

BMJ Open Mediators of change in healthcare organisations subject to external assessment: a systematic review with narrative synthesis

Einar Hovlid ,^{1,2} Geir Sverre Braut,^{1,3,4} Einar Hannisdal,⁵ Kieran Walshe,⁶ Oddbjørn Bukve,¹ Signe Flottorp,⁷ Per Stensland,² Jan C Frich⁸

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ABSTRACT

Objectives External inspections are widely used to improve the quality of care. The effects of inspections remain unclear and little is known about how they may work. We conducted a narrative synthesis of research literature to identify mediators of change in healthcare organisations subject to external inspections.

Methods We performed a literature search (1980–January 2020) to identify empirical studies addressing change in healthcare organisations subject to external inspection. Guided by the Consolidated Framework for Implementation Research, we performed a narrative synthesis to identify mediators of change.

Results We included 95 studies. Accreditation was the most frequent type of inspection (n=68), followed by statutory inspections (n=19), and external peer review (n=9). Our findings suggest that the regulatory context in which the inspections take place affect how they are acted on by those being inspected. The way inspections are conducted seem to be critical for how the inspection findings are perceived and followed up. Inspections can engage and involve staff, facilitate leader engagement, improve communication and enable the creation of new networks for reflection on clinical practice. Inspections can contribute to creating an awareness of the inspected organisation's current practice and performance gaps, and a commitment to change. Moreover, they can contribute to facilitating the planning and implementation of change, as well as self-evaluation and the use of data to evaluate performance.

Conclusions External inspections can affect different mediators of organisational change. The way and to what extent they do depend on a range of factors related to the outer setting, the way inspections are conducted and how they are perceived and acted on by the inspected organisation. To improve the quality of care, the organisational change processes need to involve and impact the way care is delivered to the patients.

BACKGROUND

External inspections are widely used in healthcare.^{1,2} They are a core element in accreditation, certification and regulation.³ These heterogeneous, complex processes consist of a set of activities that are introduced into varying organisational contexts and share a

Strengths and limitations of this study

- This is the first review addressing how external inspections can contribute to improve the quality of care.
- We used a theoretical framework to extract and analyse heterogeneous data to explore mediators of change in the inspected health organisations.
- For some of the theoretical constructs, we did not identify relevant studies and some of the review findings were graded low confidence, partly because of concerns about adequacy of data.

common ground in that 'some dimensions or characteristics of a healthcare provider organisation and its activities are assessed or analysed against a framework of ideas, knowledge or measures derived or developed outside that organisation'.⁴ The phrase 'external inspection' also implies that the inspection is initiated and conducted by an organisation external to the one being inspected. External inspections can serve different purposes like promoting accountability and transparency in a regulated society.¹ A key purpose of external inspections is that they are conducted to reveal possible substandard performance. When they reveal substandard performance, the inspected organisations are expected to implement necessary change, thereby improving the quality of care delivery.⁵

Evidence on the effect of external inspections on the quality of care remains unclear and contradictory.^{6–10} The way in which external inspections might mediate change in organisations is poorly understood.^{11,12} Better knowledge of how external inspections can contribute to improve quality of care may increase our understanding of why the effects of external inspections seem to vary and facilitate more effective ways of conducting inspections.^{6,11,13}



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For numbered affiliations see end of article.

Correspondence to
Dr Einar Hovlid;
einar.hovlid@hvl.no

We conducted a systematic review and performed a narrative synthesis to explore how external inspections can contribute to mediate change and improve the quality of care in healthcare organisations.

Theoretical framework

Quality of care is understood as a property of healthcare systems delivering care.^{14 15} Accordingly, improving the quality of care depends on changing the performance of the healthcare system, which implies change in organisational behaviour.^{16 17} Change in organisational behaviour can be understood as a complex social process that involves individuals or groups with the capacity to initiate activities that can contribute to producing change in their organisation in the presence of the appropriate antecedent conditions.^{18–20}

If external inspection is to contribute to improving the quality of care, it needs to impact organisational change, defined as ‘any modification in organisational composition, structure or behaviour’.²¹ Change activities take place in an organisation of social actors; thus, these activities are accompanied by communication among these actors. Following Schmidt,²² we suggest that the communication within the organisation can affect organisational ideas, which can be understood as the substantive content of the communication about the activities that are undertaken. These ideas represent a cognitive frame for how the organisational actors view and understand their organisation and the change activities that take place within it.²² We refer to the communication about organisational ideas as organisational discursive activities. **Figure 1** shows our study framework.

We need to explore how external inspections can affect the change and discursive activities involved in organisational change aimed at improving the quality of care. Accordingly, we need to identify the related theoretical constructs and explore how these constructs can be affected by external inspections.

The Consolidated Framework for Implementation Research (CFIR) is a metatheoretical framework based on the synthesis of constructs from existing theories, which

identifies and defines key constructs involved in effective implementation of organisational change (see online supplementary file 1).²³ The CFIR encompasses five main domains: intervention characteristics, outer setting, inner setting, characteristics of the individuals involved and the process of implementation. We regard these theoretical constructs as conceptualisations that may be impacted by external inspections during the process of implementing organisational change.

METHODS

Literature review

We performed a systematic literature search (1980–January 2020) to identify empirical studies addressing changes in healthcare organisations subject to external inspection. Our inclusion criteria were quantitative and qualitative studies about external inspections that included empirical data about mediators of change at an organisational level for care delivery. The studies also needed to include a method section describing how data were obtained and analysed. Because the purpose of our study was to explore mediators of change rather than assessing effect sizes of inspections, we found it expedient to include both qualitative and quantitative studies.

We searched the following electronic databases for studies: the Cochrane Central Register of Controlled Trials, Cochrane Database of Systematic Reviews, Database of Abstracts of Reviews of Effectiveness, Medline, Embase, The Cumulative Index to Nursing and Allied Health Literature (CINAHL), PsychINFO and Web of Knowledge. A detailed description of the searches in all of the databases is provided in online supplementary file 2.

Data extraction and analysis

An overview of the article selection process is shown in **figure 2**. EHø performed an initial screening of the article titles and the abstracts, focusing on relevance. EHø, GSB and EHå independently reviewed the full text articles and then discussed which articles that should be included in the review.

The main reasons for exclusion were that articles did not include an external inspection, did not address how the external inspection affected the organisation, were not based on empirical findings or did not address clinical care. We included 95 articles for further analysis.

The articles used a range of study designs addressing different types of external inspections in different settings. Thus, we used narrative synthesis as our analytical strategy.²⁴ Narrative synthesis comprises four main elements: developing an initial theory of how the intervention works, developing a preliminary synthesis of findings from the included studies, exploring relationships in the data and assessing the robustness of synthesis. Our initial theory of how external inspections might affect the involved organisations was built around the CFIR. This framework defines key constructs involved in effective implementation of change in an organisation.



Figure 1 Study framework.

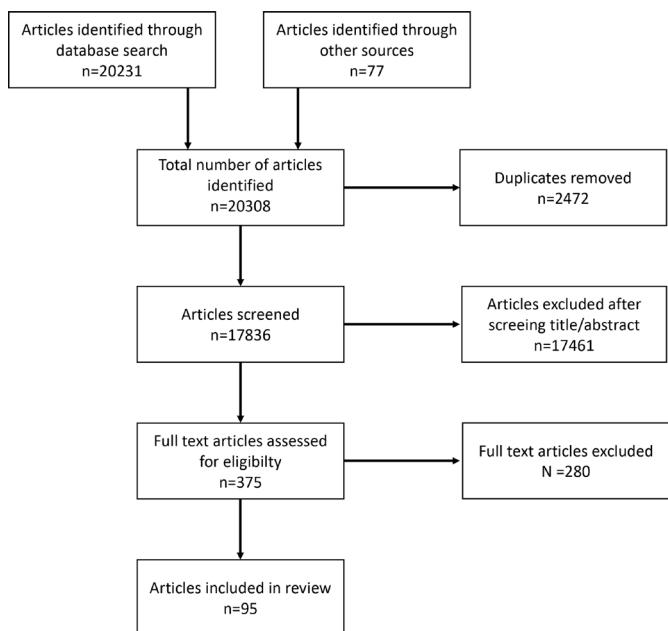


Figure 2 Flow chart of article selection process.

Accordingly, we explored how external inspections could affect the theoretical constructs identified in the framework.

For each of the included studies, EH_o extracted data about the study aim, study method, participants, setting, type of inspection and main findings. EH_o conducted the preliminary synthesis of the data for how external inspection affected the involved organisations. The data extraction was guided by the theoretical constructs in the CFIR and comprised written summaries of key findings, excerpts of results from the included studies that addressed the constructs in the CFIR, including illustrative quotations used in qualitative studies. GSB read the included articles to validate the data extraction.

To analyse and explore relationships in the extracted data, we conducted a thematic content analysis of all data included in the preliminary synthesis. We used a combination of direct and indirect approaches as described by Hsieh and Shannon.²⁵ Our initial coding scheme was guided by theory and comprised the theoretical constructs in the CFIR. During the analysis, we added codes derived from the data. Using an iterative process of coding, reflecting on the codes and condensing, we identified themes describing how external inspections could affect organisational change.²⁶ The extracted data and analysis were shared and discussed among all authors.

GRADE (Grading of Recommendations, Assessment, Development and Evaluations)-Confidence in the Evidence from Reviews of Qualitative Research (GRADE-CERQual) was developed to assess the confidence of review findings from qualitative evidence synthesis and is based on four components: methodological robustness, relevance, adequacy of data and coherence of findings. Because most of our included studies used a descriptive design and were based on qualitative data, we found it

expedient to apply the GRADE-CERQual principles to assess the confidence of our review findings.

To determine the methodological robustness of the included studies, we applied previously used assessment criteria²⁷ which were adapted from criteria developed by Cunningham *et al*²⁸ and the Australian National Health and Medical Research Council.²⁹ These criteria were developed to assess the methodological quality of a range of study designs. Based on the criteria, studies were scored from 1 to 3, where 3 denotes the most robust study methodology.

The criteria and the rating scheme are displayed in online supplementary file 3. EH_o and GSB independently rated all of the included studies and then discussed each article to reach consensus on a CERQual statement for each review finding. Our review is based on previously published and publicly available data; therefore, ethical approval was not needed.

Patient and public involvement

No patients involved.

RESULTS

Table 1 presents the characteristics of the included studies. In total, 95 studies met the eligibility criteria. Accreditation was the most frequent type of inspection (n=68), followed by statutory inspections (n=19), and external peer review (n=9). A descriptive design was used in 46 of the studies, implying that the data were collected merely to describe and characterise the study population. An analytical design was used in 49 of the studies, implying that the data were collected to test a hypothesis or associations between the variables. Five of the analytical studies included an intervention and randomisation. Data collection methods included surveys, performance indicators based on administrative data or patient records, interviews, focus group interviews, document analysis and observation. None of the studies used an experimental design to test the mediators of change in organisations subject to external inspections.

