Comparison of external evaluation policies and regulations for quality improvement and safety of health services in Norway and the United States

Journal:	*International Journal of Health Governance*
Manuscript ID	ijhg-06-2023-0065.R1
Manuscript Type:	Original Article
Keywords:	Patient safety < Health Service Quality Assurance, Accreditation < Health Service Quality Assurance, Health care quality < Health Service Quality Assurance, Audit < Health Service Quality Assurance, Continuous quality improvement < Health Service Quality Assurance, Adverse events or outcomes < Health Service Quality Assurance

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Abstract

Purpose

We compare perspectives on external evaluation of health service provision between Norway and the U.S.A. External inspection and accreditation are examples of internationally wide-spread external evaluation methods used to assess the quality of care given to patients. Different countries have different national policy strategies and arrangements set up to do these evaluations. Although there is growing attention to the impact and effects on quality and safety from external evaluation, we still know too little about how structures and processes influence these outcomes. Accordingly, our aim is to describe the structures and processes in external evaluation designed to promote quality improvement in Norway and the U.S. with attention to comparison of enablers and barriers in external evaluation systems.

Design/methodology/approach

Data collection consisted of documentary evidence retrieved from governmental policies, and reviews of the Joint Commission (the U.S.), international guidelines, recommendations and reports from the International Society for Quality in Health Care, and the World Health Organization, and policies and regulations related to Norwegian governmental bodies such as the Ministry of Health and Care Services (MHCS), the Norwegian Directorate of Health (NDH), the Norwegian Board of Health Supervision (NBHS); the Inspectorate. Data were analyzed inspired by a deductive, direct content analytical framework.

Findings

We found that both accreditation and inspection are strategies put in place to ensure that healthcare providers have adequate quality systems as well as contributing to the wider risk and safety enhancing management and implementation processes in the organizations subjected to evaluation. The U.S. and the Norwegian external regulatory landscapes are complex and include several policymaking and governing institutions. The Norwegian regulatory framework for inspection has replaced an individual blame logic with a model which “blames” the system for inadequate quality and patient harm. This contrasts with the U.S. accreditation system, which focuses on accreditation visits. Although findings indicate an ongoing turning point in accreditation, findings also demonstrate that involving patients and next of kin directly in adverse event inspections is a bigger part of a change in external inspection culture and methods than in processes of accreditation.

Research implications

The message of this paper is important for policymakers, and bodies of inspection and accreditation because knowledge retrieved from the comparative document study may contribute to better understanding of the implications from the different system designs and in turn contribute to improving external evaluations.

Originality/value

Although there is growing attention to the impact and effects on quality and safety from external evaluation, the implications of different regulatory strategies and arrangements for evaluation on quality and safety remain unclear**.**

Keywords external evaluation, accreditation, inspection, the U.S., Norway

Paper type General review (the paper provides an overview of the concept of external evaluation and comparison of external evaluation policies and regulations for quality improvement and safety of health services in Norway and the United States).

Background

External inspection and accreditation are internationally wide-spread evaluation methods used to assess quality of patient care. The importance of inspection and accreditation is widely accepted, but there is little knowledge of how and if the structures and processes of external evaluations improve healthcare (Araujo *et al.,* 2020; Hussein *et al.,* 2021). National policy strategies for health care assessment differ, as do the processes of evaluation. Two countries with very different health care systems are Norway and the United States. These two countries have systems for external evaluation, but how they differ with respect to structure, and process have not previously been described. In this study, we therefore compare perspectives on external evaluation of health service provision between Norway and the U. S.

In an international perspective, the methods of external inspection and accreditation are frequently linked, with accreditation being contingent on a satisfactory inspection, and with external reporting of certain types of severe adverse events often being required (van Wilder *et al.,* 2021). Despite significant efforts to improve quality and safety, international research demonstrates that adverse events rates among hospitalized patients remain high (Wears and Sutcliffe, 2020; WHO, 2021; Bates *et al.,*2023). One of the key efforts is the introduction of external feedback to the internal systems responsible for providing healthcare services. Although there is growing attention to the impact and effects on quality and safety from external evaluation, we know too little about real impact of these methods (Brubak *et al.,* 2015; WHO, 2022). This applies especially to how structure and process versus performance play on outcomes, which enablers and/or barriers external evaluation may entail, and to how and to what extent perspectives from health care professionals and patients are included in the evaluation processes (Wiig *et al.,* 2019; Allen *et al.,* 2020; Øyri *et al.,* 2021; Weenink *et al.,* 2022; Hovlid *et al.,* 2022).

The findings of the Commonwealth Fund study (Schneider *et al.,* 2021) demonstrated that Norway was found to be the country with the best overall performance in healthcare while U.S. ranked last among 11 well-developed countries surveyed. By using the examples of the Norwegian and the U.S. health systems, the aim of this paper is to describe the structures and processes in external evaluation designed to promote quality improvement in Norway and the U.S. with attention to comparison of enablers and barriers in external evaluation systems.

Methods

Design and Data Collection

This is an instrumentally designed case study with data based on publicly accessible policy and regulatory documents as well guidelines, recommendations, and research regarding external evaluation of quality improvement and patient safety (Stake, 2005; Yin, 2014). The case was defined as external evaluation of service provision in healthcare in Norwegian and U.S. based contexts. The design was chosen to understand the phenomenon of external evaluation generally with the exemplars of the more specific phenomenon of inspection and accreditation (Crowe *et al.,* 2011; Yin, 2014). Please see Table 1 below for definitions of key terms and topics applied in this general review.

Table 1. Key terms and topics

External evaluation	External evaluators evaluate performance against a defined set of standards (Van Vliet *et al.,* 2021).
Structure	Structure is "the minimum or basic conditions for safe care and are related to quality planning and control" (Van Vliet *et al.,* 2021).
Process	Process is "the mechanisms that organizations use to enhance safety and minimize risk" (Van Vliet *et al.,* 2021).
Internal control; performance-based regulation	Regulatory governmental control of self-regulation where the government requires the regulatees to achieve or avoid certain outcomes without specifying solutions (Coglianese and Lazer, 2003, Øyri, 2021).
Compliance-based regulation	Principles of "command and control"; penalties expected to deter the regulatees from breaking the rules in combined effort with education, persuasion, and dialogue (Hood *et al.,* 2001).
Quality improvement	"The framework used to systematically improve care" (CMS, n.d.)
Patient safety	Defined as "the avoidance, prevention and amelioration of adverse outcomes or injuries stemming from the process of healthcare" (Vincent, 2006; 2010).

