BMJ Open

Promoting leadership and quality improvement through external inspections: a focus group study

Journal:	*BMJ Open*
Manuscript ID	bmjopen-2020-041997
Article Type:	Original research
Date Submitted by the Author:	22-Jun-2020
Complete List of Authors:	Husabø, Gunnar; Høgskulen på Vestlandet, Department of Social Science; Universitetet i Bergen, Department of Global Public Health and Primary Care Teig, Inger Lise; Universitetet i Bergen, Frich, Jan; Universitetet i Oslo Bondevik, Gunnar; Universitetet i Bergen, Department of Global Public Health and Primary Care; NORCE Norwegian Research Centre AS Hovlid, Einar; Høgskulen på Vestlandet, Department of Social Science; Universitetet i Bergen, Department of Global Public Health and Primary Care
Keywords:	Quality in health care < HEALTH SERVICES ADMINISTRATION & MANAGEMENT, Organisational development < HEALTH SERVICES ADMINISTRATION & MANAGEMENT, Clinical governance < HEALTH SERVICES ADMINISTRATION & MANAGEMENT

I, the Submitting Author has the right to grant and does grant on behalf of all authors of the Work (as defined in the below author licence), an exclusive licence and/or a non-exclusive licence for contributions from authors who are: i) UK Crown employees; ii) where BMJ has agreed a CC-BY licence shall apply, and/or iii) in accordance with the terms applicable for US Federal Government officers or employees acting as part of their official duties; on a worldwide, perpetual, irrevocable, royalty-free basis to BMJ Publishing Group Ltd ("BMJ") its licensees and where the relevant Journal is co-owned by BMJ to the co-owners of the Journal, to publish the Work in this journal and any other BMJ products and to exploit all rights, as set out in our licence.

The Submitting Author accepts and understands that any supply made under these terms is made by BMJ to the Submitting Author unless you are acting as an employee on behalf of your employer or a postgraduate student of an affiliated institution which is paying any applicable article publishing charge ("APC") for Open Access articles. Where the Submitting Author wishes to make the Work available on an Open Access basis (and intends to pay the relevant APC), the terms of reuse of such Open Access shall be governed by a Creative Commons licence – details of these licences and which Creative Commons licence will apply to this Work are set out in our licence referred to above.

Other than as permitted in any relevant BMJ Author's Self Archiving Policies, I confirm this Work has not been accepted for publication elsewhere, is not being considered for publication elsewhere and does not duplicate material already published. I confirm all authors consent to publication of this Work and authorise the granting of this licence.

Promoting leadership and quality improvement through external inspections: a focus group study

Corresponding author
Gunnar Husabø: gunnar.husabo@hvl.no
tel +47 971 82 327

Authors
Gunnar Husabø: Department of Social Science, Western Norway University of Applied Sciences, Sogndal, Norway; Department of Global Public Health and Primary Care, University of Bergen, Bergen, Norway

Inger Lise Teig: Department of Global Public Health and Primary Care, University of Bergen, Bergen, Norway

Jan C. Frich: Institute of Health and Society, University of Oslo, Oslo, Norway

Gunnar Tschudi Bondevik: Department of Global Public Health and Primary Care, University of Bergen, Bergen, Norway; National Centre for Emergency Primary Health Care, NORCE Norwegian Research Centre, Bergen, Norway

Einar Hovlid: Department of Social Science, Western Norway University of Applied Sciences, Sogndal, Norway; Department of Global Public Health and Primary Care, University of Bergen, Bergen, Norway

Word count
4508

ABSTRACT

Objectives To study how external inspections may foster clinical improvement in hospitals.

Design Focus group study.

Setting Research into inspections and other forms of external assessment needs to explore how these activities can contribute to positive changes in the services offered by health care providers. The study is a part of an ongoing research on the impact of external inspection of sepsis diagnosis and treatment in emergency departments in Norwegian hospitals. The inspections under study were planned and directed by the Norwegian Board of Health Supervision (NBHS) at 24 hospitals with acute care functions.

Participants Clinicians, managers, and inspection teams involved with the inspections of sepsis treatment in emergency departments at four different hospitals. Twelve focus groups interviews were carried out, with a total of 47 participants.

Interventions Statutory inspections of sepsis treatment in hospital emergency departments.

Results Three themes emerged as central for understanding how the inspections could contribute to clinical improvement in the emergency departments: 1) Increasing awareness about the need to improve the quality of care by providing data on clinical performance 2), Building acceptance for improvement through professional credibility and focus on clinical practice, and 3) Fostering leadership commitment.

Conclusions Our findings suggest that the inspections have the potential to enhance hospital management and staff's understanding of complicated care processes and help strengthen the organizational commitment to bring about systematic quality improvements.

STRENGTHS AND LIMITATIONS OF THIS STUDY

- Focus group interviews in hospitals that had achieved improvement in key clinical procedures following an inspection provided information-rich cases of how inspections can contribute to quality improvement.
- The interviews elicited new insights into how inspections can enhance understanding of the clinical system and promote leadership in quality improvement efforts.
- We did not explore change mechanisms related to anticipatory effects resulting from the announcement of upcoming inspections.
- The generalizability of our findings and interpretations are dependent on the organizational and procedural context in which inspections are being held.

INTRODUCTION

External inspection, also referred to as statutory supervision, is an external assessment stragegy which is used to evaluate if health care providers meet accepted quality standards. Compared to other forms of external assessment, such as certification and accreditation, external inspections differ in that they are run by government bodies and subject to country-specific regulations.[1] While the subject and scope vary greatly from one inspection to another, most inspections have in common the goal of improving the quality of care provided by the institutions subject to the inspection.[2]

The rationale for why external assessment strategies could lead to improved quality, is that managers will review the results of assessments and implement changes that are necessary for better and safer healthcare.[1] Such effects might function through directive steps, in which the inspectors guide or force the health organization to act in a specific way. They can also be a result of 'softer' mechanisms, such as if inspections lead to a shift in focus and organizational objectives at the service provider.[3] In either case, the inspectors themselves cannot directly affect the quality of care being provided. As such, they must find ways to improve the quality of care through influencing the care processes and internal controls at the hospitals. External inspection can thus be seen as a way of boosting the internal quality and patient safety improvement work.[4]

Following the argument above, the effectiveness of inspections would likely depend on the degree to which they support organizational attributes and work processes associated with successful improvement. The literature describes readiness for change as a main dimension influencing the chance of success when implementing improvement efforts in health care organizations.[5] This view is rooted in a notion of organizations as communities that contribute to the amplification and development of knowledge, rather than merely entities of hierarchical information processing.[6]

While there has been research into accreditation [7] and, to a lesser degree, statutory inspections [4, 8] of health organizations, there is a need for a deeper insight into the mechanisms of change in connection with external inspections.[9] Moreover, recent research has questioned if inspections have any potential at all for bringing about quality improvement, finding that in certain instances, rates of improvement have slowed down following inspections.[10] Governments and health organizations devote considerable resources to external assessment and inspections, and there is a need for knowledge of how and under what circumstances inspections might lead to substantial long-lasting improvement.[11]

Our overall aim was to study how external inspections may foster clinical improvement, using the case of a nationwide inspection of sepsis treatment in emergency departments at Norwegian hospitals. We sought to explore clinicians', managers', and inspection teams' experiences of being involved in the inspection process, and to explore their views on how inspections can affect the quality of care.

