. I Norge er det varierende bruk av sertifisering basert på internasjonale kvalitetsstandarder, og er i sin helhet fortrinnsvis basert på frivillige ordninger. Dette forskningsprosjektet følger implementeringen og bruken av ISO 9001:2008 i sykehus. Ulik forståelse og implementering av standardene kan føre til ulike effekter i virksomheten.

Hensikten med studien:
- Vurdere hvordan og hvorfor sertifisering og akkreditering er forankret i sykehus.
- Studere forståelsen av sertifisering og akkreditering.
- Studere hvordan sertifisering og akkreditering møter dagens krav om kontroll.
- Bidra til å forklare ulike aspekter som kan ha betydning for sertifiserings- og akkrediteringssystemer.

Det samfunnsvitenskapelige fakultet
Institutt for medie-, kultur- og samfunnsfag

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Hvorfor inkludere · i studien?
Sykehuset . Dette gjør det mulig å studere sertifisering og sertifiseringsprosessen i et retrospektivt perspektiv, hvor ulike erfaringer, forståelser og meninger har etablert seg i organisasjonen over noe tid.

Hvorfor observere revisjonsprosessen?
Sertifiseringsorganet, , i aktør i oversettelsen og forståelsen av ISO standarden. De er også et uavhengig organ som kan være viktige aktører i måten vi generelt utvikler og kontrollerer kvalitet og sikkerhet på ved sykehusene i Norge. Hovedfokuset under observasjonen vil være på revisjonsteamet og deres metoder og samhandling med virksomheten som revideres.

Om observasjonen
Observasjonen vil gjennomføres av undertegnede som en ikke-deltakende (passiv) observasjon, innenfor den tidsrammen som er satt av for revisjonsteamets aktivitet ved din virksomhet. Under observasjonene vil jeg kunne få innblikk i de systemer, prosesser og dokumentasjon som presenteres (muntlig og skriftlig) under den den respektive revisjonen.

Hva skjer med informasjonen om deg
Det vil tas håndskrevne notater under observasjonen. Det vil ikke registreres navn i forbindelse med observasjonsstudien. Indirekte personidentifiserbare opplysninger som for eksempel roller og tilknytning til virksomhet vil oppbevares konfidensielt. Det er ingen andre enn min veileder, professor Preben Hempel Lindøe, og jeg som vil få tilgang til de indirekte personidentifiserbare opplysningene. Det vil bli benyttet elektronisk bearbeidingen og analyse av de innsamlede data. Ved prosjektslutt vil alle data anonymiseres. Publikasjoner fra denne studien vil være anonymiserte.

Frivillig deltakelse
Det er frivillig å delta i studien. Du kan når som helst og uten å oppgi noen grunn reservere deg fra å delta i studien, ved å ta kontakt med undertegnede eller evt. din nærmeste leder. Hvis du velger å reservere deg vil jeg som observatør da **ikke** delta under den aktuelle perioden du er involvert i revisjonen.

Hvis du deltar i studien, har du rett til å få innsyn i hvilke opplysninger som er registrert om deg. Du har videre rett til å få korrigert eventuelle feil i de opplysningene vi har registrert. Dersom du senere ønsker å trekke deg fra studien kan du når som helst kontakte undertegnede.

Forskningsprosjektet er meldt til Personvernombudet for forskning, Norsk samfunnsvitenskapelig datatjeneste A/S, prosjektnr.: 27543. Prosjektet er finansiert av Forskningsrådet gjennom den ordinære tildelingen til Universitetet i Stavanger.

Slutten på forskningsprosjektet er berammet til juni 2014.

Ta gjerne kontakt hvis du har noen spørsmål i forbindelse med studien, eller ønsker å reservere deg.

Med vennlig hilsen

Dag Tomas Sagen Johannesen
Doktorgradsstipendiat i Risikostyring og samfunnssikkerhet

Mob: 91873799
E-post: dag.t.johannesen@uis.no

Appendix 9 – Observation guide

Observasjon av revisjonsleder - revisjon for ISO 9001 sertifisering i sykehus

Om informasjon og samtykke under observasjon

Til revisjonsledere og andre i revisjonsteamet:
Før revisjonsstart:

- Gjennomgå informasjon sendt i forkant av observasjonen
- Formålet med studien
- Observasjonsfokus på revisjonsleder
- Info og avklaring om observatørrollen
    - Observerer og følger revisjonsleder
    - Avklare rolle og kommunikasjon under revisjonsprosessen
    - Observere uten aktiv deltakelse i revisjonsintervjuer / -samtaler med organisasjonen
    - Tar håndskrevne notater
- Hva skjer med dataene fra observasjonene
- Anonymitet og konfidensialitet
- Samtykke til deltakelse. Samtykke skal bekreftes **aktivt** (muntlig, evt. skriftlig) av alle i revisjonsteamet