Database searches in Google Scholar for the period 2012 to 2022 were undertaken to find international policies; guidelines and research of external evaluation, with certain attention to Norwegian and U.S. context-based research. Publicly available governmental, national policy documents from the U.S. and Norway were searched for based on the researchers' pre-existing familiarity with the topic of inspection and accreditation, and by hand searches in relevant journals and reference lists. As official, governmental policy documents do not appear in traditional research data bases, nor in Google Scholar, hand searches were a precondition for the collection of these documents on the Internet from relevant bodies. Guidelines, regulations, and recommendations framed the study's U.S. and Norwegian based contexts and consisted of international policies and reviews of the Joint Commission (the U.S.), the International Society for Quality in Health Care, and the World Health Organization (see Table 2 for an overview of the documents included). Moreover, it included policies and regulations related to Norwegian governmental bodies such as the Ministry of Health and Care Services, the Norwegian

Directorate of Health, the Norwegian Board of Health Supervision. The documentary evidence was supplemented by scientific papers and reports on the topic of external evaluation (Bowen, 2009). We have used material in report format, as this gives us a thorough insight into the field of external evaluation. This methodological approach has also been employed by others in the past, as a strategy to gain insight into a field of lacking peer reviewed material (Wiig *et al,* 2020).

Table 2. Empirical Foundation of the Study

U.S. official, policy documents		
Publication year	**Source**	**Title**
n.d	Centers for Medicare & Medicaid Services (CMS)	Quality Measurement and Quality Improvement
n.d.	Centers for Medicare & Medicaid Services (CMS)	Quality, Safety & Oversight - Certification & Compliance
n.d.	Joint Commission	About Our Standards
n.d.	Joint Commission	Facts about The Joint Commission
n.d.	Joint Commission	State Recognition
n.d.	Joint Commission	Joint Commission FAQs
2014	Smits *et al.*	Hospital accreditation: lessons from low- and middle-income countries
2019	Patient Safety Network	Reporting Patient Safety Events
2020	Agency for Healthcare Research and Quality (AHRQ)	Understanding Quality Measurement
2021	U.S. Department of Health & Human Services	Hospitals
2022	Ibrahim *et al.*	The evidence base for US joint commission hospital accreditation standards: cross sectional study
U.S. context-based research		
Publication year	**Source**	**Title**
2003	Sage	Medical liability and patient safety
2004	Studdert *et al.*	Medical malpractice
2006	Studdert *et al.*	Claims, errors, and compensation payments in medical malpractice litigation
2010	Kachalia *et al.*	Liability claims and costs before and after implementation of a medical error disclosure program.
2015	Morey *et al.*	Joint Commission and Regulatory Fatigue/Weakness/Overabundance/Distraction: Clinical Context Matters
2016	Makary and Daniel	Medical error-the third leading cause of death in the US
2016	Kachalia *et al.*	Legal and Policy Interventions to Improve Patient Safety
2018	Lam *et al.*	Association between patient outcomes and accreditation in US hospitals: observational study
2021	Gallegos	Medscape Malpractice Report
2022	Kato, M. & Zikos, D.	Association between hospital accrediting agencies and hospital outcomes of care in the United States

2023	Rodziewicz *et al.*	Medical Error Reduction and Prevention
2023	Bates *et al.*	The Safety of Inpatient Health Care
Norway official, policy documents		
Publication year	**Source**	**Title**
n.d.	DNV	Course in the Quality Standard NS 15224
1983	Ministry of Health and Care Services	Dental Health Services Act
1999	Ministry of Health and Care Services	Specialized Health Services Act
1999	Ministry of Health and Care Services	Health Personnel Act
1999	Ministry of Health and Care Services	Patients and User Rights Act
2001	Ministry of Health and Care Services	Patient Injury Act
2005	Ministry of Justice	Penal Code
2011	Ministry of Health and Care Services	Municipal Health and Care Services Act
2015	Ministry of Health and Care Services	Kvalitetssertifisering av norske sykehus.
2016	Ministry of Health and Care Services	Quality Improvement Regulation
2017	Ministry of Health and Care Services	Health Services Supervision Act
2017	Norwegian Directorate of Health	Guidelines to Regulation on management and quality improvement in the healthcare services
2018	Norwegian Directorate of Health	Revocation of authorization, license or professional specialty
2018; 2021	Norwegian Board of Health Supervision	Guidelines for system audits
2019	Norwegian Board of Health Supervision	Recommendations related to stakeholder involvement in external inspection.
2019	Norwegian Board of Health Supervision	Introduction to the Supervisory Authorities and the Supervision of Child Welfare Services, Social Services and Health and Care Services in Norway
2010	Ministry of Labour and Social Inclusion	Regulations relating to health, safety and the environment in the petroleum activities and at certain onshore facilities
2021	Norwegian Directorate of Health	Patient injuries in Norway 2021. Measured by Global Trigger Tool
2021	Standards Norway	Ledelsessystemer for kvalitet i helse- og omsorgstjenesten
2023	Norwegian Board of Health Supervision	Annen tilsynsmessig oppfølging etter varsel om alvorlig hendelse - innhenting av redegjørelse, egenvurdering, egenrapport
Norwegian context-based research		
Publication year	**Source**	**Title**
2003	Lilleholt	Knophs oversikt over Norges Rett.
2015	Lindøe *et al.*	Risiko og tilsyn. Risikostyring og rettslig regulering
2017	Hovlid *et al.*	Effects of external inspection on sepsis detection and treatment: a study protocol for a quasiexperimental study with a stepped-wedge design
2018	Lindøe *et al.*	Regulering og standardisering. Perspektiver og praksis