METHODS

Study design

The study is a part of an ongoing research on the impact of external inspection of sepsis diagnosis and treatment in emergency departments in Norwegian hospitals.[12, 13] The inspections were planned and directed by the Norwegian Board of Health Supervision (NBHS) at 24 hospitals with acute care functions.

While external inspections can be studied through a number of different research designs, we chose a qualitative approach, using focus groups with clinicians, managers, and inspectors. We found this approach well suited to explore how inspections may foster clinical improvement, as the focus group discussion can provide interpretive insights into the participants experiences and opinions.[14]

The sepsis inspections

NBHS chose sepsis treatment as a subject of these inspections because the condition is deemed critical, judged by criterions of severity and incidence. Estimated at 48.9 million yearly incident cases and 11 million sepsis-related deaths globally, sepsis is one of the leading causes of death world-wide.[15]

The County Governors, who are local representatives of the central government, were charged with performing the inspections. There were six regional inspection teams. Each team included three to four inspectors from the County Governors' health and welfare departments who had prior training and experience from either health care or law. Additionally, each team had an external medical specialist who had extensive clinical experience from working with sepsis diagnosis and treatment.

Methodologically, the inspections were system audits.[16] The NBHS used existing guidelines and conferred with experts to formulate a set of quantitative criteria for recommended diagnosis and treatment of sepsis. At inspection, the team gathered data from the electronic health records of a set of 33 recent patients with sepsis and evaluated the care given against the criteria. As is customarily done in system audits, the inspection teams also reviewed documentation of relevant procedures, as well as performing interviews with clinicians and managers who were engaged daily with the care of patients with sepsis. At the final day of each inspection, the main findings were presented to the hospital management and staff in a closing meeting. Afterwards, the inspection team wrote up a report which included findings and a list of nonconformities. The report was sent as a draft to the hospital's executive management for comments and eventually finalized and released to the public via the Internet.

Participants and data collection

This study draws on data from twelve focus group interviews with clinicians, managers, and inspection teams involved in the inspection of four of the hospitals (designated A, B, C, and D). The interviews were conducted after the initial inspection, in the period from March 2017 to November 2018. The four hospitals were selected because they showed substantial improvements in key process measures of care quality following the inspection. An overview of the inspection process and improvements in a key indicator, time to antibiotic treatment, is provided in Supplementary file 1.

We conducted separate focus group interviews with clinicians, managers, and the inspection teams at each hospital. The focus groups were sized from three to five participants and included in total 47 interviewees: 15 clinicians, 16 managers, and 16 inspection team members.

The groups of clinicians consisted of physicians and nurses who had diagnosis and treatment of sepsis patients in the emergency department as a part of their daily tasks. The managers were either head nurses at emergency departments, chief physicians, or heads of clinics. As such, the manager focus groups had a mix of interviewees in managerial roles and interviewees with combined responsibility for management and patient care. Clinicians and managers were recruited to the focus groups via contact persons with responsibility for quality management in the hospitals. We recruited all members currently on the inspection team who were available to attend the interview. As the

members of the inspection teams changed over time, some inspection team interviewees had not participated in the inspections at the specific hospitals included in our study. The participants were informed beforehand about the purpose of the interviews and they signed a form agreeing to participate in the study. No compensation was given for participation in the study.

The interviews were conducted by GH (male, M.Sc.), except for two interviews that were conducted in collaboration with EH (male, M.D. /Ph.D.). GH had no previous affiliation with the NBHS but had experience from performance audit work in health care organizations. EH had a part-time position as a researcher in the NBHS and had previously participated in NBHS inspections. He was acquainted with some of the interviewees from his work in the NBHS.

For hospitals A, B, and C, the interviews with clinicians and managers were conducted at the respective hospitals. The interviews with the inspection teams were conducted at County Governors' offices. For hospital D, all interviews were conducted by conference call, due to vast travel distances and logistical challenges with convening the inspection team to a physical meeting. The interviewers and the participants were the only ones attending the interviews.

We used three different interview guides, one for each of the three types of groups. The interview guides focused on the impact of the inspections on the quality of care, and the interviews were centered on the experiences from the sepsis inspections. Additionally, time was devoted to discussing sepsis care in general and specific issues surrounding the organization of work in emergency departments.

The focus group interviews lasted from 35 to 105 minutes. After each session, field notes were recorded describing how the interview went and whether there were important contextual factors that should be taken into account in the analysis.

The research project was reviewed and approved by the Regional Ethics Committee of Norway Nord (Identifier: 2015/2195) and the Norwegian Data Protection Authority (Identifier: 15/01559).

Transcription and analysis

Interviews were digitally recorded and subsequently transcribed and imported to NVivo qualitative data analysis software. Participants did not receive copies of transcripts.

We analysed the data using a thematic analytic approach.[17] After the first interview, before analyzing the transcript, EH and GH introduced some preliminary codes (awareness of current and desired practice, leader commitment, use of performance metrics, communication and network, staff engagement, and systems thinking). Other codes gradually emerged throughout the interviews and the subsequent coding of the material.

Once GH had done the initial coding of the interview transcriptions, EH and GH identified potential themes from the data material. We grouped the codes we considered relevant for understanding the relationship between inspections and improvement work into these themes. Next, we analysed the interviews, first within each hospital, and then cross-case including all interviews, using the themes as an analytical framework.

As the focus groups were made up of three distinct roles, clinicians, managers, and inspection team, we took extra care to compare and contrast the analyses between these roles. The interviews with

clinicians and managers were more specific to the inspection in their hospital, as compared to the interviews with the inspection teams, because the inspection teams could draw on experiences from all inspected hospitals in their region.

We read the transcripts and listened to the recorded interviews numerous times to ensure immersion, and we refined, synthesized, and reorganized the identified themes according to our developing understanding of the material. We also extracted quotations from the material to illustrate themes and analytical points.

GH translated the quotes into English, and the translations were checked by all co-authors.

RESULTS

Three themes emerged as central for understanding how the inspections could contribute to clinical improvement in the emergency departments: 1) Increasing awareness about the need to improve the quality of care by providing data on clinical performance 2) Building acceptance for improvement through professional credibility and focus on clinical practice, and 3) Fostering leadership commitment.