The presentation of the findings is structured according to the mediators of change identified in our analysis guided by the theoretical constructs in the CFIR. For clarity, some of the mediators of change are presented together. The theoretical constructs, the mediators of change identified in our analysis and the corresponding articles are shown in **table 2**.

Self-assessment

Survey and interview data suggest that the self-assessment tools were considered useful and initiated critical reflection on the organisation's current practice.^{30–34} Four other studies reported that the self-assessment tool was confusing and time consuming and was concerned with finding and producing documentation rather than reviewing practice.^{35–38} Four case studies, three using interview data and one using time series analysis of performance indicators

Table 1 Characteristics of the included studies, Consolidated Framework for Implementation Research (CFIR) constructs addressed and quality rating

Articles	Purpose of study	Study design	Data source and method	Setting	Type of inspection	CFIR construct addressed in article	Quality rating (1–3, 3 is most robust)
Boyd et al ⁶⁴	To explore how inspection team members work together to conduct hospital inspections	Case study	Mixed methods study with interviews (N=78), observation, survey of 369 team members, response rate 66%	Hospital England	Statutory inspection	7	3
Boyd et al ⁶⁰	To investigated the inter-rater reliability of assessments made by inspectors inspecting acute hospitals in England	Cross sectional	Survey data (N=286, response rate 65%). Analysis: multinomial logistic regression and Krippendorff's alpha (K _a)	Hospital England	Statutory inspections	7	3
Alqahtani et al ⁶⁷	To assess impact the perceptions of health professionals on the impact of accreditation	Cross sectional	Survey (N=901, response rate 67%). Analysis: t-test, ANOVA	Hospital Saudi Arabia	Accreditation	19, 21, 31, 32	2
Allen et al ¹⁰	To examine the effect of inspections by the Care Quality Commission on emergency department performance	Cross sectional	Analysis of six standard emergency department performance indicators for 118 hospitals.	England, hospitals	Statutory inspection	7	3
Almasabi and Thomas ¹¹²	To examine factors explaining quality results in accreditation	Case study	Mixed methods, survey (N=669, response rate 69%), 12 interviews with managers, and document analysis. Regression analysis	3 hospitals in Saudi Arabia	Accreditation	27, 28, 31	3
Alyahya et al ⁷⁸	To explore how accreditation was perceived by primary care centres	Case study	Qualitative interviews with 56 healthcare professionals and staff centres Jordan	One university	Accreditation	10, 11, 12, 19	2
Andres et al ¹⁰⁹	To assess association between accreditation and staff perception of organisational culture	Cohort study	Survey at three time points before and after accreditation. N=545, response rate 20%. Analysis: regression and t-test	hospital in Hong Kong	Accreditation	26	1

Continued

Table 1 Continued

Articles	Purpose of study	Study design	Data source and method	Setting	Type of inspection	CFIR construct addressed in article	Quality rating (1–3, 3 is most robust)
Andres et al ⁷⁴	To evaluate impact of hospital accreditation on patient experience	Cross sectional	Three consecutive surveys, with totally 3083 patients, response rate 84%, analysed with t-test, ANOVA, and regression analysis	Hospital Hong Kong	Accreditation	9	3
Arianson et al ⁶⁵	Evaluation of effect of inspection with delivery institutions	Cross sectional	Survey of staff at 26 delivery institutions (N=208, 89% response rate). Interviews	Norway, hospital	Statutory inspection	7, 32	2
Askim ⁴⁴	Assess county experiences with statutory inspections	Case study	Document analysis, interviews with inspection teams, 8 county managers, government officials. Survey of inspection teams	Norway, primary care	Statutory inspection	4, 11, 32	1
Baskind et al ⁸³	To explore the effects of a standards-based, peer review, accreditation model on standards of care in acute inpatient wards and explore how staff achieved change	Qualitative	8 telephone interviews with local project leaders	England, mental health wards	Accreditation	19, 21, 26, 28, 33	1
Benson et al ⁶¹	To examine the impact of Commission for Health Improvement's clinical governance reviews on NHS trusts in England.	Cross sectional	30 NHS trusts. Interview Document analysis, 17 interviews with hospital staff, survey of key stakeholders (N=90, 44% response rate)	England, 30 NHS trusts	Statutory inspection	4, 9, 11, 21, 22, 28, 30, 32, 33	2
Bogh et al ⁹¹	To identify predictors of the effectiveness of hospital accreditation on process performance measures	Cohort study, with a stepped wedge design	1 624 518 processes of care. Logistic regression analysis	Hospital Denmark	Accreditation	18	3

Continued

Table 1 Continued

Articles	Purpose of study	Study design	Data source and method	Setting	Type of inspection	CFIR construct addressed in article	Quality rating (1–3, 3 is most robust)
Braithwaite et al. ⁶⁴	To determine whether accreditation performance is associated with self-reported clinical performance and independent ratings of four aspects of organisational performance	Cross sectional	19 health service organisations. Indicators for clinical performance. Assessment of organisational context measures through observation and interviews. Variance and correlation analysis	Australia, acute care: large, medium and small healthcare service organisations	Accreditation	19, 26, 27	2
Braun et al. ¹²¹	To study the impact of organisational characteristics on quality-related activities in health centres	Cross sectional	Survey of executive directors at health centres (N=830 to 35% response rate). Bivariate analysis	USA, 830 health centres	Accreditation	33	2
Campbell et al. ⁴⁵	To describe the development, content and piloting of version one of the Primary Medical Care Provider Accreditation scheme	Cross sectional	36 general practices. Nonparametric analysis of compliance with quality criteria. Interviews with general practitioners, practice managers, nurses	England, 36 practices	Accreditation	4, 8, 9, 26, 31, 32	1
Castro-Avila et al. ⁸	To evaluate the effect of Care Quality Commission external inspections of acute trust on adverse event rates	Interrupted time series analysis	Multilevel-random coefficient modelling of rates of falls with harm and pressure ulcers from 155 acute trusts	Hospital England Statutory inspection	23	2	
Chuang et al. ¹¹⁹	To determine accreditation surveyors' and hospitals' use and perceived usefulness of clinical indicator reports and the potential to establish the control relationship between the accreditation and reporting systems.	Cross sectional	Survey of 306 surveyors, 24% response rate. Pearson χ^2 tests.	Australia	Accreditation	33	2

Continued

Table 1 Continued

Articles	Purpose of study	Study design	Data source and method	Setting	Type of inspection	CFIR construct addressed in article	Quality rating (1–3, 3 is most robust)
Collopy et al ¹²	Assess the use of clinical indicators in the accreditation process	Case study	Performance indicators from 667 hospitals	Australia, hospitals	Accreditation	33	1
Commonwealth of Australia ⁴⁶	To evaluate the impact of accreditation on the delivery of quality of care and quality of life to residents in aged care homes	Cross sectional	Survey of quality managers (N=1884, 33% response rate) and care staff (N=1116, 47% response rate). Interviews. Literature review	Australia, care homes	Accreditation	4, 8, 9, 12, 33	1
Correia et al ¹⁰	To develop a system measurement model of the Brazilian hospital accreditation system	Cross sectional	Survey sent to 515 accredited institutions, response rate 49%, analysis with χ^2 test	515 hospitals Brazil	Accreditation	27	2
Daucourt and Michel ⁹⁸	To identify the areas of needed improvement that were most frequently identified in the first 100 accredited hospitals by the French Accreditation College	Cross sectional	Archive data on accreditation. Parametric and non-parametric tests	France, hospitals	Accreditation	21	3
Davis et al ⁷⁹	To survey accredited healthcare departments on barriers to and supports of accreditation preparation, performance on accreditation standards, and benefits and improvements after accreditation	Cross sectional	48 accredited healthcare departments. Survey of 48 managers, 100% response rate. Document analysis	USA	Accreditation	8, 10, 32, 33	3

Continued

Table 1 Continued

Articles	Purpose of study	Study design	Data source and method	Setting	Type of inspection	CFIR construct addressed in article	Quality rating (1–3, 3 is most robust)
Devkaran and O'Farrell ³⁹	To evaluate whether accredited hospitals maintain quality and patient safety standards over the accreditation cycle by testing a life-cycle explanation of accreditation on quality measures	Case study	Case study. Register data with 23 quality indicators. Interrupted time series and regression analyses	United Arab Emirates, hospital	Accreditation	1, 21, 32	3
Devkaran et al ¹⁶	To evaluate whether hospital reaccreditation can sustain improvement over three accreditation cycles	Case study	Interrupted time series analysis of 27 quality measures using regression equations	Hospital United Arab Emirates	Accreditation	32, 33	3
Doyle and Gramp ³⁵	To estimate the cost of the accreditation process and to analyse the effect of the accreditation process within the organisation	Case study	Case study of three hospitals. 73 interviews, 7 focus group interviews with hospital staff and team leaders. Survey 1 staff (N=500, 10% response rate) survey 2 team members (N=100, 19% response rate) survey 3 key staff (N=1) Observation	Ireland, 3 hospitals	Accreditation	1, 8, 12, 22, 26, 28	1
Duckett ⁴⁰	To explore the impact of the accreditation programme on a random sample of 23 Australian hospitals	Case study	Case study with 23 hospitals. Interviews with senior hospital personnel.	Australia, 23 hospitals	Accreditation	1, 10, 12, 19, 21, 26, 27, 32	1
Due et al ³⁶	To explore how general practitioners and their staff perceive the accreditation standards	Case study	Two rounds of qualitative interviews with 39 staff and general practitioners from 11 general practices	11 general practices Denmark	Accreditation	4, 28	3
Ehlers et al ⁷¹	To evaluate effectiveness of unannounced versus announced surveys in detecting quality problems	Cluster-randomised controlled trial	Level of compliance with 113 performance indicators. Binomial regression analysis	23 hospitals Denmark	Accreditation	7	3