2020	Øyri *et al.*	Exploring links between resilience and the macro-level development of healthcare regulation- a Norwegian case study
2020	Hovlid *et al.*	Mediators of change in healthcare organisations subject to external assessment: a systematic review with narrative synthesis
2020	Hovlid *et al.*	Inspecting teams' and organisations' expectations regarding external inspections in health care: a qualitative study
2021	Øyri *et al.*	Investigating Hospital Supervision: A Case Study of Regulatory Inspectors' Roles as Potential Co-creators of Resilience
2021	Wiig *et al.*	Next of Kin Involvement in Regulatory Investigations of Adverse Events That Caused Patient Death: A Process Evaluation (Part I - The Next of Kin's Perspective)
2021	Wiig *et al.*	Next-of-Kin Involvement in Regulatory Investigations of Adverse Events That Caused Patient Death: A Process Evaluation (Part II: The Inspectors' Perspective)
2021	Øyri	Healthcare Regulation and Resilience - a Norwegian Multilevel Case Study
2022	Øyri and Wiig	Linking resilience and regulation across system levels in healthcare - a multilevel study
International policies; guidelines and research		
Publication year	**Source**	**Title**
n.d.	Government of the Netherlands	Quality requirements for care providers
n.d.	United Nations Association of Norway	Statistics
1999	Baldwin and Cave	Understanding Regulation. Theory, Strategy, and Practice
2000	Institute of Medicine	To Err is human: building a safer health system
2001	Shaw	External assessment of health care
2002	Hopkins and Hale	Issues in the Regulation of Safety; setting the scene
2003	Walshe	Regulating Healthcare: A Prescription for Improvement?
2003	Coglianese and Lazer	Management-Based Regulation: Prescribing Private Management to Achieve Public Goals
2011	Flodgren *et al.*	Effectiveness of external inspection of compliance with standards in improving healthcare organisation behaviour, healthcare professional behaviour or patient outcomes
2011	Warren *et al.*	Evaluation of the impact of the voucher and accreditation approach on improving reproductive health behaviors and status in Kenya
2015	Brubakk *et al.*	A systematic review of hospital accreditation: the challenges of measuring complex intervention effects
2016	Vincent and Amalberti	Safety Strategies in Hospitals
2016	Wilson *et al.*	Meta-audit of laboratory ISO accreditation inspections: measuring the old emperor's clothes
2019	Øyri and Wiig	Regulation and resilience at the macro-level healthcare system – a literature review
2019	Due *et al.*	Understanding accreditation standards in general practice - a qualitative study
2019	Chuang *et al*	An international systems-theoretic comparison of hospital accreditation: developing an implementation typology.
2019	Kousgaard *et al.*	Experiences of accreditation impact in general practice – a qualitative study among general practitioners and their staff
2019	Shaw *et al.*	External institutional strategies: accreditation, certification, supervision.

2020	Wiig *et al.*	What methods are used to promote patient and family involvement in healthcare regulation? A multiple case study across four countries.
2020	Wiig *et al.*	The patient died: What about involvement in the investigation process?.
2020	Leistikow and Bal	Resilience and regulation, an odd couple? Consequences of Safety-II on governmental regulation of healthcare quality
2020	Van de Bovenkamp *et al.*	Tackling the problem of regulatory pressure in Dutch elderly care: The need for recoupling to establish functional rules
2020	Ellis et *al.*	Accreditation as a management tool: a national survey of hospital managers' perceptions and use of a mandatory accreditation program in Denmark. B
2020	Mansour *et al.*	The development of hospital accreditation in low- and middle-income countries: a literature review.
2020	Kok *et al.*	"The doctor was rude, the toilets are dirty". Utilizing 'soft signals' in the regulation of patient safety
2021	Kok	A standard story: On the use and consequences of standards in healthcare regulation
2021	van Vliet *et al*	Clarifying the concept of external evaluation.
2021	Batomen *et al.*	Impact of trauma centre accreditation on mortality and complications in a Canadian trauma system: an interrupted time series analysis.
2021	Sun *et al.*	Effectiveness of chest pain centre accreditation on the management of acute coronary syndrome: a retrospective study using a national database
2021	Weenink*, et al.*	Publication of inspection frameworks: a qualitative study exploring the impact on quality improvement and regulation in three healthcare settings
2022	World Health Organization (WHO)	Health care accreditation and quality of care: exploring the role of accreditation and external evaluation of health care facilities and organizations
2022	Yeung *et al.*	Patient Safety and Legal Regulations: A Total-Scale Analysis of the Scientific Literature

Analysis

Data were analyzed by a deductive, direct content analytical framework, identifying processes and structures in the two external evaluation systems, mapping similarities and differences. According to Hsieh and Shannon (2005), the deductive analytical approach provides a constructive starting point because it enables the researchers to identify key concepts or variables based on existing theory or research. It is also considered a relevant approach when there is an urge to develop a complete understanding of the context (Hsieh and Shannon, 2005). Thus, relevant previous research findings and the researchers' pre-existing knowledge related to the topic of external evaluation were used as guidance in the interpretation of document data. Moreover, the deductive approach was chosen to reflect the study's aim of finding explanations for the potential enablers and barriers in the two different external evaluation systems designs (Blaikie, 2010).

Author XX read through all publications and analyzed abstracts and/or full text papers in table 2 "Empirical foundation of the study", and identified elements related to structure, process and enablers and barriers to quality and safety. Authors XX and XX discussed these elements in collaboration. All three authors contributed with relevant publications and supplied the analysis with in-depth knowledge of respectively the Norwegian and the U. S. contexts.

Findings

The aim of this study was to describe the structures and processes in external evaluation designed to promote quality improvement in Norway and the U.S. with attention to comparison of enablers and barriers in external evaluation systems. In the following, we present the findings related to different definitions of health care quality and external evaluations, followed by examples of external evaluation structures and processes in Norway and the U.S. comparing external inspection in the Norwegian health system with characteristics of accreditation in the U.S. Finally, we present enablers and barriers in the two system designs.