Increasing awareness about the need to improve the quality of care by providing data on clinical performance

According to the clinicians, managers, and inspection teams, the discrepancy between guidelines and clinical practice was in part caused by the heterogenous nature of the group of patients with sepsis and by how sepsis can manifest itself through various symptoms. They explained that deciding the course of the patient care is challenging, that the clinical processes of diagnosing and treating sepsis is complex, and that judgments often are being made under quite stressful conditions.

A point that was clearly made during the interviews was that the hospitals lacked systems to monitor the extent to which diagnosis and treatment complied with desired practice and procedures. Though data is entered into patients' electronic health records from the time the patients are admitted to the hospitals, the information is not structured in a way that is easily aggregated so that the hospital can track the performance statistically over time.

One of the members of the inspection team at Hospital C, who had long experience from leading system audits, told that this was the first time she had dared to state that an inspection had saved lives. She pointed to the systematic collection and analysis of patient data as the main reason for why the inspection had made a difference:

> I think what makes a difference, and impacts very strongly, is simply that we have measured, that we have systematised the findings from the electronic health records, [and] presented this using bar charts. The hospital employees were deeply affected by seeing these data. Across-the-board everyone thought they were very good and [in reality] no one were up to the mark.

Some clinicians found that, while they were not exceedingly surprised by the results, the data presented by the inspection team helped frame the challenges they experienced in their day-to-day activities. Describing how the efforts of improving the patient care had changed after the inspection, a clinician from Hospital A referred to how the attention to completing diagnostic procedures quickly

increased after the inspection results were presented. It made them "see through other's eyes" what they already knew:

> After the inspection, and after [one of the managers] presented the findings in the auditorium, [the diagnostic work] got a lot more focused. It was nice because in a way… we saw through other´s eyes what we in reality knew, and then we focused on that work in a whole other way. So these patients have been given much better treatment after the inspection, compared to before.

Having performance data presented by the inspection team can help managers and clinicians re-evaluate their own experiences and assessment of clinical performance. The inspection team of hospital B described how their presentation of data in a closing meeting at one of the hospitals had encouraged the participants at the meeting to share and discuss recent experiences of challenges in the emergency department:

> We just displayed our own data, but [the managers and clinicians] brought it up on the agenda. And then someone just pointed out: "We heard that there was a surge of patients yesterday as well". We overheard that a discussion and a dynamic emerged that we could pitch into.

Building acceptance for improvement through professional credibility and focus on clinical practice

Professional credibility was a topic that was underscored by inspection teams, clinicians, and managers. The clinicians and managers expected the inspection teams to include professionals with medical background, and they expected the inspection team to have insight into the requirements and practices of acute functions in hospitals. A manager at hospital A argued that the inclusion of medical experts was important for the legitimacy of the findings from the inspections:

> It is crucial that there is someone [on the inspection team] who comes from clinical practice, and possibly also from clinical research, and sort of knows the details of the issues that they enquire into; and who also is going to have an understanding of what the management component of these issues might be. So I think this is crucial for the legitimacy of this inspection.

The view that medical experts enhanced the legitimacy of the external inspection was also shared by the inspection teams themselves, both because regular team members with medical background were no longer in clinical practice and because their medical background was not likely to be specific to the type of patient care that the inspection covered.

Clinicians and managers stressed the need for the inspection teams to have a clear understanding of the work processes in emergency departments. One of the managers from Hospital D pointed out that one of the strengths of the inspection had been how the findings were related to issues critical to patient care, even when such findings were on a system level:

> The direct effect of the inspection is obvious. In this case one can relate it directly to the patient, even though much is related to systems and how systems are in place to take care of patients presenting with sepsis. But [the inspection] is very efficient, benefiting the patient directly.

A factor that both clinicians and managers pointed out across interviews, is that diagnosing and treating sepsis patients involve several different organizational subunits within the hospitals. As such, there are very real organizational hurdles that need to be overcome in order to achieve the desired improvement in clinical performance. The inspection teams' understanding of complicated care processes was especially important because it enabled them to direct the inspection on how different groups of clinicians worked together. This forced the different organizational subunits to take a more birds-eye view of the patient care processes as a whole. A manager from hospital B explained:

> I believe that it is positive that someone comes from the outside and then points out that you have to have these things up and running. Because […] the workday is so hectic that every department is preoccupied with themselves and their work […] And I think that [the inspection] is a good pry tool, because then we have to cooperate between departments. And you could say that as a hospital we should be able to do this of our own volition, but this has turned out to be difficult.

Fostering leadership commitment

Because of the challenges of making improvements across different subunits within the hospital, hospital management had an important role in the improvement efforts. In this context, leadership commitment refers to the whole chain of command from the executive director on top to the senior nurses in the emergency department.

Both clinicians, managers, and the inspection teams argued that without bringing the clinical managers and leaders on board and making sure that they were invested in this work, it would be exceedingly difficult to achieve successful improvement of the patient care. When discussing experiences with the improvement initiatives that started up after the inspections, a clinician at hospital D commented on the role of managers:

> Of course they nag a bit, but often because they want to get better. They are genuinely concerned with the medical issues, and that makes one want to join in.

Similarly, one of the clinicians at hospital C pointed out that it was important that clinical managers were genuinely interessed in the improvement efforts:

> The clinical managers are actually interested in putting much effort into it, ensuring that one has resources, and that time is allocated to this. And in a way … they join in and look at the results of what is being presented. […] And this holds true both for nurses and for doctors; that one gets motivated to continue working [with improvements] and feel a bit acknowledged for the work one does.

An important function of the inspections was how they precipitated communication between different leadership levels on matters related to patient care. A clinician from hospital B described how the inspection report affected the hierarchy from clinic to department, and how this caused ripple effects throughout the organization:

> An inspection makes an impact on the management. The head of clinic just said: "This is not good, this is not good enough. Now; who takes care of what? Now we have to do something different." And the head of department joins in. The heads of departments talk together and

> in a way you get a whole organization joining … This is clearly an effect of the inspection; from the top management and downwards. It feels more momentous: Here we need to do something, to close the nonconformities, we need to … And this has yet more ripple effects. So in that sense, [the inspection] has major consequences, in my opinion.

Facilitating communication networks that also included the managerial level was reported to be an important part of achieving organizational commitment to the issues of the inspection. The inspection facilitated that a large group of decision makers came together to discuss issues related to patient care.

In the period following the initial report from the inspection, hospitals are expected to develop a response and action plan to the NBHS. Many interviewees explained that this was an occasion for mutual learning between different disciplines and different hierarchies of management. A manager from hospital A argued:

> Almost nothing happens one-to-one, right? It happens across supporting professions or laboratory professions and radiology and shift teams and positions. So to get some of this reciprocity in the learning process we have tried bringing together these groups and develop a common response [to the NBHS inspection report].