Til deltakere fra organisasjonen:
Ved åpningsmøtet:
Felles informasjon til alle deltakere

- Gjennomgå informasjon til deltakerne som sendt i forkant
- Tilgjengeliggjør / del ut informasjonsskriv
- Formålet med studien
- Observasjonsfokus er på revisjonsleder
- Anonymitet og konfidensialitet
- Samtykke til deltakelse. Hvis deltakere ikke samtykker til observasjon, skal observatør forlate det aktuelle revisjonsintervjuet / -møtet.
- Spørsmål om samtykke tas opp i starten av alle revisjonsintervju / -møter

Ved revisjonsintervjuer / -møter med personell

- I starten av revisjonsintervjuet: Forsikre om at informasjon om studien og observasjon under intervjuet / møtet er mottatt og forstått
    - Obs: - personer som ikke deltok på åpningsmøtet
- Samtykke til deltakelse. Samtykke skal bekreftes **aktivt** (muntlig, evt. skriftlig) av alle deltakerne i revisjonsintervjuet / -møtet

Om revisjonsleder og sammensetning av revisjonsteam

Revisjonsteam:

Observasjon av revisjonsleder - revisjon for ISO 9001 sertifisering i sykehus

- Antall i teamet
- Roller i teamet
- Bakgrunn

Revisjonsleder:

- Bakgrunn
- Erfaring fra revisjonsarbeid

Om deltakere og plassering av revisjonsintervju / -møtet

- Hvilken avdeling / enhet / funksjon
- Hvilket personell deltar (ledere/ mellomledere/ annet personell)
- Antall deltakere
- Plassering for intervju

Omfang, hensikt og hovedfokus for revisjonen

Hva er revisjonsomfanget definert i programmet for sertifiseringsrevisjonen?

Hva retter revisoren fokuset / omfanget på?

- Ledelsens ansvar og håndtering av kvalitetssystemet
- Resurshåndtering
- Levering av tjenester
- Måling / analyser
- Forbedring
- Risikohåndtering / risikovurdering
- Dokumentgjennomgang
- Interne revisjoner

Hva er den overordnede retningen og tilnærmingen i revisjonsintervju / -møter:
Samsvarsvurdering/ kontroll **---** Veiledning /rådgivning / forbedring

Gjennomføring av revisjonsintervju / -møter

Tilnærming til intervjuspørsmål:
Strukturert **---** Opportunistisk

- Forhåndsdefinerte spørsmål
- Åpne – Lukkede spørsmål
- Spørsmål – svar tilnærming
- Samtale / dialog
- Hvem leder / fører samtalen

Observasjon av revisjonsleder - revisjon for ISO 9001 sertifisering i sykehus

- Starter direkte på spørsmål – Innleder til samtale
- Digitale hjelpemidler: eks. projector

Tilnærming til dokumentasjon- / notering av svar og funn
Skriftlig **--** Hukommelse

- Bruker forhåndsdefinert skjema for
- Noterer på «tomt» ark
- Noterer systematisk fortløpende
- Noterer sporadisk underveis
- Noterer etter intervju

Fokus på krav og evt. mangler og avvik
- Viser til krav
- Viser til mangler
- Etterspør dokumentasjon
- Kontrollspørsmål

Hva i organisasjonen rettes fokuset for mangler og avvik mot?
Hvilke krav henvises til som grunnlag for mangler og avvik?
- til ISO 9001 standarden
- til andre krav (interne/eksterne)

Fokus på forbedring / veiledning
- Veileder
- Gir råd
- Viser til potensielle forbedringsområder
- Viser til ulike løsningsforslag

Hva i organisasjonen rettes fokuset for forbedring og veiledning mot?
Hva henvises til som grunnlag for potensialet for forbedring?

Andre elementer som kan ha betydning for intervjusituasjonen
- Vendepunkter
- Overraskelser

Signaler/ ytringer relatert til deltakernes motivasjon for revisjon / sertifisering
- Motstand / negative ytringer
- Ønske / positive ytringer

Hvordan brukes ISO 9001 standarden under intervjuer/ møtet?
- Viser og refererer direkte til krav i standarden
- Refererer til standarden generelt

Observasjon av revisjonsleder - revisjon for ISO 9001 sertifisering i sykehus
- Refererer ikke/ i liten grad til standarden **Henvisning til andre standarder / reguleringer** - ISO standarder - Internkontrollforskriften - Krav i lov og forskrifter - Kravet om faglig forsvarlighet **Henvisning til revisjonserfaringer med andre organisasjoner** - Andre sykehus - Andre bransjer
Avslutning
- Stille oppklarende spørsmål til revisjonsledere - Avklare eventuelle misforståelser

The end