Definitions of health care quality

The U.S. government Centers for Medicare & Medicaid Services adopts and applies the definition of quality as defined by the National Academy of Medicine: "the degree to which health services for individuals and populations increase the likelihood of desired health outcomes and are consistent with current professional knowledge" (CMS, n.d.). The Agency for Healthcare Research and Quality (the lead Federal agency for safety and quality in the U.S.) refers to the definition provided by the Institute of Medicine (IOM, 2000; AHRQ, 2020). In that perspective, quality consists of six dimensions: clinical effectiveness, patient safety, patient centeredness, care coordination, efficiency, timeliness, and equity (IOM, 2000). The Norwegian governmental understanding and adoption of the conceptualization of quality are in line with the conceptualization given by the Institute of Medicine (IOM, 2000; NDH, 2017). This paper focuses on quality as a universal feature in healthcare and thus applies the term generically with no attempt of distinguishing between the dimensions. In the literature, quality and safety are often referred to in pairs.

Definitions of external evaluation

Different systems exist for external evaluation of quality and patient safety, with regulatory external inspection and accreditation as two of the main categories of evaluation methods. The basic idea to both evaluation methods is to ensure that healthcare providers have adequate quality systems as well as contributing to the wider risk and safety enhancing management and implementation processes in the organizations subjected to evaluation (Shaw, 2001; WHO, 2022; van Vliet *et al.,* 2021).

- External inspection is a regulatory approach to which external inspectors assess the performance of a healthcare organization, or delegate parts of the assessment to the organization, by either planned, system audits of performance initiated by the inspectorate body or individual cases of adverse events related external inspection reported to the inspectorate body (Baldwin and Cave, 1999; Hopkins and Hale, 2002; Walshe, 2003).

- Accreditation (including licensing and certification) is a form of external evaluation performed by an external accreditation body. The assessment is performed based on benchmarks for measuring patient safety and the quality of care provided by a healthcare organization (JC, n.d).

Whilst external inspection may best be described as a process where the accountability of the assessment of the system rests on the subjected organization, the subjected organizations under a process of accreditation is rather externally accounted for by the means of accreditation. The risk management and quality systems are thus respectively based on assessment of principles for high quality versus measurement of indicators against predefined performance standards for quality and safety.

Examples of external evaluation structures and processes in Norway and the U.S.

The occurrence of serious adverse events constitutes a collective, societal challenge with comprehensive individual implications for the patients and their families, as well as having implications for healthcare professionals involved. In Norway, a patient related injury was registered in roughly 12 % of hospital stays in 2019 (NDH, 2021). In the U.S., a past study from John Hopkins indicated that medical errors represented the third leading cause of death in the U.S., with a 10% of all deaths suggested as due to medical error (Makary and Daniel, 2016). Latest results from U.S. hospitals show that one adverse event occurred in 23.6% of hospital admissions (Bates *et al.,*2023). These numbers in both countries, speak for reduction and close attention to underlying causes and solutions that may have an impact on improving the services (Øyri, 2021; Rodziewicz *et al.,* 2023).

According to The International Society for Quality in Health Care (ISQua), strategies of external evaluation through accreditation provide assurance that healthcare providers and organizations possess adequate quality systems (van Vliet *et al.,* 2021). Moreover, it may contribute to "quality improvement, risk mitigation, patient safety, improved efficiency and accountability, and sustainability of the healthcare system" (van Vliet *et al.,* 2021). A similar multifaceted purpose sits with the Norwegian regulatory framework for external inspection (NBHS, 2019; 2019; Øyri, 2021; Øyri and Wiig, 2022). Thus, both accreditation and inspection are strategies put in place to ensure that healthcare providers have adequate quality systems as well as contributing to the wider risk and safety enhancing

management and implementation processes in the organizations subjected to evaluation. The relevance however also links with the body of previous studies indicating inconclusive results regarding the impact on quality and safety from external evaluation (Flodgren *et al.,* 2011; Hovlid *et al,* 2017; Lam *et al.,* 2018; Øyri *et al.,* 2021; van Vliet *et al.,* 2021). Lam and colleagues (2018) did not find any association between hospital accreditation and lower mortality and only a slight association between accreditation and lower readmission rates. In their systematic review of hospital accreditation found the role of accreditation in improving outcomes, to be "largely undefined" (Lam *et al.,* 2018). On the other hand, they also did reveal interesting results of accreditation impact that were not possible to statistically measure, specifically that accreditation could have important implications organizational processes and structures (Lam *et al.,* 2018). A more recent publication also did not find an association between patient outcomes and accreditation, but accreditation did entail beneficial value for organizations with decreasing performance prior to the accreditation process (Sun *et al.,* 2021; Batomen *et al.,* 2021). Evidence on the contrary points to external evaluation as a means of contributing constructively to organizational change in process, structure or even culture (Brubakk *et al.,* 2015; Shaw *et al.,* 2019; van Vliet *et al.,* 2021).

External inspection in the Norwegian health system

External inspection is performed by the Norwegian Board of Health Supervision (NBHS) and 11 regional County Governors (2018; 2021). The national government represented by the Ministry of Health and Care Services (MHCS), provides the Inspectorate and the County Governors with regulations and policies applied to the evaluation of quality and safety provided by the healthcare services. Evaluation is mandatory in the sense that the hospitals are obliged to notify external regulators about serious adverse events, through incident reporting systems. Hospitals may become externally evaluated either based on the incidents reported or based on planned system audits addressing topics of significant risk potential.

Three key characteristics of the Norwegian model for external evaluation of quality and safety are: 1) internal control principles in evaluation of structure and process, 2) the idea of blaming the system rather than individual performance with attention to system performance and management responsibilities, 3) inclusion of internal stakeholders in the evaluation processes.

1) Internal control principles in evaluation of structure and process

Even though some areas of the Norwegian healthcare services are strictly governed by prescriptive rules, for instance using standardization and checklists which are highly structured, and compliance based, quality and safety of the services provided is generally governed by the basic legal standard and principle of "sound professional practice" and "prudent conduct" (MHCS, 1999 a; the Health Personnel