DISCUSSION

Setting out to explore how inspections may foster clinical improvements in hospitals, the first theme we identified was related to how the inspections provided data on the quality of care for patients with sepsis. Our findings suggest that by providing these data, the inspection promotes increasing awareness of clinical performance.

Secondly, we found that there was a need for inspection teams to have a clear understanding of the clinical work and of work processes in the emergency department. Without such knowledge, the legitimacy of the inspection would suffer, and the inspection would be rendered ineffective as a tool for systematic improvements. By directing attention to the interdependencies of the clinical care processes, the inspection could help the hospital to target their efforts on improving the clinical system as a whole.

Lastly, the hospital management seems to be the main conduit through which the inspection team can affect the hospitals´ work on improving a clinically complex task such as sepsis management. Not only do inspection teams engage managers directly; they also play a role in opening up channels of communication between clinical and top-level management and leadership. External inspections could therefore create arenas for discussion and interprofessional reflection between different levels of management on how the hospital as a whole could improve their services to the sepsis patients.

Strengths and limitations

The findings and interpretations of this study are intrinsically linked to the organizational and procedural context in which they are being held. Inspections are complex interventions. Reviewing their effects, we need explanatory analyses that bring to bear both theoretical and practical understanding of the intervention and the contexts within which it is being implemented.[18] The generalizability of the findings should be judged accordingly. We have purposively chosen to study the experiences of actors involved in presumptively successful inspections within a clinically

demanding field of patient care. If we had selected less successful cases within another type of inspection, for instance administrative tasks, one could expect our findings to diverge substantially. However, we are convinced that the cases we have chosen illuminate important aspects of what is needed to make inspections work.

Furthermore, we do not argue that the aspects highlighted in this study are the only mechanisms that might be set in motion during an inspection process. One line of argument worth mentioning in this respect, is that the prospect of being inspected in itself can initiate improvement efforts.[3, 19] Though the search for such anticipatory effects is an important avenue of research, the focus of this study has been on how the findings and recommendations from the inspections, and the interaction with the inspection teams, might influence the hospitals' improvement efforts.

Interpretation in relation to previous studies

Our analyses echo previous research regarding how inspections with a patient-centered focus might promote awareness among clinicians and managers.[20] Furthermore, our analyses lend support to studies highlighting how using data in external assessments of quality of care can help hospitals track improvement.[21] Providing measurable data seems especially pertinent in the case of the sepsis inspections, as previous studies have shown the importance of performance metrics in fostering change in clinical behavior in care for patients with sepsis.[22]

Some authors have argued that if external assessment schemes lead to increased use of data, they do so primarily through a strengthening of the bureaucratic control in the organization.[23] We, however, found that the quality metrics were not considered as being solely within the purview of bureaucratic control; the professionals in the organization viewed the use of data as a necessity for improving quality.

Our analyses nonetheless show that clinical leads played a key role in any improvement effort. Making leaders commit to improving patient care was seen as a *sine qua non* for the inspections to succeed. While this supports an argument for seeing external assessments as a platform from which clinicians can negotiate with senior management,[24] we would add that inspections might empower leaders and managers as well as clinicians.[25] Some important ways in which leaders wield power within organizations are by calling on shared organizational values and by leveraging facts and reasoning.[26] Clinical leaders can facilitate change processes and organizational learning by providing front-line clinicians with an arena for sharing information and a context for reflecting on shared information.[27] The effectiveness of such leadership approaches can be bolstered by the inspections. The sepsis inspections highlight patient safety, which is a laudable and legitimate shared value goal in the emergency departments, and they do so by providing tangible facts for the leaders to leverage vis-à-vis their subordinates and team members.

Recent research has found that educative approaches to regulation can succeed when regulators are able to leverage existing norms and accountability structures in the regulated community.[28] This seems to be the case for the sepsis inspection. They have resulted in an improved understanding of the inherent complexities in the care of sepsis patients, and the improved understanding brings forth organizational commitment and readiness for change, which are pivotal for improvement to take place. These processes also parallel findings from a study of professionals' motivation in hospital accreditation, which showed that external assessment opened up opportunities for collaborative learning and promoted understanding of the whole organization across organizational boundaries.[29] Similarly, the importance of the system perspective runs like a red thread through

our interviews, both in terms of the inspection teams' competencies, and in terms of how clinicians and managers address quality challenges in their own organizations.

Policy implications

Even if performance data is key, focusing exclusively on performance data and quantifiable targets might pose a risk by underestimating the measurement problems or risks of health organizations gaming the system.[30] There is a risk that externally imposed standards in external assessment schemes may end up being perceived as a 'tick-box' exercise for the clinicians involved.[31]

When using indicators to assess performance, one needs to choose indicators that carry a clinical relevance to those working in the inspected organizations. It is also necessary to combine the evaluation of the indicators with a thorough understanding of the clinical processes at work. The task of the inspectors is to review the numbers and in additional bring to the table an assessment of why the hospital might fail to meet the standards.

Organizations do of course review their own performance data and make efforts to improve without the help of external inspections. When it is feasible to make improvements through smaller adjustments, it is likely that the hospitals will do so. Addressing the underlying challenges inherent in tasks like sepsis diagnosis and treatment, on the other hand, entails both deeper analysis and more profound structural changes. Here, inspection teams can play a crucial role. Yet, their regulatory responses should allow the management and staff to find flexible solutions for quality improvement.[32] This calls for a refined balancing act on the part of the inspectors: Their goal is to lay the groundwork for the organization to self-improve, but to do so requires a sustained commitment to change that perhaps is unlikely to be achieved without a certain amount of external pressure or expectations.

Contributors

All authors contributed to the study conception, design, and interpretation of data. GH and EH conducted the focus group interviews and the initial analysis of data. GH drafted the first version of the manuscript. All authors critically reviewed the manuscript and approved the final version.

Funding

This research received no specific grant from any funding agency in the public, commercial or not-for-profit sectors.

Competing interests

All authors have completed the ICMJE uniform disclosure form at www.icmje.org/coi_disclosure.pdf and declare: no support from any organisation for the submitted work; no financial relationships with any organisations that might have an interest in the submitted work in the previous three years; no other relationships or activities that could appear to have influenced the submitted work.