Continued

Table 1 Continued

Articles	Purpose of study	Study design	Data source and method	Setting	Type of inspection	CFIR construct addressed in article	Quality rating (1–3, 3 is most robust)
El-Jardali <i>et al</i> ³⁶	To examine impact of accreditation of primary healthcare centres	Cross sectional	Mixed methods, survey (N=403, response rate 76%), 22 qualitative interviews. Analysis: linear regression	25 primary healthcare centres Lebanon	Accreditation	12, 21, 28, 30, 31, 32	3
El-Jardali <i>et al</i> ¹³	To assess the perceived impact of accreditation on quality of care and investigate the perceived contributing factors that can explain change in quality of care.	Cross sectional	Survey, 1485 nurses, 75.5% response rate, regression analysis	Lebanon, hospitals	Accreditation	27, 31, 33	3
Esik <i>et al</i> ⁴⁷	To present an example of how external audit can be used to improve quality of care	Case study	2 radiotherapy departments. Adherence to predefined quality criteria. Variance analysis	Austria and Hungary	External peer review	4, 11, 21, 27	1
Fairbrother and Gleeson ³⁷	Evaluate accreditation process	Cross sectional	Survey with closed/open-ended questions. 88 respondents from clinical and managerial staff. 44% response rate	Australia, hospital	Accreditation	1, 28, 32	1
Greenfield <i>et al</i> ⁷²	To evaluate short-notice surveys in accreditation programmes	Cross sectional	Two trials, one from hospital (N=20) and one from primary care and hospitals (N=7). Regression analysis of performance data	Primary care and hospitals Australia	Accreditation	7	3
Greenfield <i>et al</i> ⁵³	To identify resources and expertise required for the revision of accreditation standards	Case study	Expert panel and document analysis	General practice Australia	Accreditation	4	1
Greenfield <i>et al</i> ⁵⁸	To examine challenges to surveyor reliability	Case study	Qualitative data from group interview with survey coordinators	Hospital Australia	Accreditation	7	2
Greenfield <i>et al</i> ⁵⁴	To explore development and implantation of an accreditation scheme in Australia	Case study	Multi method case study using document analysis, observations, interview with 197 stakeholders	Hospital Australia	Accreditation	4, 12	3

Continued

Table 1 Continued

Articles	Purpose of study	Study design	Data source and method	Setting	Type of inspection	CFIR construct addressed in article	Quality rating (1–3, 3 is most robust)
Greenfield et al ⁴⁸	To investigate understandings and concerns of stakeholders regarding evolution of accreditation programmes in Australia	Case study	47 group and individual interviews with 258 stakeholders	Healthcare Australia	Accreditation	4, 11, 12, 19, 21, 31, 33	2
Greenfield et al ⁵⁹	To investigate accreditation survey coordinators' perceptions of reliability issues	Cross sectional	Survey data from two surveys. (N=53 and N=35). Descriptive analysis	Hospital Australia	Accreditation	7	1
Greenfield et al ³⁰	To investigate whether an accreditation programme facilitates healthcare organisations to evolve and maintain high-performance human resource management systems	Cross sectional	Cross-sectional multimethod study of 6 high performing accredited healthcare organisations. Document analysis, interviews.	Australia	Accreditation	1, 10, 11, 12, 21, 30, 32, 33	3
Greenfield et al ⁹²	To examine whether longitudinal participating on accreditation is translated into improvements in continuity of quality of patient care	Cohort study	Accreditation panel data from 311 hospitals. Regression analysis	Hospital Australia	Accreditation	18	3
Greenfield et al ³¹	To explore the experiences of health executives, managers and frontline clinicians who participated in organisational accreditation processes; what motivated them to engage, and what benefits accrued?	Qualitative	Case study. Interviews with 30 staff involved in an accreditation process at one hospital	Australia, teaching hospital	Accreditation	1, 7, 10, 21, 26, 28, 30, 33	2

Continued

Table 1 Continued

Articles	Purpose of study	Study design	Data source and method	Setting	Type of inspection	CFIR construct addressed in article	Quality rating (1–3, 3 is most robust)
Greenfield et al ⁶²	To examine if accreditation survey processes are reliable	Case study	Mixed methods, 193 stakeholders participated in interviews and a survey	Hospital Australia	Accreditation	7	2
Greenfield et al ⁶³	To examine survey reliability	Case study	Mixed methods with document analysis, observation and interviews of stake holders	Hospital Australia	Accreditation	7	2
Grenade and Boldy ³⁸	Explore participants experience with accreditation in residential aged care facilities	Case study	Case study of 15 residential aged care facilities. 30 interviews with nurses and managers	Australia, residential aged care facilities	Accreditation	1, 8, 26, 28	1
Hayes et al ¹¹⁷	Compare the effect of two external feedback strategies on the adherence to congestive heart failure guidelines	Randomised controlled trial	32 hospitals randomised to two different strategies for external feedback. Performance indicators and interviews with 32 quality managers before and after intervention. Multivariate analysis and t-test.	USA, 32 hospitals	Statutory inspection	32	3
Hinchcliff et al ⁴⁹	Identify factors enabling effective implementation of accreditation programmes across different healthcare settings	Qualitative	Qualitative interviews with 258 healthcare stakeholders. 39 focus group interviews and 8 individual interviews	Australia	Accreditation	4, 12, 22, 27, 28, 32	3
Hinchcliff et al ⁵⁵	To examine how consumer engagement can be promoted in accreditation	Case study	Multimethod, survey data (84% response rate), group and individual interview of 258 health professionals and stakeholders	Hospital Australia	Accreditation	4, 9	3
Hofhuis et al ⁹⁸	Evaluate the effects of visitation and to determine which factors are related to the effectiveness of visitation	Cross sectional	Survey of 151 allied health professionals. 73% response rate	The Netherlands	External peer review	21, 32	2

Continued

Table 1 Continued

Articles	Purpose of study	Study design	Data source and method	Setting	Type of inspection	CFIR construct addressed in article	Quality rating (1–3, 3 is most robust)
Hogden et al ⁷⁵	To explore staff perceptions on factors influencing an aged care accreditation programme	Case study	Focus group interviews with 66 aged care staff from 11 aged care Australia facilities	Primary care	Accreditation	9, 12, 28	2
Hovlid et al ¹⁰⁰	To explore how inspecting organisations express and follow-up non-compliant behaviour	Case study	Document analysis of correspondence between county governors and healthcare organisations in 36 inspections	Healthcare Norway	Statutory inspection	21, 30, 32	2
Kilsdonk et al ⁸⁵	To explore the value and perceived impact of external review in cancer care	Case study	Qualitative data from interview with 31 stake holders from 15 hospitals	15 hospitals Netherlands	External review	19, 21, 23, 26, 28	2
Kilsdonk et al ¹⁰⁵	To examine the clinical impact of peer review on colorectal cancer care.	Case control	Performance indicators from 30 hospitals, 23 intervention and 7 control. Multivariate logistic analysis	The Netherlands	External peer review	22	2
Knutson et al ⁸⁵	Explore beliefs and perceptions regarding the importance of accreditation, and to evaluate possible correlations between standard compliance and improved patient care and oncologic outcomes	Cross sectional	Performance indicators. Survey (N=2038 to 50% response rate)	USA, cancer facilities	Accreditation	12, 33	2
Kousgaard et al ⁹⁶	To explore how general practitioners and their staff experienced mandatory accreditation	Case study	Qualitative data from 11 clinics, 42 interviews	General practices Denmark	Accreditation	1, 19, 21, 22, 26, 28, 30, 31, 32	3
Lam et al ⁹⁰	To compare performance of hospitals accredited by The Joint Commission and state survey hospitals	Cross sectional	4 242 684 patients aged 65 years and older. Main outcome: risk adjusted mortality, readmission rates and patient satisfaction scores	4400 hospitals in USA	Accreditation	18	3

Continued

Table 1 Continued

Articles	Purpose of study	Study design	Data source and method	Setting	Type of inspection	CFIR construct addressed in article	Quality rating (1–3, 3 is most robust)
Lee ¹⁰⁷	To compare safety climate among nurses before and after accreditation	Cross sectional	Survey before (N=217, response rate 58%) and after accreditation (N=373 response rate 87%). Analysis: t-test and Pearson's correlation coefficient	Hospital South Korea	Accreditation	26	1
Lombarts and Klazinga ³²	Evaluate effect of supporting implementation processes after external peer review	Cross sectional	Survey. Telephone interviews. 25 specialist group practices, 67 specialists	The Netherlands	External peer review	1, 9, 22, 26, 32	1
Lombarts et al ⁵⁷	To evaluate the impact of facilitation by management consultants on implementing recommendations from external peer review.	Cross sectional	Survey of 205 medical specialists, representing 50 hospital-based specialist groups, 54% response rate. Analysis: correlation using Spearman's test	The Netherlands	External peer review	4, 32	2
Pomey et al ⁸⁰	Explore organisational changes following accreditation	Case study	Single case study. Hospital staff. Survey (N=3362, 52% response rate), 67 interviews, interviews, document analysis and observation	France, university hospital	Accreditation	10, 12, 19, 21, 25, 26, 27, 28, 31, 32	2
Pomey et al ⁴¹	To explore how accreditation can facilitate organisational change	Case study	Case study based on document analysis, 25 individual interviews, 10 focus group interviews with hospital staff	Canada, 5 hospitals	Accreditation	1, 10, 12, 19, 21, 23, 26, 28, 31, 32	2
Melo ⁵¹	To explore how accreditation can lead to improvement	Case study	Qualitative interview with 49 staff members	One hospital Portugal	Accreditation	4, 12, 19, 23, 26, 27, 31, 32, 33	2
Moe et al ⁸¹	To examine the impact of accreditation on community family practices	Case study	Performance indicators and survey data (N=82, response rate 81%). Analysis: t-test and ANOVA	5 family practices in Canada	Accreditation	10, 26, 27	2

Continued

Table 1 Continued

Articles	Purpose of study	Study design	Data source and method	Setting	Type of inspection	CFIR construct addressed in article	Quality rating (1–3, 3 is most robust)
Mumford et al ⁷³	To assess direct costs of hospital accreditation in Australia	Cohort	Mixed methods design incorporating stakeholder analysis, survey, activity-based cost analysis, and expert panel review	6 acute care hospitals in Australia	Accreditation	8	3
Nekoei-Moghaddam et al ¹¹⁴	To explore staff perceptions of hospital accreditation	Case study	Qualitative interviews with 17 staff members	Hospital Iran	Accreditation	28	1
Nouwens et al ⁷⁶	To identify determinants of impact of a practice accreditation programme in primary care	Case study	Qualitative data from 33 primary care professionals	General practices Netherlands	Accreditation	9,12,18,19,26,28, 30,31,32,33	2
Nouwens et al ¹⁰¹	To evaluate the effectiveness of improvement plans in practice accreditation in primary care	Randomised controlled trial	45 primary care practices randomised to intervention and control. Primary outcome: blood pressure, low-density lipoprotein (LDL) cholesterol and prescription of antiplatelet drugs. Analysis: regression	45 primary care practices in the Netherlands	Accreditation	21,30,32	3
Office of Public Management ¹³⁰	Evaluation of a national audit of specialist inpatient healthcare services for people with learning difficulties in England	Cross sectional	72 NHS trusts. Survey of managers (N=242, 97% and 93% response rates)	England, hospitals	Statutory inspection	1,21	1
Oliveira et al ¹⁰²	To explore managers' and professionals' perception on changes deriving from accreditation	Case study	Qualitative interviews with 5 managers and 91 professionals from 5 hospitals	Hospital Brazil	Accreditation	21,27,30,32	2