Act § 4). The implication is that the quality of the services should correspond to a certain level, which may fluctuate with time, societal changes, development in technology and medical knowledge (Lilleholt, 2003; Lindøe *et al.,* 2015). The required level of quality applies to all types of private and public healthcare providers and organizations. Any subsequent external evaluation is required to assessing the quality and safety of the services along the same line of "sound professional practice". (Lindøe *et al.,* 2018). This implies that the Norwegian regulatory system for external inspection is based on internal control and performance-based principles, requiring certain outcomes (achieved or avoided) without specifying solutions (Coglianese and Lazer, 2003). These principles were originally retrieved from safety and risk management in the Norwegian petroleum industry and transferred to the healthcare regulatory context (MLSI, 2010; Øyri, 2021). These regulations aim at securing a certain level of system performance, without specifying *how* healthcare organizations may achieve or ensure this level of quality and safety. External inspections, either with the aim of conducting a system audit or incident-based inspection, therefore base their assessments on whether the organizations have implemented adequate safety barriers and risk management measures to ensure sound professional practice, and whether the organizations are having a systematic and continuous improvement focus (Øyri *et al.,* 2020, 2021). The assessment is done with the help of a set of regulations such as the Specialized Health Services Act (MHCS, 1999), the Municipal Health and Care Services Act (MHCS, 2011), the Dental Health Services Act (MHCS, 1983), the Health Personnel Act (MHCS, 1999), the Health Services Supervision Act (MHCS, 2017), the Quality Improvement Regulation (MHCS, 2016) which entails generic principles for internal control. Besides, the ISO 9001:2015 NS15224 standard specifies requirements for an organization's quality management system, which aligns with the internal control requirements in the Quality Improvement Regulation (DNV, n.d; SN, 2021). The assumption with this regulatory approach is that it provides the organizations with further incentives to ensure a strong quality system in accordance with governmental requirements (MHCS, 2015).

2) The idea of blaming the system rather than individual performance with attention to system performance and management responsibilities

In the Norwegian context, an i*ndividual blame logic has been replaced with a model which "blames" the system for inadequate quality and patient harm. The Norwegian Penal Code Sections 27-28 (Ministry of Justice, 2005) regulates penalties for enterprises and is applicable in cases where* a penal provision is "violated by a person who has acted on behalf of an enterprise", whereas the Norwegian System of Patient Injury Compensation (NPE) is a government agency handling compensation claims related to errors or injuries that are results from healthcare treatment (MHCS, 2001). Both arrangements represent the Norwegian system design's attention to collective efforts and system level accountability and less attention to individual performance or individual accountability for health professionals. Health professionals are however occasional subjects to potential individual sanctions such as revocation of authorization or license, mostly in cases related to "unsuitability" due to mental illness, drug abuse or sexual misconduct (NDH, 2018).

3) Inclusion of internal stakeholders in the evaluation processes

The rights of patients and users are outlined in the Patients and User Rights Act (1999). In recent years, stakeholder involvement of patients, users, and next of kin has become one of the key principles for efficient external evaluation of the services (Wiig *et al.,* 2020, 2020). The value of including patients, users, and next of kin is mentioned in both the official guidelines document and in a separate white paper providing the inspectors with recommendations for relevant and sensible stakeholder involvement pre, during and post external inspection. The Inspectorate has an independent user panel/council, assisting the government in different aspects of the strategies related to evaluation process (NBHS, 2019; 2019). In the external evaluation process, the organization is often requested to do a self-assessment of their risk management system and performance (NBHS, 2023). This interaction between inspection team and organization is part of the self-regulation processes, which is viewed as essential in the Norwegian regulatory system in healthcare. Self-regulatory approaches may increase the feeling of responsibility for the risk management system, providing incentives for actively being involved in quality improvement due to autonomy, enabling the organizations to pay attention to and adapt to local conditions, uncertainties, and variations (Øyri and Wiig, 2019). Stakeholder inclusion in external inspection in the Norwegian system therefore promotes decentralized implementation and decision-making, provided by a centralized-regulatory system level.

Characteristics of accreditation in the U.S. health system

Although self-regulation in the U.S. system is an important aspect in keeping oversight of the medical profession, external evaluation plays a key role in assuring quality (JC, n.d.; Kachalia et al., 2016). The U.S. system for external evaluation is based on accreditation of healthcare organizations (Kato and Zikos, 2022). Accreditation is executed on behalf of the government by accreditation organizations, which often also perform inspections. Several accreditation bodies exist in the U.S. healthcare system,

but the non-profit organization Joint Commission serves as the largest standard setting and accrediting body (U.S. Department of Health & Human Services, 2021; JC, n.d.). It is voluntary to become accredited, but very strong financial incentives apply such as the eligibility for receiving federal reimbursement (Medicare and Medicaid) and general federal funding (Ibrahim *et al.,* 2022), and practically speaking nearly all hospitals elect to be accredited. State granted hospital licensure is in many states preconditioned by meeting with the Joint Commission standards (Ibrahim *et al.,* 2022). Reporting of particularly serious adverse events—sometimes termed "never events," is required, both to the Joint Commission and to states. Certain of these events then trigger inspections related to the events (PSNet, 2019).

Two key characteristics of the U.S. model for external evaluation of quality and safety relate to: 1) individual liability in cases of medical error: malpractice insurance, 2) compliance-based, management-oriented evaluation of structure and process.

1) Individual liability countered by a system of torts; insurance

Most clinicians and hospitals in the U.S. are covered by malpractice insurance, and the penalties issued in cases of medical malpractice are civil and usually covered by insurance companies, counteracted through "professional liability" (Studdert *et al.,* 2004; Yeung *et al.,* 2022). In the U.S, links between medical liability and concepts of patient safety have been a hot topic for decades, and the initial thought about liability insurance is that it can offer compensation to patients who have suffered from negligent treatment, and help enforcing standards of quality of care set by U.S. courts (Sage, 2003). The system of torts has thus played a key part in ensuring accountability (Kachalia *et al.,* 2016). However, many patients who are harmed—even negligently—do not get compensated.

In recent years state "apology laws" for malpractice and disclosure programs for adverse events have been implemented by several states in the U.S. (Gallegos, 2021). Past results have shown that the average monthly rate of new claims decreased, after a medical disclosure program was fully implemented (Kachalia *et al.,* 2010). In addition, there has been discussions in the U.S. about whether a shift from personal risk of getting sued over negligence towards blaming the system by "enterprise liability" could contribute constructively (Kachalia *et al.,* 2016). Numbers have indeed shown that in 3 percent of the claims in U.S. malpractice lawsuits, no verifiable medical injuries were found, and 40 percent of the claims did not involve medical errors (Studdert *et al.,* 2006).

2) Compliance-based, and management-oriented evaluation of structure and process.