References

1. Shaw C, Groene O, Berger E. External institutional strategies: accreditation, certification, supervision. *Improving healthcare quality in Europe*2019:203.
2. Sutherland K, Leatherman S. Regulation and quality improvement - A review of the evidence. London: The Health Foundation; 2006.
3. Smithson R, Richardson E, Roberts J*, et al.* Impact of the Care Quality Commission on provider performance: Room for improvement? 2018.
4. Schaefer C, Wiig S. Strategy and practise of external inspection in healthcare services – a Norwegian comparative case study. *Safety in Health*. 2017;**3**:3 doi: 10.1186/s40886-017-0054-9 [published Online.
5. Weiner BJ, Amick H, Lee SY. Conceptualization and measurement of organizational readiness for change: a review of the literature in health services research and other fields. *Med Care Res Rev*. 2008;**65**:379-436 doi: 10.1177/1077558708317802 [published Online First: 2008/05/31].
6. Nonaka I. A Dynamic Theory of Organizational Knowledge Creation. *Organization Science*. 1994;**5**:14-37 Online.
7. Hinchcliff R, Greenfield D, Moldovan M, Westbrook JI, Pawsey M, Mumford V. Narrative synthesis of health service accreditation literature. *BMJ Qual Saf*. 2012;**21** doi: 10.1136/bmjqs-2012-000852 [published Online.
8. Arianson H, Elvbakken K, Malterud K. Hvordan opplevde helsepersonell tilsynet med fødeinstitusjoner? *Tidsskrift for Den norske legeforening*. 2008;**128**:1179-81 Online.
9. Hovlid E, Braut GS, Hannisdal E*, et al.* Mediators of change in health care organizations subject to external inspections: a systematic review with narrative synthesis. Manuscript submitted for publication. 2020.
10. Castro-Avila A, Bloor K, Thompson C. The effect of external inspections on safety in acute hospitals in the National Health Service in England: A controlled interrupted time-series analysis. *J Health Serv Res Policy*. 2019;**24**:182-90 doi: 10.1177/1355819619837288 [published Online.
11. Flodgren G, Goncalves-Bradley DC, Pomey MP. External inspection of compliance with standards for improved healthcare outcomes. *Cochrane Database Syst Rev*. 2016;**12**:Cd008992 doi: 10.1002/14651858.CD008992.pub3 [published Online First: 2016/12/03].
12. Hovlid E, Frich JC, Walshe K*, et al.* Effects of external inspection on sepsis detection and treatment: a study protocol for a quasiexperimental study with a stepped-wedge design. *BMJ Open*. 2017;**7**:e016213 doi: 10.1136/bmjopen-2017-016213 [published Online First: 2017/09/08].

13. Husabø G, Nilsen RM, Flaatten H*, et al.* Early diagnosis of sepsis in emergency departments, time to treatment, and association with mortality: An observational study. *PLoS One*. 2020;**15**:e0227652 Online.

14. Morgan DL. The Focus Group Guidebook. Thousand Oaks, CA: SAGE Publications; 1997.

15. Rudd KE, Johnson SC, Agesa KM*, et al.* Global, regional, and national sepsis incidence and mortality, 1990-2017: analysis for the Global Burden of Disease Study. *Lancet*. 2020;**395**:200-11 doi: 10.1016/S0140-6736(19)32989-7 [published Online First: 2020/01/20].

16. ISO. ISO/IEC TS 17022:2012. Conformity Assessment -- Requirements and Recommendations for Content of a Third-Party Audit Report on Management Systems. Geneva: International Organization for Standardization 2012.

17. Braun V, Clarke V. Using thematic analysis in psychology. *Qualitative research in psychology*. 2006;**3**:77-101 Online.

18. Pawson R, Greenhalgh T, Harvey G, Walshe K. Realist review - a new method of systematic review designed for complex policy interventions. *J Health Serv Res Policy*. 2005;**10**:21-34 doi: 10.1258/1355819054308530 [published Online.

19. Walshe K, Phipps D. Developing a strategic framework to guide the Care Quality Commission's programme of evaluation. *London: CQC*. 2013; Online.

20. Åsprang AF, Frich JC, Braut GS. Organizational impact of governmental audit of blood transfusion services in Norway: A qualitative study. *Transfus Apher Sci*. 2015;**53**:228-32 doi: 10.1016/j.transci.2015.04.015 [published Online.

21. El-Jardali F, Jamal D, Dimassi H, Ammar W, Tchaghchaghian V. The impact of hospital accreditation on quality of care: perception of Lebanese nurses. *Int J Qual Health Care*. 2008;**20**:363-71 doi: 10.1093/intqhc/mzn023 [published Online First: 2008/07/04].

22. Levy MM, Rhodes A, Phillips GS*, et al.* Surviving Sepsis Campaign: association between performance metrics and outcomes in a 7.5-year study. *Crit Care Med*. 2015;**43**:3-12 doi: 10.1097/ccm.0000000000000723 [published Online First: 2014/10/03].

23. Paccioni A, Sicotte C, Champagne F. Accreditation: a cultural control strategy. *Int J Health Care Qual Assur*. 2008;**21**:146-58 doi: 10.1108/09526860810859012 [published Online First: 2008/06/27].

24. Baskind R, Kordowicz M, Chaplin R. How does an accreditation programme drive improvement on acute inpatient mental health wards? An exploration of members' views. *J Ment Health*. 2010;**19**:405-11 doi: 10.3109/09638230903531118 [published Online First: 2010/09/15].

25. Walshe K. Regulating Healthcare : A Prescription for Improvement? Berkshire: McGrawHill Education; 2003.

26. Van Wart M, Suino P. Leadership in public organizations : an introduction. 2nd ed. ed. Armonk, N.Y.,London: M.E. Sharpe; 2012.

27. Hovlid E, Bukve O, Haug K, Aslaksen AB, von Plessen C. Sustainability of healthcare improvement: what can we learn from learning theory? *BMC Health Serv Res*. 2012;**12**:235 doi: 10.1186/1472-6963-12-235 [published Online.

28. van Erp J, Wallenburg I, Bal R. Performance regulation in a networked healthcare system: From cosmetic to institutionalized compliance. *Public Administration*. 2020;**98**:46-61 doi: 10.1111/padm.12518 [published Online.

29. Greenfield D, Pawsey M, Braithwaite J. What motivates professionals to engage in the accreditation of healthcare organizations? *Int J Qual Health Care*. 2011;**23**:8-14 doi: 10.1093/intqhc/mzq069 [published Online First: 2010/11/19].

30. Bevan G, Hood C. What's Measured Is What Matters: Targets and Gaming in the English Public Health Care System. *Public Administration*. 2006;**84**:517-38 doi: 10.1111/j.1467-9299.2006.00600.x [published Online.

31. Campbell SM, Chauhan U, Lester H. Primary Medical Care Provider Accreditation (PMCPA): pilot evaluation. *Br J Gen Pract*. 2010;**60**:295-304 doi: 10.3399/bjgp10X514800 [published Online First: 2010/07/03].

32. Healy J, Braithwaite J. Designing safer health care through responsive regulation. *Med J Aust*. 2006;**184**:S56-S9 Online.

Supplementary file 1: The inspection process in the four hospitals

As part of the preparations for the interviews, we read the publicly available inspection reports. These reports were also used to describe the inspection process and findings from the inspections.