Continued

Table 1 Continued

Articles	Purpose of study	Study design	Data source and method	Setting	Type of inspection	CFIR construct addressed in article	Quality rating (1–3, 3 is most robust)
OPM Evaluation team ⁶⁶	To assess how the inspection programme on healthcare-associated infections is working to achieve its intended outcomes over time	Cross sectional	80 health trusts. Performance indicators. 98 interviews with board members, managers, hospital staff. Focus group interview with 20 service users. Survey of managers, 134 responders, 78% response rate	UK, hospitals	Statutory inspection	7, 11, 12, 19, 21, 22, 25, 26, 27, 28, 31, 32, 33	
Oude Wesselink et al ¹³¹	To evaluate the effects of a supervision programme on the provision of smoking-cessation counselling	Three substudies. 1: observational before-after study, 2 and 3: randomised controlled trial with only postintervention measurements	233 primary care midwifery practices. Performance indicators. Survey A (n=113, 94% response rate), survey B (N=71, 75% response rate), survey C (N=11, 79% response rate). Analysis: linear and logistic regression	The Netherlands, primary care	Statutory inspection	32	3
Paccioni et al ¹⁰⁸	Describe and understand the effects of the accreditation process on organisational control and quality management	Case study	Longitudinal case study of 2 primary care centres. Group interview (N=1) individual interviews (N=35), observation. Survey (N=328, response rate institution A 27%, institution B 47%). Bivariate analysis and t-test.	Canada, primary care	Accreditation	26, 27, 31, 33	2
Pedersen et al ⁸⁹	To test whether accreditation contributes to foster intrinsic motivation	Cluster randomised stepped wedge	Baseline and follow-up survey of 1164 general practitioners. Response rate 56% and 54%. Analysis: mixed effects multilevel models	General practice Denmark	Accreditation	14	2
Pham et al ⁵⁶	To examine the impact of quality reporting on hospitals' data collection and review processes	Cross sectional	36 hospitals. 111 interviews with hospital staff, hospital association leaders, JCAHO representatives	USA, 36 hospitals	Accreditation	4, 8, 12, 21, 23, 25, 28, 33	1

Continued

Table 1 Continued

Articles	Purpose of study	Study design	Data source and method	Setting	Type of inspection	CFIR construct addressed in article	Quality rating (1–3, 3 is most robust)
Pollard et al ¹⁵	To examine unit characteristics and the use of seclusion and restraint in a mental health unit before and after the promulgation of the Joint Commission on Accreditation of Healthcare Organizations (JCAHO) 2000 standards	Case study	Performance indicators, t-test to compare prepolicy and postpolicy implementation	USA, acute mental health unit	Accreditation	32	3
Rajan et al ⁸²	To explore staff perceptions about changes following accreditation	Case study	Qualitative interviews with managers and staff	8 cancer centres in Netherlands	Accreditation	10, 19, 21, 32, 33	2
Reisi et al ¹⁰⁶	To explore facilitators and barriers for implementation of accreditation	Cross sectional	Survey of 1706 respondents (response rate 76%) from 43 hospitals, multiple regression analysis	43 hospitals in Iran	Accreditation	24, 27, 31	3
Rivas et al ⁸³	Examine perceptions of local service change and concepts of change among participants in a UK nationwide randomised controlled trial peer reviewed with feedback to promote quality improvement	Qualitative	43 interviews with hospital staff (24 in intervention group and 11 in control group)	England, NHS	External peer review	10, 11, 19, 21, 26, 31, 32	3
Saleh et al ⁵²	To assess views of hospitals on worthiness of accreditation	Cross sectional	Survey (N=110 hospitals, response rate 63%). Analysis: Pearson χ^2 , Fischer's exact test. Qualitative analysis of open-ended answers in survey	Hospital Lebanon	Accreditation	4, 8	2

Continued

Table 1 Continued

Articles	Purpose of study	Study design	Data source and method	Setting	Type of inspection	CFIR construct addressed in article	Quality rating (1–3, 3 is most robust)
Salmon et al ¹¹⁸	To assess the effects of an accreditation programme on public hospitals' processes and outcomes	Randomised controlled trial	53 hospitals randomised to accreditation or control. Performance indicators and degree of compliance with accreditation standard. χ^2 , correlation and analyses of variance	South Africa, 20 hospitals	Accreditation	32	2
Schaefer and Wig ⁶⁷	To examine how count governors contribute to improvement through external inspections	Case study	Qualitative data from interview with 10 inspectors from two county governor offices	Healthcare Norway	Statutory inspection	7, 10, 21	2
Shah et al ⁸⁷	To assess the impact of Local Boards of health of governance function on Local Health Departments	Cross sectional	Survey data from 329 Local Health Departments. Response rate 58%. Analysis with logistic regression models.	Primary care USA	Accreditation	12	2
Shakespeare et al ¹⁰³	Explore effect of external audit on clinical practice and medical decision making in an oncology centre	Cross sectional	Assessment of 100 randomly chosen patient records according to predefined criteria. Univariate and multivariate analysis	Asia, cancer centre	External peer review	21, 25	2
Shaw et al ¹¹¹	To investigate the relationship between ISO 9001 certification, accreditation and quality management	Cross sectional	Mixed methods multilevel study with data from 73 hospitals in seven countries. Performance data about care delivery and survey data. Analysis: multivariable linear regression	Hospital Europa	Accreditation	27	3
Smithson et al ⁴³	To evaluate the impact of the Care Quality Commission (CQC) on provider performance	Cross sectional	Document review, observation of inspections, 170 qualitative interviews with senior CQC leaders, NHS trusts, clinical staff and stakeholder organisations. Analysis different performance indicators.	The UK, hospitals, and general practices.	Statutory inspection	1, 7, 8, 10, 11, 12, 18, 19, 21, 26, 27, 31, 32, 33	3

Continued

Table 1 Continued

Articles	Purpose of study	Study design	Data source and method	Setting	Type of inspection	CFIR construct addressed in article	Quality rating (1–3, 3 is most robust)
Teymourzadeh et al ⁶⁸	To identify factors affecting survey or management of hospital accreditation	Case study	Qualitative interview with 21 stakeholders	Hospital, Iran	Accreditation	7	1
The Norwegian Board of Health Supervision ⁵⁰	Evaluation of Statutory inspections with primary elderly care	Cross sectional	41 interviews with inspection team members, municipality managers and staff. Survey of municipality managers (N=325, 68% response rate)	Norway, primary care	Statutory inspection	4, 7, 10, 32, 33	2
Triantafillou ⁸⁸	To explore the emergence of accreditation of hospitals in Denmark	Case study	Document analysis and qualitative interviews with 8 key informants	Hospital Denmark	Accreditation	12	1
Tuijn et al ⁶³	To examine the effect of two interventions on reliability and validity of regulatory judgements	Randomised controlled trial	Variance and regression analysis of inspectors' judgements and control variables	Nursing homes Netherlands	Statutory inspections	7	3
Uren et al ⁷⁰	To evaluate stakeholder perception of short-notice (48 hours) assessment	Cohort	Repeated survey to 115 participants. Response rate 28%–46%. Outcomes analysed with Student's t-test.	2 hospitals in Australia	Accreditation	7	1
van Doorn-Klomberg et al ¹²⁰	To examine the effect of accreditation on quality of care for diabetes, chronic obstructive pulmonary disease and cardiovascular disease.	Cohort	138 family practices. Comparative observational study with two cohorts. Performance indicators from patient records. Multilevel regression analysis	The Netherlands, primary care	Accreditation	33	2
Vanoli et al ³³	Evaluate effects of accreditation system	Cross sectional	19 internal medicine units. Performance indicators	Italy, hospitals	Accreditation	1, 21	1
Walsh et al ⁴²	To evaluate the Care Quality Commission's acute hospital regulatory model	Cross sectional	79 interviews with staff from the Care Quality Commission, inspection team members, hospital staff. Survey of inspection team members and hospital staff. Observation	England, NHS	Statutory inspection	1, 6, 7, 9, 10, 19, 21, 23, 26, 28, 30, 31, 32	2

Continued

Table 1 Continued

Articles	Purpose of study	Study design	Data source and method	Setting	Type of inspection	CFIR construct addressed in article	Quality rating (1–3, 3 is most robust)
Walsh et al ¹⁰⁴	To explore the use of external approaches to quality improvement in healthcare organisations following external reviews	Cross sectional	47 NHS trust. Interviews with clinicians and managers, and 12 review team members	England, 47 NHS Trusts	Statutory inspection	21, 30, 32	3
Åsprang et al ⁷⁷	To explore organisational impact of inspections on blood transfusion services	Case study	Qualitative group interviews with 18 professionals	Hospital Norway	Statutory inspection	10, 12, 21, 23, 27	2

The assessment criteria for the quality rating are presented in online supplementary additional file 3. Studies were scored from 1 to 3, where 3 denotes the most robust study methodology.

found that most substantial changes were made during the self-assessment phase,^{36 39–41} where as one study using interview data found that the organisation did not make improvements during the self-assessment phase because it was considered sufficient just to identify improvement needs.⁴² Another case study found that changes made before the site visit were superficial and sought to achieve ritual compliance, focusing more on getting through the inspection process than on really improving the quality of care.⁴³

Importance of valid and relevant inspection standards

Survey and interview data suggest that the standards used for inspections must be valid, focused on clinical practice and benefits for the patients, and should be translated into something perceived as relevant and useful for the services in their improvement work.^{36 44–50} To be perceived as relevant, the standards should be adapted to the local context.^{51 52} Development and revision of standards require a collaborative approach and the expertise of a range of stakeholders including the patients.^{53–55}

Guidance on how to follow up inspection findings

Qualitative data indicate that inspected organisations want guidance on how to improve following an inspection,^{44 50 56} and two studies using survey data and interview data found that organisations receiving support and guidance from a consultant were more successful in implementing changes after the inspection.^{43 57}

Complexity of inspections

Interview data suggest that the inspection teams gather large amounts of qualitative and quantitative data during the inspections, and that it can challenging to synthesis, weigh and make sense of all the gathered information for the inspection team.⁴²

Knowledge and skills of surveyors and credibility of inspections schemes

Ensuring trust and credibility of assessment schemes requires collaboration between regulators, assessment agencies and health services.⁵⁸ A key factor for credibility is surveying reliability,⁵⁹ and qualitative and quantitative date suggest that reliability and validity of surveyor judgements and how they interpret and apply the standards can be a challenge.^{44 49 59–63} The relationship between surveyors and the staff in the organisations being inspected fundamentally affect the way inspections work.⁴³ Qualitative data indicate that the inspection teams should be multiprofessional, and that they need specific knowledge about the services being inspected along with good communication skills, because such knowledge and skills were considered important for the inspected organisations' confidence in the inspection findings.^{31 43 50 64–68} Skill and competence of surveyors along with active collaboration and consensus meetings between surveyors can improve reliability and validity of their judgements.^{60 63 69}

**Table 2** Consolidated Framework for Implementation Research (CFIR) constructs, mediators of change identified in our analysis and the relevant articles