Healthcare organizations must be surveyed, on-site, every three years at a minimum (JC, 2023). These visits are generally unannounced. The quality measurement systems applied in the survey process are

clinical indicators and patient satisfaction indicators (Chuang *et al.,* 2019). The basic principle in the on-site survey is to enforce "compliance with various performance-based standards" (Ibrahim *et al.,* 2022). Past criticism has however been raised towards the Joint Commission standards' evaluation resulting in compliance or noncompliance, marked as "met" or "not met" (Morey *et al.,* 2015).

Enablers and barriers in external evaluation systems

Achieving safety demands that policy and decision makers have a multifactorial mindset. This includes regulations, evaluation, standardization of specific processes according to best practices to avoid harm. It further implies improving working conditions and organizational practices and enforcing risk management, as well as building system resilience. The latter includes building adaptive capacity to enable the processes of monitoring, anticipating, and responding to risks to ensure safe care (Vincent and Amalberti, 2016, Leistikow and Bal, 2020, Øyri and Wiig, 2022). Enablers for successful implementation and process of external evaluation have shown to be associated with external expectations being clearly stated, tools, guidance, and support being offered along with regulations and rules. This includes efforts to stimulate reflection within the organizations and between external regulators and stakeholders, and internal stakeholders in the healthcare system (Due *et al.,* 2019; Wiig *et al.,* 2021, 2021; Øyri *et al.,* 2021). Inspections have proven to engage staff and leaders and assist in framing quality and safety issues into relevant measures for improvement (Hovlid *et al.,* 2020; 2020; Øyri *et al.,* 2021). Likewise, accreditation can be a favorable management tool according to Ellis and colleagues (2020). Moreover, accreditation almost certainly offers more benefit in healthcare systems in countries which are less developed than in other countries, implying that accreditation may have a major impact especially if the baseline is low and many things demonstrated to improve safety may not be available (Warren *et al.,* 2011; Smits *et al.,* 2014; Mansour *et al.,* 2020).

Barriers to accreditation include that evaluation is time-consuming, may not address core services, can interfere with autonomy, and is sometimes not based on "sound evidence" as well as confusion about what strategies hospitals should implement (Brubakk *et al.,* 2015; Wilson, 2016; Kousgaard *et al.,* 2019). One specific point of criticism points to the lack of transparency about evidence related to the recommendations the Joint Commission are giving to U.S. hospitals having negative impact on the organizations and clinicians' motivation to implement essential policies (Ibrahim *et al.,* 2022). Omission of the recommendations' underlying rationale could therefore potentially have a negative impact on the safety of patients (Ibrahim *et al.,* 2022). "Regulatory pressure" and "regulatory fatigue" are well-known hinders for constructive implementation of regulation and policies in healthcare in general (Morey *et al.,* 2015; van de Bovenkamp *et al.,* 2020; Ibrahim *et al.,* 2022). Regulating complex systems is difficult, as providers often need to resort to workarounds, make tradeoffs and adaptations to get

complex systems to function (Kok, 2021). The latter requires flexibility and adaptive capacity and hence the organizations need their sufficient autonomy to make relevant decisions (Øyri and Wiig, 2022). The approaches taken by inspectors, whether "soft" or "hard", can have variable impacts on the organizations involved and these "signals" transcend the formal assessments of performance and compliance (Kok *et al.,* 2020). Application of soft signals specifically could be productive and help inspectors "read between the lines" during conversations with managers and healthcare professionals (Kok *et al.,* 2020).

Discussion and Implications

In this general review we have displayed some distinct contrasts between the two countries in scope. First, the Norwegian regulatory framework for external inspection has replaced an individual blame logic with a model which "blames" the system for inadequate quality and patient harm. Despite of this, the regulator still has the possibility of imposing individual sanctions (NDH, 2018). The Norwegian System of Patient Injury Compensation is designed to pay attention to collective efforts and system level accountability, with less attention to individual performance. This contrasts with the U.S. accreditation system, which focuses on accreditation visits, and where most clinicians and hospitals are covered by malpractice insurance to counteract individual professional liability in cases of medical errors. Secondly, involving patients and next of kin directly in adverse event related external evaluations is a bigger part of a change in external inspection culture and methods than in processes of accreditation, although findings indicate an ongoing turning point in accreditation. These regulatory system design features have implications, shown as enablers and barriers to external inspection and the assessment of quality and patient safety, which we discuss in the forthcoming.

Implications of different regulatory frameworks on assessment of quality and patient safety

Past studies have raised concerns about the increase in complexity and demands of external regulation, due to the potential of distracting internal stakeholders in healthcare rather than supporting their efforts to improve quality and safety (Oikonomou *et al.,* 2019). As our aim in this study fixates, there is uncharted knowledge about the enablers and barriers to structures and processes in external evaluation designed to promote quality improvement. Thus, policy makers need to pay close attention to regulatory pressure and consider innovations to evaluating quality and safety in healthcare (van de Bovenkamp *et al.,* 2020). How governments seek to design and co-shape external regulations, policies, and strategies for evaluation, vary greatly with country and healthcare system designs, with implications for differences in quality and safety outcomes, efficiency, administrative burdens, spending, and legitimacy to mention a few. Differences in healthcare system design across the globe is therefore an important factor in the discussions about impact and implications from

heterogeneous external evaluation methods (Bracewell and Winchester, 2021). Comparisons of accreditation standards specifically may even not be possible to do due to differences in transparency, and some countries do not even reveal their accreditation standards to the public (Breuckmann *et al.,* 2015; Bracewell and Winchester, 2021). According to the 2021 Commonwealth Fund's report Norway ranks as one of the top-performing countries overall, with the U.S. ranked last in four of five domains that were assessed (equity, access to care, administrative efficiency, health care outcomes, and care process) (Schneider *et al.,* 2021). Explanations for the ranking are multifaceted. One obvious explanation relates to the highly complex U.S. healthcare system, contrasted to the Norwegian system which is less complex geographically and demographically (Walshe, 2003; Field, 2017), as well as the diversity of the underlying population—certain areas of the U.S. are very poor and often have low-quality health care. Another is the difference in the systems' financial foundation: whilst Norway has a universal health care system, the U.S. system is predominantly based on insurance coverage (Walshe, 2003; MHCS, 2014; Schneider *et al.,* 2021). The U.S. is far more diverse in all these aspects than Norway, which constitutes one of the biggest differences with implications for quality. However, due to less governmental policies and investments in for instance education, employment and social programs in the U.S. compared to Norway, U.S. health outcomes could be improved through targeted actions to social and economic factors *beyond* health care (Schneider *et al.,* 2021).