We used data collected by the inspection teams, as well as data collected independently in the research project to assess time to antibiotic treatment before and after the inspections. Patients were identified through the Norwegian Patient Registry. We then assessed the patient records and included patients with clinically suspected infection and two systemic inflammatory response syndrome signs.[1] Patients were sampled from four time periods specific to each hospital: two before the inspection and two after. For each time period, 83 patients were sampled, though the number of patients included in the analyses in some cases ended up being slightly smaller due to duplicate records. We used the patient records to determine hours from admission to antibiotic treatment.

Hospital	Population*	Main findings from the inspection	Follow-up by hospital	Percent of patients with antibiotic administration within one hour		
				Before insp.	After insp.	n
Hospital A	350 000	The inspection found that for a substantial proportion of patients, time from presentation to examination by physician and administration of antibiotics was delayed.	In response to the inspection, the hospital evaluated their procedures in inter-professional meetings and implemented changes in procedure and training initiatives.	22%	49%†	123
Hospital B	100 000	Some of the main findings from the inspection were delays in examination by physician and antibiotic administration. There were also inadequacies in documentation of responsibility and medical procedures. The emergency department in Hospital B had already started an improvement project for sepsis care prior to the inspection. The inspection nevertheless found deficiencies that the hospital had not been aware of.	The inspection led to a deepened commitment by the top-level management for the ongoing improvement project.	22%	35%†	122
Hospital C	50 000	The inspection found that for many patients, antibiotic treatment started too late. Furthermore, there were at times not enough available physicians to attend to patients in emergency department and not clear	Following the inspection, the hospital started measuring indicators related to treatment in the emergency department, and clinicians and managers used these measurements for quality improvement purposes. In	18%	41%‡	77

		designation of responsibility for treatment between interns and resident physicians.	addition, there was a change in prehospital practice where more patients were administered antibiotics before being sent to the hospital.			
Hospital D	300 000	The inspection found delays in antibiotic treatment and inadequate triage and observation of patients in emergency department.	After the inspection the hospital has implemented several initiatives, including training, revised procedures, and stand-up improvement board meetings.	15%	43%†	121

* The hospitals are publicly owned and run institutions with responsibilities for specialized acute somatic care for all inhabitants in their local area. "Population" figures reported here are (rounded off and) based on information from the governments National plan for hospitals Meld. St. 11 (2015–2016)

† P-value < 0.01 (chi square test for difference between before and after inspection)

‡ P-value < 0.05 (chi square test for difference between before and after inspection)

[1] Dellinger, R. P., Levy, M. M., Rhodes, A., Annane, D., Gerlach, H., Opal, S. M., . . . Moreno, R. (2013). Surviving sepsis campaign: international guidelines for management of severe sepsis and septic shock: 2012. Critical Care Medicine, 41(2), 580-637. doi:10.1097/CCM.0b013e31827e83af

Reporting checklist for qualitative study.

Based on the SRQR guidelines.

Instructions to authors

Complete this checklist by entering the page numbers from your manuscript where readers will find each of the items listed below.

Your article may not currently address all the items on the checklist. Please modify your text to include the missing information. If you are certain that an item does not apply, please write "n/a" and provide a short explanation.

Upload your completed checklist as an extra file when you submit to a journal.

In your methods section, say that you used the SRQRreporting guidelines, and cite them as:

O'Brien BC, Harris IB, Beckman TJ, Reed DA, Cook DA. Standards for reporting qualitative research: a synthesis of recommendations. Acad Med. 2014;89(9):1245-1251.

	Reporting Item	Page Number
Title		
#1	Concise description of the nature and topic of the study identifying the study as qualitative or indicating the approach (e.g. ethnography, grounded theory) or data collection methods (e.g. interview, focus group) is recommended	1

Abstract			
	#2	Summary of the key elements of the study using the abstract format of the intended publication; typically includes background, purpose, methods, results and conclusions	2
Introduction			
Problem formulation	#3	Description and signifcance of the problem / phenomenon studied: review of relevant theory and empirical work; problem statement	3
Purpose or research question	#4	Purpose of the study and specific objectives or questions	3
Methods			
Qualitative approach and research paradigm	#5	Qualitative approach (e.g. ethnography, grounded theory, case study, phenomenolgy, narrative research) and guiding theory if appropriate; identifying the research paradigm (e.g. postpositivist, constructivist / interpretivist) is also recommended; rationale. The rationale should briefly discuss the justification for choosing that theory, approach, method or technique rather than other options available; the assumptions and limitations implicit in those choices and how those choices influence study conclusions and transferability. As appropriate the rationale for several items might be	4

		discussed together.	
Researcher characteristics and reflexivity	#6	Researchers' characteristics that may influence the research, including personal attributes, qualifications / experience, relationship with participants, assumptions and / or presuppositions; potential or actual interaction between researchers' characteristics and the research questions, approach, methods, results and / or transferability	5
Context	#7	Setting / site and salient contextual factors; rationale	4
Sampling strategy	#8	How and why research participants, documents, or events were selected; criteria for deciding when no further sampling was necessary (e.g. sampling saturation); rationale	4
Ethical issues pertaining to human subjects	#9	Documentation of approval by an appropriate ethics review board and participant consent, or explanation for lack thereof; other confidentiality and data security issues	5
Data collection methods	#10	Types of data collected; details of data collection procedures including (as appropriate) start and stop dates of data collection and analysis, iterative process, triangulation of sources / methods, and modification of procedures in response to evolving study findings; rationale	4-5
Data collection	#11	Description of instruments (e.g. interview guides,	4-5

instruments and technologies		questionnaires) and devices (e.g. audio recorders) used for data collection; if / how the instruments(s) changed over the course of the study	
Units of study	#12	Number and relevant characteristics of participants, documents, or events included in the study; level of participation (could be reported in results)	4
Data processing	#13	Methods for processing data prior to and during analysis, including transcription, data entry, data management and security, verification of data integrity, data coding, and anonymisation / deidentification of excerpts	5
Data analysis	#14	Process by which inferences, themes, etc. were identified and developed, including the researchers involved in data analysis; usually references a specific paradigm or approach; rationale	5-6
Techniques to enhance trustworthiness	#15	Techniques to enhance trustworthiness and credibility of data analysis (e.g. member checking, audit trail, triangulation); rationale	5-6
Results/findings			
Syntheses and interpretation	#16	Main findings (e.g. interpretations, inferences, and themes); might include development of a theory or model, or integration with prior research or theory	6-9
Links to empirical data	#17	Evidence (e.g. quotes, field notes, text excerpts, photographs) to substantiate analytic findings	6-9

Discussion			
Intergration with prior work, implications, transferability and contribution(s) to the field	#18	Short summary of main findings; explanation of how findings and conclusions connect to, support, elaborate on, or challenge conclusions of earlier scholarship; discussion of scope of application / generalizability; identification of unique contributions(s) to scholarship in a discipline or field	9-11
Limitations	#19	Trustworthiness and limitations of findings	10
Other			
Conflicts of interest	#20	Potential sources of influence of perceived influence on study conduct and conclusions; how these were managed	11
Funding	#21	Sources of funding and other support; role of funders in data collection, interpretation and reporting	11