Number	CFIR constructs	Change and discursive activities identified in our empirical data analysis	Articles
1	Intervention source	Self-assessment	30–35 37–43 96
2	Evidence strength and quality		None identified
3	Relative advantage		None identified
4	Adaptability	The importance of valid and relevant inspection standards Guidance on how to follow-up inspection findings	36 44–55 61 43 44 50 56 57
5	Trialability		None identified
6	Complexity	Complexity of inspections	42
7	Design quality and packaging	Knowledge and skills of the surveyors and credibility of inspection schemes Unannounced inspections Choosing whom to inspect	31 43 50 58–60 62–69 42 66 70–72 43
8	Cost	Increased costs	35 38 43 46 52 56 73
9	Patient needs and resources	Patient focus	32 42 45 46 55 61 74–76
10	Cosmopolitanism	Improved relations and communication with external community partners	30 31 40–43 50 67 77–83
11	Peer pressure	External pressure	30 43 44 47 48 61 66 78 83
12	External policy and incentives	Public confidence in services Incentives Role of mass media Government involvement	30 40 41 43 46 48 66 78 85 35 49 56 75 76 80 35 43 48 66 77 48 51 54 86–88
13	Knowledge and beliefs about the intervention	See the constructs: intervention source, adaptability, design quality and packaging	
14	Self-efficacy	Intrinsic motivation	89
15	Individual stage of change		None identified
16	Individual identification with organisation	See the constructs: tension for change, and learning climate and culture	
17	Other personal attributes		None identified
18	Structural characteristics	Structural characteristics	43 76 90–92
19	Networks and communications	Improved communication Facilitate creation of networks	40 42 43 51 66 76 78 80 82 83 90 93–95 48 40 41 43 78 80 97
20	Culture	See the construct: learning climate and culture	
21	Tension for change	Awareness of current practice and performance gaps Awareness of more desirable practice Commitment to change	30 31 33 34 39–43 47 56 61 66 67 76 77 82 86 93 95 96 98–104 30 31 48 82 83 93 95 97 103 41 61 76 80 96 104
22	Compatibility	Perceived relevance of inspection findings	32 35 49 61 66 76 96 105
23	Relative priority	Priority of inspected area	8 41 42 51 56 77 95
24	Organisational incentives and rewards	Incentives	106
25	Goals and feedback	Goal setting	56 66 80 103
26	Learning climate and culture	Improved learning and organisational climate Reflection on clinical practice Improved understanding of organisation and interdependencies in clinical system	38 42 43 66 80 81 83 93 94 96 107–109 31 32 41–43 45 66 76 80 31 35 38 40 41 80 95 96 108
27	Leader engagement	Engage leaders in improvement	40 43 47 49 51 66 77 80 81 94 102 106 108 110–113
28	Available resources	Allocation of resources	31 35–38 41 42 49 56 61 66 75 76 80 86 93 95 96 112 114

Continued

Table 2 Continued

Number	CFIR constructs	Change and discursive activities identified in our empirical data analysis	Articles
29	Access to knowledge and information		None identified
30	Planning	Planning improvement interventions	30 31 42 61 76 86 96 100–102 104
31	Engaging	Engage and involve staff in improvement activities	41–43 45 48 51 66 76 80 83 86 96 97 106 108 112 113
32	Executing	Implementing improvement interventions	30 32 37 39–45 49–51 57 61 65 66 76 79 80 82 83 86 96 97 99–102 104 115–118
33	Reflecting and evaluating	Use of measurement systems and data Evaluation and continuous improvement	43 48 51 56 61 76 82 85 108 113 119–122 30 31 46 48 50 61 66 76 79 85 93 116

Choosing whom to inspect

Inspecting agencies can rely on a risk-based approach for choosing whom to inspect. Data from one case study suggest that the quantitative dataset used to risk assess provider performance and prioritise inspections did not correlate with the subsequent ratings of general practices and acute trusts.⁴³

Unannounced inspections

Interview and survey data suggest that unannounced inspections could limit the time spent preparing for the inspection, and could contribute to enhance the credibility of the inspection findings.^{42 66 70} Two trials using actual performance data from inspections did not find any difference between regular inspections and unannounced/short-notice (48 hours) inspections in their ability to identify quality problems,^{71 72} while survey data from stakeholders indicate that short-notice (48 hours) surveys more effectively identified true organisational performance.⁷⁰

Increased costs

Survey and interview data along with cost indicators suggest that inspections could increase costs during accreditation and inspections. The increased costs related to staff doing different type of work, for example, participating in meetings, producing new documentation and collecting evidence to fulfil documentation requirements, and smaller facilities seemed to have higher costs.^{35 38 43 46 52 56 73}

Patient focus

Three cross-sectional studies using interview and survey data found that the inspection process and recommendations following the inspection should be more directed towards patient care and clinical practice in order to contribute to improvement.^{32 45 61} Interview and survey data suggest that accreditation can contribute to increase the focus on patient needs, and promote patient involvement in care.^{55 74–76} Qualitative data suggest that inputs from patients during inspections are valuable, but more work is needed on how to incorporate such inputs in a meaningful way in the inspection processes.^{42 46}

Relations and communication with external stakeholders

Data from two case studies suggest that findings from inspections can be aggregated and used to identify systemic and interorganisational issues which can influence stakeholders and wider systems other than the inspected organisations themselves.^{43 77} Interview and survey data suggest that inspection processes can contribute to improve the relationship and communication with community partners by sharing experiences and receiving input on how to improve, and that achieving accreditation was viewed as a way to gain prestige and recognition.^{30 31 41–43 50 78–83} One case study indicated that inspection does not improve relations with community partners.⁴⁰

External pressure

Interview and survey data suggest that being reviewed by someone external and independent can be viewed as positive because external feedback can provide a stimulus for change which is based on credible evidence.^{30 43 44 47 61 83 84} Social pressure from stakeholders in the community was viewed as an external pressure to participate in accreditation.^{48 78}

Public confidence in services

Survey and interview data indicate that results from the inspection processes can be made publicly available, and that such publication can demonstrate that the quality of the services meet a certain standard, thereby contributing to public confidence in the services.^{30 40 41 43 46 55 66 78 85}

External incentives

Interview data suggest that health organisations can participate in multiple accreditation programmes, and that resources are directed towards mandatory programmes with public disclosure of results.^{56 80} Participation in accreditation and inspections are resource demanding, and to promote effective implementation of accreditation and inspections expectations to participate should be aligned and supported by other regulatory incentives.^{35 49 75 76}

Role of mass media

Interview data indicate that mass media are more likely to report bad news and shortcomings following inspection



and accreditation than positive news, thereby giving the public an unbalanced picture of the current situation.^{35 43 66} Two case studies suggest that media coverage can contribute to the implementation of improvement measures following inspections.^{48 77}

Government involvement

Qualitative data suggest that government can play an active role in developing accreditation schemes by incorporating them as requirements in their strategies for improving quality and safety, by facilitating collaboration between regulators and services, and through financial incentives.^{48 51 54 86-88}

Intrinsic motivation

A cluster randomised trial indicated that accreditation contributed to foster intrinsic motivation for staff, especially for those who perceived accreditation as an instrument for quality improvement prior to accreditation.⁸⁹

Structural characteristics

A cross-sectional study using data from 4400 hospitals did not find differences in outcomes to be associated with type of accreditation programme.⁹⁰ Performance data from two cohort studies suggest that hospital size and type did not predict effects of accreditation⁹¹; however, lower performing hospitals improved at a greater rate than moderate and higher performing hospitals.⁹² Two case studies indicate that degree of improvement can depend on improvement capability of the inspected organisation,⁴³ and that accreditation can be easier to implement in smaller facilities.⁷⁶

Creation of networks, and improved communications

Qualitative data indicate that inspections can contribute to improved teamwork and communication within existing networks in the sense that these can become more focused around how the organisation delivers clinical care.^{40 42 43 48 51 66 76 80 82 83 93-96} Involved staff members reported that inspections can expand existing networks by facilitating the creation of new meeting places.^{40 41 43 78 80 97}

Awareness of current practice, performance gaps and a more desirable practice, and commitment to change

Interview and survey data suggest that an inspection can highlight problem areas needing improvement.^{31 43 47 67 76 77 82 86 93 95 96 98-103} Case studies suggest that external inspections rarely identify problems previously unknown in the inspected organisation, but the inspections still serve the purpose of confirming these problems and bringing them into the open so that they can be addressed.^{42 61 104}

Other case studies suggest that inspections should not only address deficits in organisational performance but also be used to recognise and validate success^{30 41} so that the inspected organisation can maintain what it is currently doing well.^{30 42 66} Qualitative research indicate that the inspection can draw attention to and provide

feedback about a more desirable practice and how this can be achieved.^{30 31 48 82 83 93 95 97 103}

Data from interviews suggest that the authority of the inspecting organisation along with organisational reflections on performance gaps that take place during the inspection can contribute to creating an understanding of the necessity of improving and commitment to change.^{41 61 76 80 96 104}

Inspection findings and goal setting

Data from surveys and interviews suggest that the inspection process should be translated into something meaningful and understandable for the front line in order to contribute to involvement in improvement work.^{32 35 49 61 66 76 96 105} Problem areas identified during inspections can receive increased attention by the inspected organisation.^{8 41 42 51 56 77 95} Qualitative studies indicate that feedback from the inspection can be used to define improvement goals for the inspected organisation.^{56 66 80 103}

Organizational incentives and rewards

Survey data suggest that internal recognition and rewards were associated with perceived quality results in accreditation.¹⁰⁶

Learning climate, reflection on clinical practice and understanding the clinical system

Findings from case studies and three survey studies using organisational context measures suggest that interprofessional collaboration and reflection can contribute to improving the organisational climate during inspection^{38 42 51 83 93 94 107 108} and strengthening the social relationships between staff members.^{80 109} However, interview and survey data also suggested that inspection can lower staff morale by focusing solely on what is wrong.^{43 66 81 96}

A key feature of the new meeting places that can be created during an inspection seems to be that they can bring together a broad range of professionals and disciplines to discuss and reflect on clinical processes in a way that they had not done previously.^{31 32 41-43 45 66 76 80}

Staff members report that communication and interprofessional reflection during the inspection process can contribute to enhancing their understanding of the clinical system and its interdependencies.^{35 38 95 96} Qualitative data suggest that interprofessional reflection can promote the breakdown of organisational silos and contribute to improving individuals' understanding of the organisation as a whole, when clinicians learn about practices other than those in which they are usually involved.^{31 40 41 80 108}

Engage leaders in improvement

Leader involvement and engagement in inspection are reported to be important because they give a direction to the improvement process and can facilitate the involvement and motivation of other staff members.^{47 49} Survey and interview data indicate that inspections can facilitate leader engagement in the area that is being inspected.^{43 51 66 77 81 102 110 111} However, survey data also

indicate that accreditation has no effect—or even a negative impact—on leadership.¹⁰⁸ Qualitative case studies report that inspections can provide leaders with a platform that can enable them to act to improve clinical work.^{40 47 80} Four cross-sectional studies using survey data support the idea that leadership engagement in accreditation can be associated with perceived quality results^{106 112 113} and accreditation performance.⁹⁴