An element regarding national policy and evaluation of quality supposedly with implications for both systems, is the two countries' distinct regulatory frameworks. Whilst the Norwegian system is based on parliamentarism, the U.S. employs federalism (a system of government where federal and state governments share powers) (Constitution of the United States, 1787; Stenken and Brooks, 2022; Constitution of the Kingdom of Norway, 1814). The U.S. and the Norwegian regulatory regimes are both complex, embodying several policy-, lawmaking, and governing institutions. These institutions possess different legislative powers and their policies and strategies of accreditation and inspection have different implications for accountability and learning, including various enablers and barriers to accreditors and inspectors' adaptive capacities and leeway to meet the needs of the organizations they are set to evaluate. A variety of legal sources (primary and secondary sources) have relevance in the framing, analysis, and completions of the legislative powers, policies, and strategies.

Previous comparative research in the domain of industrial safety has identified similarities and contrasts in the way U.S. and Norwegian governments regulate risk governance of their offshore oil and gas operations (Lindøe and Baram, 2019). Technically detailed prescriptive rules, often developed by private enterprises, define the methods and practices that U.S. oil and gas companies must comply to avoid strict enforcement. Additional opportunities for compliance are given by the recommendation of recommended "guidelines for acceptable self-regulation" (Lindøe and Baram, 2019). The latter is a

typical feature with the Norwegian offshore regulatory regime. The important triangular cooperation between regulators and companies offshore in the Norwegian system is however not present in the U.S. regulatory system (Lindøe and Baram, 2019). As large parts of the Norwegian healthcare system are based on principles referred to as performance-based or outcome-based, understood as a regulatory strategy that does not specify how the process towards required outcomes should look like, these cross-industry findings demonstrate how we can draw parallels to healthcare regulation (Coglianese and Lazer, 2003). In turn, it may gain valuable lessons for cross-country learning.

The idea in a performance-based system is that "enforced self-regulation" influences and co-opt the regulatees' ability and will to establish "internal governance" with the incentive to perform in accordance with best practices and to the best interest for both external and internal stakeholders (Ayres and Braithwaite, 1992; Lindøe and Baram, 2019). Self-regulation does however raise potential issues with credibility, efficacy, accountability, and legitimacy (Lindøe and Baram, 2019).

In comparison, the U.S. system is a public-private partnership with the Joint Commission serving as an independent body working closely with external government bodies (Field, 2007, 2017; JC, 2022). The principle of federalism along with these partnerships and elements of private oversight in the system, could possibly foster an unfortunate opportunity for competition and confrontation between different bodies (Field, 2017). One key set of differences whilst external inspection in the Norwegian regime of evaluation is a mandatory control mechanism with healthcare providers' quality and safety, accreditation in the U.S. model is a voluntary, non-statutory mechanism established to advocate and oversee quality (Field, 2007, 2017). The external inspection bodies in Norway have options of enforcement set out in the Penal Code, whereas the Joint Commission cannot "regulate" the services as such. Acting according to the accreditation requirements has nevertheless implications for compliance with the U.S. federal requirement of establishing minimum health and safety and standards (CMS, n.d.; SSA, n.d.).

It is important to gain knowledge about the implications of the different national policies that these two regulatory frameworks may have for different system levels of risk management from the patient safety perspective. The aspect of cross-country learning is essential to confront the high numbers of patient injuries in both countries and crucial from the patient perspective, as patients in both countries expect high quality and safe healthcare.

The value of context - uniting accreditation standards and processes of external inspection

Our findings suggest that enablers and barriers need more scrutiny and that the value of context should be seen as an enabler for sufficient implementation of safety and quality related policies and regulation. In the context of accreditation, the WHO has raised concern about sensible application of evaluation standards (WHO, 2022). The WHO recommends asking the context sensitive question: 1)

"What aspects of accreditation might work in my context?", rather than asking "Does accreditation work?". This recommendation could push public policy development towards context-sensitivity and serve as a practical solution to potentially increase the autonomy and sense of responsibility, stimulate reflection, and thus strengthen the overall quality of external evaluation.

This review presents the findings for two fundamentally opposing approaches to regulation and external evaluation of quality and safety. The Norwegian system is a state regulated and mandatory policy that "blames" the system rather than penalizing the individual for breaches in "best practices" and national quality standards set by relevant medical and professional associations. In contrast, the U.S. approach is voluntary and primarily relies on accreditation and compliance to accepted standards to encourage quality assurance and patient safety, heavily relying on insurance and lawsuits for compensation of harm resulting from the healthcare system. Despite that the U.S. outspends other nations, it comes across as an outlier compared to all other countries measured in the Commonwealth Fund report (Schneider *et al*., 2021). Policies and practices in external inspection in other developed countries are not in this review's scope, however it is interesting to highlight that other top-performing countries in the Commonwealth Fund ranking have systems with similar features of regulatory design and external evaluation processes, for instance the Netherlands and Norway (UN, n.d.; Weenink *et al.,* 2021). However, the Netherlands has a double-based state regulated and mandatory system for external evaluation (Government of the Netherlands, n.d.), demonstrating that a system of external evaluation can include both accreditation standards and processes of external inspection, and that choosing to implement one system design or the other is not mutually exclusive. This combination of two sets of external evaluations strategies may represent a regulatory system design that may enable organizational autonomy on one hand (external inspection processes) and structured compliance (accreditation) on the other. Enablers and barriers to successful application of external evaluation need more scrutiny, and we suggest further exploration, especially related to how a combined regulatory system design may ensure and improve quality and safety in healthcare organizations. A summary of potentially key pros and cons with the two systems' policies for external evaluation is found in Table 3 and Table 4. Future studies should be exploring the experiences of enablers and barriers of different accreditation and regulatory bodies' approach to external evaluation application.

Table 3. Potential key pros and cons with the system policies for accreditation.