None The SRQR checklist is distributed with permission of Wolters Kluwer © 2014 by the Association of American Medical Colleges. This checklist can be completed online using https://www.goodreports.org/, a tool made by the EQUATOR Network in collaboration with Penelope.ai

BMJ Open

Promoting leadership and quality improvement through external inspections of management of sepsis in Norwegian hospitals: a focus group study

Journal:	*BMJ Open*
Manuscript ID	bmjopen-2020-041997.R1
Article Type:	Original research
Date Submitted by the Author:	30-Aug-2020
Complete List of Authors:	Husabø, Gunnar; Høgskulen på Vestlandet, Department of Social Science; Universitetet i Bergen, Department of Global Public Health and Primary Care Teig, Inger Lise; Universitetet i Bergen, Frich, Jan; Universitetet i Oslo Bondevik, Gunnar; Universitetet i Bergen, Department of Global Public Health and Primary Care; NORCE Norwegian Research Centre AS Hovlid, Einar; Høgskulen på Vestlandet, Department of Social Science; Universitetet i Bergen, Department of Global Public Health and Primary Care
Primary Subject Heading:	Health services research
Secondary Subject Heading:	Emergency medicine, Health policy
Keywords:	Quality in health care < HEALTH SERVICES ADMINISTRATION & MANAGEMENT, Organisational development < HEALTH SERVICES ADMINISTRATION & MANAGEMENT, Clinical governance < HEALTH SERVICES ADMINISTRATION & MANAGEMENT

I, the Submitting Author has the right to grant and does grant on behalf of all authors of the Work (as defined in the below author licence), an exclusive licence and/or a non-exclusive licence for contributions from authors who are: i) UK Crown employees; ii) where BMJ has agreed a CC-BY licence shall apply, and/or iii) in accordance with the terms applicable for US Federal Government officers or employees acting as part of their official duties; on a worldwide, perpetual, irrevocable, royalty-free basis to BMJ Publishing Group Ltd ("BMJ") its licensees and where the relevant Journal is co-owned by BMJ to the co-owners of the Journal, to publish the Work in this journal and any other BMJ products and to exploit all rights, as set out in our licence.

The Submitting Author accepts and understands that any supply made under these terms is made by BMJ to the Submitting Author unless you are acting as an employee on behalf of your employer or a postgraduate student of an affiliated institution which is paying any applicable article publishing charge ("APC") for Open Access articles. Where the Submitting Author wishes to make the Work available on an Open Access basis (and intends to pay the relevant APC), the terms of reuse of such Open Access shall be governed by a Creative Commons licence – details of these licences and which Creative Commons licence will apply to this Work are set out in our licence referred to above.

Other than as permitted in any relevant BMJ Author's Self Archiving Policies, I confirm this Work has not been accepted for publication elsewhere, is not being considered for publication elsewhere and does not duplicate material already published. I confirm all authors consent to publication of this Work and authorise the granting of this licence.

Promoting leadership and quality improvement through external inspections of management of sepsis in Norwegian hospitals: a focus group study

Corresponding author
Gunnar Husabø: gunnar.husabo@hvl.no
tel +47 971 82 327

Authors
Gunnar Husabø: Department of Social Science, Western Norway University of Applied Sciences, Sogndal, Norway; Department of Global Public Health and Primary Care, University of Bergen, Bergen, Norway

Inger Lise Teig: Department of Global Public Health and Primary Care, University of Bergen, Bergen, Norway

Jan C. Frich: Institute of Health and Society, University of Oslo, Oslo, Norway

Gunnar Tschudi Bondevik: Department of Global Public Health and Primary Care, University of Bergen, Bergen, Norway; National Centre for Emergency Primary Health Care, NORCE Norwegian Research Centre, Bergen, Norway

Einar Hovlid: Department of Social Science, Western Norway University of Applied Sciences, Sogndal, Norway; Department of Global Public Health and Primary Care, University of Bergen, Bergen, Norway

Word count
4936

ABSTRACT

Objective Inspections and other forms of external assessment may contribute to positive changes in the health services, but the mechanisms of such change remains unclear. We did a study to explore how external inspections may foster clinical improvement in hospitals.

Design Focus group study.

Setting Statutory inspections of sepsis treatment in hospital emergency departments in Norway.

Participants Clinicians, managers, and inspection teams involved with the inspections of sepsis treatment in emergency departments at four different hospitals. Twelve focus groups interviews were carried out, with a total of 47 participants.

Results Three themes emerged as central for understanding how the inspections could contribute to clinical improvement in the emergency departments: 1) Increasing awareness about the need to improve the quality of care by providing data on clinical performance 2), Building acceptance for improvement through professional credibility and focus on clinical practice, and 3) Fostering leadership commitment.

Conclusions Our findings suggest that the inspections have the potential to enhance hospital management and staff's understanding of complicated care processes and help strengthen the organizational commitment to bring about systematic quality improvements.

STRENGTHS AND LIMITATIONS OF THIS STUDY

- Focus group interviews in hospitals that had achieved improvement in key clinical procedures following an inspection provided information-rich cases of how inspections can contribute to quality improvement.
- The interviews elicited new insights into how inspections can enhance understanding of the clinical system and promote leadership in quality improvement efforts.
- We did not explore change mechanisms related to anticipatory effects resulting from the announcement of upcoming inspections.
- The generalizability of our findings and interpretations are dependent on the organizational and procedural context in which inspections are being held.

INTRODUCTION

External inspection, also referred to as statutory supervision, is an external assessment stragegy which is used to evaluate if health care providers meet accepted quality standards. Compared to other forms of external assessment, such as certification and accreditation, external inspections differ in that they are run by government bodies and subject to country-specific regulations.[1] While the subject and scope vary greatly from one inspection to another, most inspections have in common the goal of improving the quality of care provided by the institutions subject to the inspection.[2]

The rationale for why external assessment strategies could lead to improved quality, is that managers will review the results of assessments and implement changes that are necessary for better and safer healthcare.[1] Such effects might function through directive steps, in which the inspectors guide or force the health organization to act in a specific way. They can also be a result of 'softer' mechanisms, such as if inspections lead to a shift in focus and organizational objectives at the service provider.[3] In either case, the inspectors themselves cannot directly affect the quality of care being provided. As such, they must find ways to improve the quality of care through influencing the care processes and internal controls at the hospitals. External inspection can thus be seen as a way of boosting the internal quality and patient safety improvement work.[4]

Following the argument above, the effectiveness of inspections would likely depend on the degree to which they support organizational attributes and work processes associated with successful improvement. The literature describes readiness for change as a main dimension influencing the chance of success when implementing improvement efforts in health care organizations.[5] This view is rooted in a notion of organizations as communities that contribute to the amplification and development of knowledge, rather than merely entities of hierarchical information processing.[6]