Allocation of resources

Qualitative data indicate that preparing for the inspection and being inspected can be burdensome and time consuming, and that the efforts do not necessarily match the outcomes.^{35 36 38 42 49 66 76 86 95 96 112} Survey and interview data suggest that inspections can have negative consequences for the time spent on clinical work.^{31 37 66 75 96 114} Interview data indicate that there is an inherent risk that staff members who are involved in accreditation processes without sufficient resources and competence in place can become less enthusiastic about future engagement because of the constraints under which their involvement takes place.³⁵ Findings from qualitative studies suggest that resources may be allocated to areas needing improvement following the inspection.^{41 61 66 80 93}

Planning improvement interventions

Interview data indicate that external inspections can provide an opportunity to reflect on current practice and performance gaps, and to plan actions for improvements in these areas.^{30 31}

Staff members report that feedback from the inspection teams can also be used to plan improvement measures, and that perceived accreditation results were associated with quality improvement planning.^{31 42 61 76 86 96 100 101 104}

Interview data suggest that the feedback following an inspection can provide a sense of direction and validity to the planning process by requesting the inspected organisation to produce a formal action plan addressing how non-conformities should be corrected.^{30 31 104}

Engage and involve staff in improvement activities

Qualitative data indicate that the involvement of those being inspected can be a critical factor for change,^{45 108} and staff involvement in the accreditation process has been shown to be associated with perceived quality results.^{86 97 106 112 113} Case studies suggest that inspections can contribute to involving clinicians in improvement work,^{42 43 48 51 76 80 96} but there were also data indicating that an inspection only involves part of the organisation,^{41 108} with the risk of those not sufficiently involved not buying into its potential for real change.⁶⁶

Implementing improvement interventions

Findings from case studies and quantitative cross-sectional studies combining survey data and performance indicators indicate that inspections can contribute to the implementation of planned changes, addressing substandard performance identified during the inspections.^{30 41–43 49 51 66 76 79 82 86 96 97 101 102 104 115}

The inspected organisation can implement changes derived from new models of thought developed during the inspection.^{40 80}

In accreditation, qualitative data and time series analyses of performance indicators suggest that the most substantial changes are implemented during the self-assessment phase prior to the actual inspection.^{39–41 116}

In statutory inspections, survey and interview data indicate that changes were implemented throughout the inspection cycle.^{42 43 65 66 99}

Interview and observational survey data in combination with performance indicators indicate that the feedback and recommendation provided to inspected organisations can facilitate the implementation of change.^{30 41 42 49 51 66 79 86 97 115} Staff members report that recommendations need to be explicit and realistic about what needs to be changed, and these should be cast in a way that eases implementation by being explicit about the aim of the change and its relevance for patient care.^{61 104}

The inspected organisation can be held accountable for implementing changes,⁴¹ and this is reported to contribute to creating momentum to speed up the implementation process.^{42 43 61 66 104}

Findings from qualitative studies, surveys and one randomised controlled trial indicate that inspections can contribute to organisational change, but the change does not necessarily affect quality of care.^{32 37 41 42 100 101 117 118} Interview and survey data, and one randomised controlled trial indicate that changes can be implemented to make the organisation comply with the standard without actually improving patient care.^{37 40 45 66 118} According to qualitative data, non-conformities identified during inspections and the corresponding feedback can address shortcomings in the quality management system and support processes.^{44 50 61 100} However, quality management systems are not always implemented systematically and clinicians question to what degree they actually support and impact clinical work.⁴⁴ Qualitative findings suggest that there is a risk that corrective changes made to the management system will not have any impact on the quality of care.^{61 100}

Use of measurement systems and data, and evaluation and continuous improvement

Staff members report that external inspections can contribute to reinforcing a healthcare organisation's self-evaluation, which can impact the organisation's long-term performance.^{30 43 66 76} The inspecting body can express expectations as to how the inspected organisation should monitor performance and progress of improvement, and what data they can use for this purpose following the inspection.^{48 51 82} Qualitative data suggest that such expectations should be stated in a way that makes it possible to follow-up and monitor the progress of the implementation, as well as the effects of the changes on the quality of care.^{43 61} Survey data and performance data indicate that accreditation can



promote continuous improvement, and sustain improvements over time.^{46 116} However, a challenge is that the standard used for inspection is not necessarily sensitive to improvement over time, and it might not include requirements on how to use measurements to inform continuous evaluation and improvement over time.^{46 48 85}

Cross-sectional studies based on survey and performance data indicate that the inspection process can facilitate the development of measurement systems, which can be used to evaluate performance,^{51 61 82 85 108 113 119 120} and survey and interview data suggest that inspection can have a positive influence on clinicians' understanding of the necessity of measuring and evaluating improvement progress.^{56 121 122} However, contradictory findings based on survey data indicate that inspection does not affect the way the inspected organisation uses and processes data to evaluate its performance.¹⁰⁸ Survey and interview data indicate that inspection can facilitate reflection on practice in a way that can provide inspiration for further changes beyond the theme of the inspection.^{31 50 79 93}

Assessment of review findings

The assessment of confidence in our findings is shown in **table 3**. Nine findings were rated as high, 19 moderate and 8 low.

DISCUSSION

Our review suggests that the mechanisms by which external inspections might contribute to improve the quality of care are dependent on complex interactions between factors related to the outer setting, how the inspections are conducted and how they are perceived and acted on by the inspected organisations.

Inspections serve different purposes including accountability and transparency in the services.¹ Our findings indicate that public disclosure of inspection findings can contribute towards transparency about the standard of the service, and thereby public trust by ensuring that the services meet a certain minimum standard.^{66 85} Healthcare organisations serve the public, and the review findings suggest that the inspection process can contribute to accountability by creating an opportunity for community partners to provide input on how the inspected organisations should improve.^{30 41}

Regulatory guidance

The regulatory context in which the inspections take place affect how they are perceived and acted on by the organisations being inspected. An active regulator along with incentives, disclosure of inspection results and mandatory programmes seem to promote participation and increase resource allocation towards the inspected area.^{49 56} Our findings indicate that inspected organisations value guidance on how to follow up inspection findings, and that such guidance can facilitate implementation of changes.^{50 57} Another key reason for doing inspections is to promote quality improvement. Our findings suggest

that the standards used during the inspections should focus on patient needs and be translated into something that is perceived as meaningful by the front-line staff.^{45 61}

Use of self-assessment tools

Most external inspections include a self-assessment phase in which the inspected organisations are expected to prepare and review their own practice prior to the external assessment. Our findings about this phase are contradictory; the perceived usefulness and relevance of the available tools seem to have great impact on the outcome of this phase. Self-assessment tools that address patient care and that help the front-line staff to review their clinical practice are perceived as useful and can contribute to change.^{30 39} Self-assessment tools primarily concerned with providing documentation and that do not address patient care are perceived as burdensome and do not seem to contribute to changes in care delivery.^{31 35}

Credible, predictable and transparent inspection processes

External inspections represent an assessment of the inspected organisations' performance, and an evaluation of how the staff do their work. If substandard performance is identified, the performance, and consequently the way the staff do their work needs to be changed. In order to engage in change processes, the inspection scheme and the findings must be perceived as valid and reliable by the relevant stakeholders. The interaction between the surveyors and the inspected organisation is critical for establishing a credible inspection scheme in which the findings are acted on. The inspection teams' knowledge about the inspected area and their communication skills are reported to be a prerequisite for confidence in the inspection findings.^{50 65} Inspection processes should be predictable and transparent. The surveyors therefore need to ensure that the inspection findings and the judgement of them are reliable across different organisations.^{54 59}

Measures to bring about change in clinical processes

Our findings suggest that external inspections can affect different mediators of organisational change. The main activities of the improvement process following an inspection include planning and implementing improvement measures, evaluation and continuous improvement.^{23 123} The findings suggest that when substandard performance is identified, the inspected organisation is expected to plan and implement improvement measures that address the identified performance gaps and evaluate their effects. Inspections can affect all steps in this basic improvement process.

Organisational change is a precondition for improved quality of care, but it is possible to implement organisational change that does not affect the way care is delivered.¹²⁴ Our findings indicate that there is an inherent danger that improvement measures following an inspection mainly address deficiencies in management systems and support processes, that is, updating or creating new written guidelines and educational activities. Structural

Table 3 Assessment of confidence of review findings

Number for CFIR construct	CFIR construct and our review finding	Studies contributing to the review	Assessment of methodological limitations	Assessment of relevance	Assessment of coherence	Assessment of adequacy	Overall assessment of confidence	Explanation of judgement
1	Intervention source: self-assessment contributing to improvement	30-35 37-43 96	Moderate methodological limitation in seven studies, minor methodological limitations in three studies and four studies fulfilled all assessment criteria.	14 studies from different countries and inspection settings offering relevant data addressing the review question.	Inconsistent findings. Data show that self-assessment can be regarded as useful and initiating improvements, but data also indicated that self-assessment could be troublesome and not leading to improvement.	14 studies offering diverse data from different inspection settings	Low confidence	This judgement was graded low because of inconsistent findings. Our findings support that self-assessment can contribute to improvement provided certain factors.
4	Adaptability: the importance of valid and relevant inspection standards	36 44-55 61	Moderate methodological limitation in five studies, minor methodological limitations in five studies and four study fulfilled all assessment criteria.	14 studies from different countries and inspection settings offering relevant data addressing the review question.	Coherent findings indicating that standards used for inspections must be valid and focused on clinical practice and the benefits for the patients.	14 studies offered diverse data overall.	High	This judgement was graded high because of diverse, relevant and coherent data from 14 studies showing the importance of valid and relevant inspection standards.
4	Adaptability: guidance on how to follow up inspection findings	43 44 50 56 57	Moderate methodological limitation in two studies, minor methodological limitations in two studies and one study fulfilled all assessment criteria.	5 studies from different countries and inspection settings offering relevant data addressing the review question.	Coherent findings that inspected organisations want guidance on how to improve following an inspection and that guidance can facilitate implementation.	Moderate concern about the adequacy of data, 5 studies offered diverse data overall.	Moderate	This judgement was graded moderate because of moderate concern about the adequacy of data, and because of methodological limitations in four studies.
6	Complexity: complexity of inspections	42	Moderate methodological limitation in one study	1 study offering relevant data.	Only one study reported that it can be challenging for the inspection teams to synthesise, weigh and make sense of all the gathered data.	Major concern about the adequacy of data because only study was included.	Low	This judgement was graded low because of major concern about the adequacy of data.
7	Design quality and packaging: knowledge and skills of surveyors and credibility of inspection schemes	31 43 50 58-60 62-69	Moderate methodological limitation in two studies, minor methodological limitation in eight studies and four studies fulfilled all assessment criteria.	14 studies from different countries and inspection settings offering relevant data.	Coherent findings showing that knowledge and skills of the inspection teams are important for the credibility of the inspection findings.	14 studies offered diverse data.	High	This judgement was graded high because of diverse, relevant and coherent data from 14 studies showing the importance of knowledge and skills of surveyors and credibility of the inspection schemes.
7	Design quality and packaging: unannounced inspections	42 66 70-72	Moderate methodological limitation in one study, minor methodological limitations in two studies and two studies fulfilled all assessment criteria.	5 studies from different countries and different inspection settings offering relevant data.	Inconsistent finding about the role of unannounced inspections.	Moderate concern about the adequacy of data.	Low	This judgement was graded low because of moderate concerns about the adequacy of data, and inconsistent findings. There is evidence to support that unannounced and short-notice surveys require less resources for preparations, but there are inconsistent findings as to whether they more effectively can reveal substandard performance.
7	Design quality and packaging: choosing whom to inspect	43	One study fulfilled all assessment criteria.	1 study from one country and one inspection setting.	Consistent finding that data used to risk assess in advance of inspection was not correlated with subsequent ratings after the inspections.	Major concern about the low adequacy of data.	Low	This judgement was graded low because of major concern about the adequacy of data.