Pros	**Cons**
Management tool	Lack of meaningful stakeholder inclusion
Benchmark for measuring patient safety and quality of care	Can interfere with autonomy
Contributor to enhancing management and implementation processes	Lack of transparency about evidence related to the recommendations and confusion about strategies

Assurance for the public that healthcare providers and organizations possess adequate quality systems	Time-consuming and regulatory fatigue
Accountability	Compliance or noncompliance
Efficiency	Relying on insurance and lawsuits for compensation of harm resulting from the healthcare system.

Table 4. Potential pros and cons with the system policies for external inspection.

Pros	**Cons**
Decentralized implementation and decision-making	Regulatory fatigue
Autonomy and adaptive capacity to meet demands	Credibility
The value of context	Legitimacy
Engages staff and leaders in quality improvement	Efficacy
Incentive to perform in accordance with best practices	Accountability
A state regulated and mandatory policy that "blames" the system rather than penalizing the individual for breaches in "best practices" and national standards	Potential individual sanctions such as revocation of authorization or license

Achieving cross-country learning about system design

According to recent studies there is an ongoing turning point in the context of accreditation: moving from a culture of means towards evaluation of results, addressing the organizational core (Brubakk *et al.,* 2015; Johannesen and Wiig, 2017; Johannesen *et al.,* 2020; Johannesen, 2020). In late 2022, the Joint Commission announced a reduction in the number of standards with 168 accreditation requirements, as well as the revision of 14 standards (JC, 2022). Along with literature review and expert evaluation, Joint Commission issued standards recently underwent review in accordance with three questions: 1) does the requirement still address an important quality and safety issue? 2) is the requirement redundant? 3) are the time and resources needed to comply with the requirement commensurate with the estimated benefit to patient care and health outcomes? Based on the answers on these questions, standards were either revised or discontinued. Some of these standards went out of effect on January 1st, 2023. The Joint Commission's announcement and commitment to revision reflects what should be a key aspect in external evaluation: to pay constant attention to changes in the public and patients' expectations, and the development in technology, human resources and knowledge related to quality improvement and patient safety.

Stakeholder views and practices, such as involving patients and next of kin directly in adverse event inspection routines and information processes represents another future development and change in evaluation culture and methods (Øyri *et al.,* 2021; Wiig *et al*., 2021; 2021). In contrast, there has been raised concern to if accrediting organizations in the U.S. really focus on what matters to patients, and a lack of meaningful stakeholder inclusion may be part of that concern (Jha, 2018). A development of involvement in routines and processes may in turn result in a more meaningful

evaluation process and increased motivation for health professionals to make relevant contributions to processes of improvement and implementation. In turn it may contradict parts of the status of regulation and policies seen as solely oppressive in the eyes of clinicians (Øyri *et al.,* 2020). Paying more attention to relevance and multilevel stakeholder inclusion in evaluation of the systemic and structural conditions for quality and safety, could also contribute to the idea of shifting from an individual blame logic towards blaming *the system as such*. Perspectives from the Norwegian an U.S. contexts could serve as valuable contracts in the search for cross-country learning about external evaluation, particularly to how the accreditation and regulatory bodies assess their impact on service performance.

Strengths and Limitations

This comparative general review provides glimpses into two specific approaches of external evaluation, and thus reports *aspects* of structures and processes in the Norwegian and the U.S. regulatory systems. Since this is not a systematic review, the paper does not fully reflect the entire field of relevant literature. It can be viewed as both a strength and a limitation that we have used material in report format for our study's empirical foundation, as this gives us a thorough insight into the field of external evaluation. The implications of different regulatory strategies and arrangements for evaluation on quality and safety discussed in this review adds to the unclarity about impact and effects from external evaluation but are nevertheless limited to the two fundamentally opposing approaches in Norway and the U.S. The general performance of the two countries explored in this paper may be explained by other factors than external evaluation/regulation/accreditation. Further studies on other developed countries are required to allow a more complete discussion of external evaluation practices and relevant recommendations globally.

Conclusion

In this evaluation, we compared the Norwegian and U.S. regulatory approaches. The Norwegian system applies a state body to oversee and evaluate organisations and in doing so to a large degree applies a system perspective with limited attention to blaming individuals. There is a low risk of financial lawsuits in the Norwegian regulatory system. In contrast, the U.S. system relies on accreditation, insurance and more patients bring lawsuits to be compensated for harm resulting from the healthcare system, even though the evidence suggests that few patients suffering even negligent injuries receive compensation. Given the differences between the countries, it is not clear that one system is better that the other even though the countries score differently on health indicators, with Norway having better performance. Both accreditation and external inspection are strategies put in place to ensure that healthcare providers have adequate quality systems as well as contributing to the

wider risk and safety enhancing management and implementation processes in the organizations subjected to evaluation. This paper therefore highpoints the idea that achieving safety must include a multifactorial mindset for policy and decision makers, and to inspectors and accreditors. Successful evaluation process and implementation shown to associate with external expectations needs to be clearly stated, with guidance and support offered along with the required compliance with standards and regulations. Paraphrasing the famous quote of Montesquieu "Useless laws weaken the necessary laws", we believe that useless evaluation weakens the necessary evaluation. The design of the Norwegian and the U.S. distinct regulatory frameworks have implications for the national policies implemented and the processes of evaluation of quality. In turn, these implications may result in differences in quality and safety outcomes, efficiency, administrative burdens, spending, and legitimacy. Thus, knowledge retrieved from the comparative document study may contribute to better understanding of the different system designs' enablers and barriers and may in turn add to learning potentials for cross country improvement at the health policy level.

Conflict of Interest

The authors declare that the research was conducted in the absence of any commercial or financial relationships that could be construed as a potential conflict of interest.

XXX reports grants and personal fees from EarlySense, personal fees from CDI Negev, equity from ValeraHealth, equity from Clew, equity from MDClone, personal fees and equity from AESOP, personal fees and equity from Feelbetter, equity from Guided Clinical Solutions, and grants from IBM Watson Health, outside the submitted work. XXX has a patent pending (XXX), on intraoperative clinical decision support.

Author Contributions

XX had the idea and developed the first draft of the paper, followed by revision in collaboration with XX and XXX.

Funding

The authors are supported by XXXX.

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