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Table 3 Continued

Number for CFIR construct	CFIR construct and our review finding	Studies contributing to the review	Assessment of methodological limitations	Assessment of relevance	Assessment of coherence	Assessment of adequacy	Overall assessment of confidence	Explanation of judgement
8	Cost: increased cost	35 38 43 46 52 56 73	Moderate methodological limitation in four studies, minor methodological limitations in one study and two studies fulfilled all assessment criteria.	7 studies from different countries offering data about different inspection settings.	Coherent findings that inspections increased costs.	Minor concern about the adequacy of data, 7 studies offered diverse data overall.	Moderate	This judgement was graded moderate because of minor concern about the adequacy of data and methodological limitations in five studies.
9	Patient needs and resources: Inspection can contribute to increase patient focus	32 42 45 46 55 61 74–76	Moderate methodological limitation in one study, minor methodological limitations in three studies and three studies fulfilled all assessment criteria.	9 studies from different countries and inspection settings offering relevant data addressing the review question.	Coherent findings showing that inspections should be more directed towards patient care and clinical practice in order to contribute to improvement, and that standard that address patient needs can contribute to increased patient focus.	Minor concern about the adequacy of data.	Moderate	This judgement was graded moderate because of minor concern about the adequacy of data, and methodological limitations in four studies.
10	Cosmopolitanism: improved relations and communication with external community partners	30 31 40–43 50 67 77–83	Moderate methodological limitation in one study, minor methodological limitations in five studies and four studies fulfilled all assessment criteria.	15 studies from different countries and inspection settings offering relevant data addressing the review question.	Coherent findings in that 14 out of 15 studies reported that inspections improved relations and communication with external partners.	15 studies that together offered moderately diverse data.	High	This judgement was graded high because of diverse, relevant and coherent data from 14 studies showing that inspections can contribute to improve relations and communication with external community partners.
10	Cosmopolitanism: improvement in other organisations besides the one being inspected	43 77	Minor methodological limitations in one study, and one study fulfilled all assessment criteria.	2 studies from different countries, but same inspection setting offering relevant data addressing the review question.	Coherent finding from two case studies that inspections can contribute to improvement in other organisations than the one being inspected.	Major concerns about adequacy of data, Two studies that together offered diverse data.	Low	This judgement was graded low because of major concerns about the adequacy of data.
11	Peer pressure: external pressure	30 43 44 47 61 66 78 83	Moderate methodological limitation in two studies, minor methodological limitations in four studies and three studies fulfilled all assessment criteria.	9 studies from different countries and inspection settings offering relevant data addressing the review question.	Coherent findings, indicating that being reviewed by someone external and independent, can create an external pressure for change.	Minor concerns about adequacy of data, 9 studies that together offered diverse data.	Moderate confidence	This judgement was graded moderate because of minor concerns about the adequacy of data, and methodological limitations in six studies.
12	External policies and incentives: public confidence in services	30 40 41 43 46 48 66 78 85	Moderate methodological limitation in three studies, minor methodological limitations in five studies and one study fulfilled all assessment criteria.	9 studies from different countries and inspection settings offering relevant data addressing the review question.	Coherent findings that making the inspection finding publicly available can contribute to public confidence in the services.	Minor concerns about adequacy, 9 studies that together offered diverse data.	Moderate confidence	This judgement was graded moderate because of minor concerns about adequacy of data, and methodological limitations in eight studies.
12	External policies and incentives: incentives	35 49 56 75 76 80	Moderate methodological limitation in two studies, minor methodological limitations in three studies and one study fulfilled all assessment criteria.	6 studies from different countries, but only one inspection setting offering relevant data addressing the review question.	Coherent findings that incentives can promote the implementation of accreditation programmes.	Moderate concerns about adequacy of data, 6 studies that together offered diverse data from one inspection setting.	Moderate confidence	This judgement was graded moderate because of minor concerns regarding adequacy of data, and six studies from one inspection setting.
12	External policies and incentives: role of mass media	35 43 48 66 77	Moderate methodological limitation in one study, minor methodological limitations in three studies and one study fulfilled all assessment criteria.	5 studies from different countries and inspection settings offering relevant data addressing the review question.	Coherent findings that mass media tends to focus on shortcomings following inspections, and can contribute to the implementation of change.	5 studies that together offered diverse data.	Moderate confidence	This judgement was graded moderate because of moderate concerns regarding adequacy of data and methodological limitation in four studies.

Continued

Table 3 Continued

Number for CFIR construct	CFIR construct and our review finding	Studies contributing to the review	Assessment of methodological limitations	Assessment of relevance	Assessment of coherence	Assessment of adequacy	Overall assessment of confidence	Explanation of judgement
12	External policies and incentives; government involvement	48 51 54 86–88	Moderate methodological limitation in one study, minor methodological limitations in three studies and two studies fulfilled all assessment criteria.	6 studies from different countries but only one inspection setting offering relevant data addressing the review question.	Coherent findings that government involvement can promote participation on accreditation.	Moderate concerns about adequacy of data. 6 studies that together offered diverse data from one inspection setting.	Moderate	This judgement was graded moderate because of moderate concerns regarding adequacy of data and methodological limitation in four studies.
14	Self-efficacy	89	One study with minor methodological limitation.	1 study from one country and one inspection setting.	Coherent finding that accreditation can crowd in intrinsic motivation	Major concern about adequacy of data.	Low	This judgement was graded low because of major concerns about adequacy of data.
18	Structural characteristics	43 76 90–92	Minor methodological limitations in one study, and four studies fulfilled all assessment criteria.	5 studies from different countries and inspection settings addressing the review question.	Mixed and inconclusive findings regarding how structural characteristics affect inspections.	Major concern about adequacy of data.	Low	This judgement was graded low because of major concerns about adequacy of data and inconsistent findings.
19	Networks and communications: improved communication and creation of networks	40–43 48 51 66 76 78 80 82 83 93–96	Moderate methodological limitation in two studies, minor methodological limitations in 12 studies and two studies fulfilled all assessment criteria.	16 studies from different countries and inspection settings offering relevant data addressing the review question.	Coherent findings that external inspections can contribute to facilitation of networks and improved communications in these networks.	16 studies that together offered moderately diverse data.	High	This judgement was graded high because of diverse, relevant and coherent data from 16 studies.
21	Tension for change: awareness of current practice and performance gaps	30 31 33 34 39–43 47 56 61 66 67 76 77 82 86 93 95 96 98–104	Minor methodological limitation in 8 studies, moderate methodological limitations in 13 studies and 7 studies fulfilled all assessment criteria.	28 studies from different countries and inspection setting offering relevant data addressing the review question.	Coherent findings that external inspections can contribute to awareness of current practice and performance gaps.	28 studies offering diverse data.	High confidence	This judgement was graded high because of diverse, relevant and coherent data from 28 studies.
21	Tension for change: awareness of more desirable practice	30 31 48 82 83 93 95 97 103	Minor methodological limitation in six studies, moderate methodological limitations in one study and two studies fulfilled all assessment criteria.	9 studies from different countries and inspection setting offering relevant data addressing the review question.	Coherent findings that external inspections can contribute to awareness of more desirable practice.	Minor concerns about adequacy. 9 studies that together offered diverse data from interviews	Moderate confidence	This judgement was graded moderate because of minor concern about adequacy of data, and methodological limitations in seven studies.
21	Tension for change: commitment to change	41 61 76 80 96 104	Moderate methodological limitations in one study, minor methodological limitation in four studies and one study fulfilled all assessment criteria.	6 studies from different countries and inspection settings offering relevant data addressing the review question.	Coherent findings that external inspections can contribute to commitment to change.	Moderate concern about adequacy of data. 6 studies offering moderately diverse data.	Moderate confidence	This judgement was graded moderate because of minor concern regarding adequacy of data, and methodological limitations in four studies.
22	Compatibility: perceived relevance of inspection findings	32 35 49 61 66 76 96 105	Minor methodological limitation in four studies, moderate methodological limitations in two studies and two studies fulfilled all assessment criteria.	8 studies from different countries and inspection setting offering relevant data addressing the review question.	Coherent findings that perceived relevance of inspection findings is important for engagement.	Minor concern about adequacy. 8 studies offered moderately diverse data overall.	Moderate confidence	This judgement was graded moderate because of minor concern regarding adequacy of data, and methodological limitations in six studies.
23	Relative priority: priority of inspected area	8 41 42 51 56 77 95	Minor methodological limitation in six studies, and moderate methodological limitations in one study.	7 studies from different countries and inspection settings offering relevant data addressing the review question.	Coherent findings in the seven studies that external inspections can contribute to priority of the inspected areas.	Moderate concern about adequacy of data, because of the number of studies.	Moderate confidence	This judgement was graded moderate because of moderate concern regarding adequacy of data, and methodological limitations in six studies.

Continued

Table 3 Continued

Number for CFIR construct	CFIR construct and our review finding	Studies contributing to the review	Assessment of methodological limitations	Assessment of relevance	Assessment of coherence	Assessment of adequacy	Overall assessment of confidence	Explanation of judgement
24	Organisational incentives and rewards; incentives	106	One study fulfilled all assessment criteria	1 study from one country and one inspection setting	Coherent finding that recognition and rewards were associated with perceived quality results	Major concern about adequacy of data	Low	This judgement was graded low because of major concerns about adequacy of data.
25	Goals and feedback; goal setting	56 66 80 103	Minor methodological limitation in three studies, and moderate methodological limitations in one study.	4 studies from different countries and inspection settings offering relevant data addressing the review question.	Coherent findings in the four studies that external inspections can contribute to setting improvement goals.	Moderate concern about adequacy because of the number of studies.	Moderate confidence	This judgement was graded moderate because of moderate concern regarding adequacy of data, and methodological limitations in four studies.
26	Learning climate: improved organisational climate and learning climate	38 42 43 51 66 80 81 83 93 94 96 107–109	Moderate methodological limitation in four studies, minor methodological limitations in seven studies and three study fulfilled all assessment criteria.	14 studies from different countries and inspection settings offering relevant data addressing the review question.	In coherent findings that external inspections can contribute to improved organisational climate and learning climate, but can also lower staff moral by solely focusing on what is wrong.	Minor concerns about adequacy, 14 studies that together offered moderately diverse data.	Moderate confidence	This judgement was graded moderate because of minor concerns regarding adequacy of data, combined with methodological limitations in seven studies and the findings that inspections can lower staff moral if solely focusing on what is wrong.
26	Learning climate: reflection on clinical practice	31 32 41–43 45 66 76 80	Moderate methodological limitation in two studies, and minor methodological limitations in six studies, and one study fulfilled all assessment criteria.	9 studies from different countries and inspection settings offering relevant data addressing the review question.	Coherent findings that external inspection can facilitate reflection on clinical practice.	Minor concerns about adequacy of data, 9 studies that together offered moderately diverse data.	Moderate confidence	This judgement was graded moderate because of minor concerns regarding adequacy of data, and methodological limitations in eight studies.
26	Learning climate: improved understanding of organisation and interdependences in clinical system	31 35 38 40 41 80 95 96 108	Minor methodological limitation in two studies, and moderate methodological limitations in three studies and one study fulfilled all assessment criteria.	Moderate concern about the relevance of studies because all are from an accreditation context.	Coherent findings that external inspection can contribute to improved understanding of clinical system and the organisation as a whole.	Moderate concerns about adequacy, 9 studies that together offered moderately diverse data.	Moderate confidence	This judgement was graded moderate because of coherent findings, but moderate concerns regarding adequacy of data and methodological limitations in seven studies.
27	Leadership engagement: leader engagement	40 43 47 49 51 66 77 80 81 94 102 106 108 110–113	Moderate methodological limitation in two studies, minor methodological limitations in nine studies and six studies fulfilled all assessment criteria.	17 studies from different countries and inspection settings offering relevant data addressing the review question.	Findings are incoherent. The vast majority of the studies show that external inspections can contribute to leader engagement, but a few studies show that it does not.	Moderate concern about adequacy of findings because of conflicting evidence.	Moderate confidence	This judgement was graded moderate because of relevant and coherent data in 11 studies indicating that inspection contribute to alter allocation of resources.
28	Available resources: allocation of resources	31 35–38 41–42 49 56 61 66 75 76 80 86 93 95 96 112 114	Minor methodological limitation in nine studies, moderate methodological limitations in five studies and five studies fulfilled all assessment criteria.	19 studies from different countries and inspection setting offering relevant data addressing the review question.	Coherent findings that external inspection can affect allocation of resources in different ways.	19 studies offering diverse data about how external inspections can affect allocation of resources.	High confidence	This judgement was graded high because of diverse, relevant and coherent data from 19 studies indicating that inspection contribute to alter allocation of resources.
30	Planning; planning improvement interventions	30 31 42 61 76 86 96 100–102 104	Minor methodological limitation in six studies, and five studies fulfilled all assessment criteria.	5 studies from different countries and inspection settings offering relevant data addressing the review question.	Coherent findings that external inspections can contribute to plan improvement interventions.	Minor concerns about adequacy of data, 11 studies that together offered moderately diverse data.	Moderate confidence	This judgement was graded moderate because of minor concerns regarding adequacy of data, and methodological limitations in six studies.

Continued

Table 3 Continued

Number for CFIR construct	CFIR construct and our review finding	Studies contributing to the review finding	Assessment of methodological limitations	Assessment of relevance	Assessment of coherence	Assessment of adequacy	Overall assessment of confidence	Explanation of judgement
31	Engaging; engage and involve staff in improvement activities is important for impact of inspections	41-43 45-48 51 66 76 80 83 86 96 97 106 108 112 113	Moderate methodological limitation in one study, minor methodological limitations in nine studies and seven studies fulfilled all assessment criteria.	17 studies from different countries and inspection settings offering relevant data addressing the review question.	Coherent findings; inspections can contribute to engaging staff in improvement activities, and that involvement of staff is important because it can be associated with quality results.	17 studies offering diverse data about how external inspections can contribute to engage staff.	High confidence	This judgement was graded high because of diverse, relevant and coherent data from 17 studies indicating that inspection can contribute to staff engagement.
32	Executing; implementing improvement interventions	30 32 37 39-45 49-51 57 61 65 66 76 79 80 82 83 86 96 97 99-102 104 115-118	Moderate methodological limitation in 5 studies, minor methodological limitations in 16 studies and 13 studies fulfilled all assessment criteria.	34 studies from different countries and inspection settings offering relevant data addressing the review question.	Coherent findings that external inspections can affect implementation of improvement measures, but this kind of change does not necessarily imply that the quality of care is improved.	34 studies offering diverse data.	High confidence	This judgement was graded high because of diverse, relevant and coherent data from 34 studies.
33	Reflecting and evaluating; evaluation and continuous improvement if that is incorporated in the standard	30 31 46 48 50 61 66 76 79 85 93 116	Moderate methodological limitation in two studies, minor methodological limitations in seven studies and three studies fulfilled all assessment criteria.	12 studies from different countries and inspection settings offering relevant data addressing the review question.	Inconsistent findings. Data support that external inspections can contribute to evaluation and continuous improvement when it is incorporated in the standard.	Minor concern about adequacy of findings.	Moderate confidence	This judgement was graded moderate because of methodological limitations in nine studies combined with minor concern about adequacy of data and.
33	Reflecting and evaluating; use of measurement systems and data	43 48 51 56 61 76 82 85 108 113 119-122	Minor methodological limitation in 10 studies, moderate methodological limitations in 3 studies and 1 study fulfilled all assessment criteria.	14 studies from different countries and inspection settings offering relevant data addressing the review question.	Coherent findings that external inspection can contribute to use of measurement systems.	14 studies offered diverse and relevant data.	High confidence	This judgement was graded high because of diverse, relevant and coherent data from 14 studies.

CFIR, Consolidated Framework for Implementation Research.



changes of this kind can be a precondition for making changes in the corresponding clinical processes.¹²⁵ However, structural changes not sufficiently linked to corresponding changes in the clinical processes can have limited effect on the quality of care.^{126 127}

We found evidence that inspections can affect other organisational change and discursive activities beside the basic steps in the improvement process. Our findings indicate that the change and discursive activities can interact and affect the improvement process in complex ways. Based on our theoretical framework, we argue that the way and to what extent inspections affect these change and discursive activities can be crucial for whether the inspection actually leads to organisational change that improve the quality of care.

Strengthening networks and promoting learning

Inspections can contribute to enhancing communication about clinical work and facilitating the development of networks through which organisational members meet and reflect on their own clinical practice and the findings of the inspection, thereby improving the learning climate. Involvement and engagement from leaders and staff can be a prerequisite for such multiprofessional reflection, which can be key to shaping a shared organisational understanding of the organisation's actual performance and of areas needing improvement, thus contributing to readiness and acceptance for change. Moreover, the reflection can improve the organisational members' understanding of their clinical system and its interdependencies, on which they can base their planning and implementation of improvement measures. We argue that improvement measures that are planned and implemented based on a new and enhanced understanding of the clinical system and its interdependencies are more likely to produce organisational change that change the way clinical care is delivered and thereby improve the quality of care.

Strengths and limitations

The strength of our study is that we conducted a systematic literature search to identify relevant studies and used a theoretical framework to extract and analyse heterogeneous data to identify possible mediators of change. Our theoretical framework does not represent a complete list of all possible constructs that might contribute to explaining how external inspection affects organisational change and the quality of care. Nevertheless, the theoretical framework was sufficiently comprehensive to include a wide range of constructs for exploring how inspections affect organisations, which in turn can advance our understanding of how inspections can contribute to improving the quality of care.

We assessed nine of our findings to have high confidence and 19 of our findings to have moderate confidence, which indicates that it is highly likely or likely that our findings represent the phenomenon of interest (table 3). The fact that we assessed a finding to have high confidence does not necessarily imply that inspections always will have that particular impact, because they are complex and context

dependent. Two of the findings assessed to have high confidence were external inspections' contribution towards *awareness of current practice and performance* and *implementing improvement interventions*. These findings might seem contradictory to previous research suggesting that external inspections have limited impact on the quality of care.¹²⁸ We argue that these findings illustrate what seem to be a key challenge for external inspections. Even though they might contribute to discover substandard performance and facilitate implementation of organisational change, the quality of care is not improved unless the change processes affect care delivery to patients. Eight findings were assessed to have low confidence, indicating that it is possible that the review findings are a reasonable representation of the phenomenon at interest. One of the main reasons for grading a finding as low was inadequacy of data and inconsistent findings, which can partly be explained by the fact that external inspections are complex interventions introduced into different organisational contexts.¹²⁹

Implications and future research

In order to contribute to quality improvement, inspections need to affect organisational change activities involved in improving care delivery. We found that inspections can affect different mediators of organisational change, and our findings can thereby enhance our understanding of why inspections seem to have varying effects. Our findings can provide guidance for policy makers and inspectors on how future inspections should be designed and conducted to be more effective. Organisational change to improve clinical services may be promoted by regulatory guidance, use of self-assessment tools as part of the inspection, a credible, predictable and transparent inspection process, and development of measures to bring about change in clinical processes.

This is the first review addressing how external inspections can contribute to improve the quality of care. Future studies should further explore relationships between how the inspections are carried out, their contextual setting and the way they can mediate change in care delivery in the inspected organisations.

CONCLUSION

External inspections can affect different mediators of organisational change. The way and to what extent they do depend on a range of factors related to the outer setting, the way inspections are conducted and how they are perceived and acted on by the inspected organisation. They can affect the key activities involved in planning, implementing and evaluating organisational change and the organisational discourse about these ongoing change activities. To improve the quality of care, the organisational change processes need to involve and affect the way care is delivered to the patients.

Author affiliations

¹Institute of Social Science, Western Norway University of Applied Sciences, Sogndal, Norway



- ²Department of Global Public Health and Primary Care, Universitetet i Bergen, Bergen, Norway
³Department of Research, Stavanger University Hospital, Stavanger, Norway
⁴Western Norway University of Applied Sciences, Haugesund, Norway
⁵Department of health, County Governor in Oslo and Akershus, Oslo, Norway
⁶The University of Manchester Alliance Manchester Business School, University of Manchester, Manchester, UK
⁷Folkehelseinstituttet, Oslo, Norway
⁸Institute of Health and Society, Universitetet i Oslo, Oslo, Norway

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ORCID iD

Einar Hovlid <http://orcid.org/0000-0003-0300-4405>

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