Research has shown mixed effects of inspections on improvement in health organizations. Some studies have found care practices to improve following inspections, but not been able to fully establish the association between the inspections and the improvements.[7, 8] Other studies have not found any improvements following inspections at all.[9, 10] Gaining a deeper insight into the mechanisms of change in connection with external inspections is needed in order to understand how and under what circumstances inspections might lead to substantial, long-lasting improvement.[11, 12]

In Norway, health services are publicly funded and based on the principle of universal and equitable access. They are mandated by legislation to be safe, effective, and provided in accordance with sound professional standards, and health care organizations are required to implement quality management systems. The Norwegian Board of Health Supervision (NBHS) is responsible for ensuring that health services are provided in accordance with these requirements. One of their main supervision approaches is nationwide thematic inspections of services, prioritized on the basis of information about risk and vulnerability. During these inspections, NBHS, or the County Governors, who are local representatives of the central government, investigate services and reports any identified nonconformities, i.e. conditions deemed not to be in accordance with the requirements. While NBHS can impose its authority on healthcare organizations and individual healthcare workers through a wide range of responses and sanctions, including handing out fines and revoking authorization, the reactions issued after nationwide inspections are normally limited to instructing the organizations to correct the situation. The inspectors will then follow up the organization until the nonconformity is considered satisfactorily corrected.[13]

NBHS chose diagnosis and treatment of sepsis in hospital emergency departments as a subject of a thematic inspection starting in 2016 because patients presenting to emergency departments with sepsis often receive substandard care.[14] Delayed treatment is a major challenge, as time is of paramount importance in treatment of sepsis.[15, 16] Because early treatment depends on early diagnosis and recognition,[17, 18] the failures in expediting the treatment often come down to failures in recognizing the diagnosis at an early stage.[14]

The County Governors were charged with performing the inspections. There were six regional inspection teams. Each team included three to four inspectors from the County Governors' health and welfare departments who had prior training and experience from either health care or law. Additionally, each team had an external medical specialist who had extensive clinical experience from working with sepsis diagnosis and treatment.

Methodologically, the inspections were system audits.[19] NBHS used existing guidelines and conferred with experts to formulate a set of quantitative criteria for recommended diagnosis and treatment of sepsis.[20, 21] At inspection, which typically lasted for two days, the team gathered data from the electronic health records of a set of 66 patients with sepsis and evaluated the care given against the criteria. As is customarily done in system audits, the inspection teams also reviewed documentation of relevant procedures, and they interviewed clinicians and managers who were engaged daily with the care of patients with sepsis. At the final day of each inspection, the main findings were presented to the hospital management and staff in a closing meeting. Afterwards, the inspection team wrote up a report that included findings and a list of nonconformities. The report was sent as a draft to the hospital's executive management for comments and eventually finalized and released to the public via the Internet. A translated version of the report from one of the inspections is provided as supplementary file 1, and an overview of the findings from the four inspections included in this study is provided as supplementary file 2.

Our overall aim was to study how external inspections may foster clinical improvement, using the case of NBHS' sepsis inspections. We sought to explore clinicians', managers', and inspection teams' experiences of being involved in the inspection process, and to explore their views on how inspections can affect the quality of care.

METHODS

Study design

The study is a part of an ongoing research on the impact of external inspection of sepsis diagnosis and treatment in emergency departments in Norwegian hospitals. The study protocol has been described previously.[22] The inspections were planned and directed by the Norwegian Board of Health Supervision (NBHS) at 24 hospitals with acute care functions.

For this study, we chose a qualitative approach, conducting focus group interviews with clinicians, managers, and inspectors. We found this to be a well suited method of inquiry, as the focus group discussion can provide interpretive insights into the participants experiences and opinions.[23] Our approach is informed by a realist paradigm, its concept of causal mechanisms providing a theoretical framework for understanding the conditions under which inspections may foster clinical improvement.[24] The study follows Standards for Reporting Qualitative Research (SRQR) guidelines.[25]

The research project was reviewed and approved by the Regional Ethics Committee of Norway North (Identifier: 2015/2195) and the Norwegian Data Protection Authority (Identifier: 15/01559).

Participants and data collection

This study draws on data from twelve focus group interviews with clinicians, managers, and inspection teams involved in the inspection of four of the hospitals (designated A, B, C, and D). The interviews were conducted after the initial inspection, in the period from March 2017 to November 2018. The four hospitals were selected because they showed substantial improvements in key care process measures following the inspection. An overview of the improvements in a key indicator, time to antibiotic treatment, is provided in supplementary file 2.

We conducted separate focus group interviews with clinicians, managers, and the inspection teams at each hospital. The focus groups were sized from three to five participants and included in total 47 interviewees: 15 clinicians, 16 managers, and 16 inspection team members.

The groups of clinicians consisted of physicians and nurses who had diagnosis and treatment of sepsis patients in the emergency department as a part of their daily tasks. The managers were either head nurses at emergency departments, chief physicians, or heads of clinics. As such, the manager focus groups had a mix of interviewees in managerial roles and interviewees with combined responsibility for management and patient care. Clinicians and managers were recruited to the focus groups via contact persons with responsibility for quality management in the hospitals. We recruited all members currently on the inspection team who were available to attend the interview. As the members of the inspection teams changed over time, some inspection team interviewees had not participated in the inspections at the specific hospitals included in our study. The participants were informed beforehand about the purpose of the interviews and they signed a form agreeing to participate in the study. No compensation was given for participation in the study.

The interviews were conducted by GH (male, M.Sc.), except for two interviews that were conducted in collaboration with EH (male, M.D. /Ph.D.). GH had no previous affiliation with the NBHS but had experience from performance audit work in health care organizations. EH had a part-time position as a researcher in the NBHS and had previously participated in NBHS inspections. He was acquainted with some of the interviewees from his work in the NBHS.

For hospitals A, B, and C, the interviews with clinicians and managers were conducted at the respective hospitals. The interviews with the inspection teams were conducted at County Governors' offices. For hospital D, all interviews were conducted by conference call, due to vast travel distances and logistical challenges with convening the inspection team to a physical meeting. The interviewers and the participants were the only ones attending the interviews.

We used three different interview guides, one for each of the three types of groups. The interview guides focused on the impact of the inspections on the quality of care, and the interviews were centered on the experiences from the sepsis inspections (see Table 1). Additionally, time was devoted to discussing sepsis care in general and specific issues surrounding the organization of work in emergency departments.

Table 1 Interview topics

Topic	Probes (sample items)
General experience of the inspection process	

Relevance	• What was the focus of the inspection? • Are the themes covered in the inspection relevant for clinical practice?
Dialog between inspection team and hospital	• How were findings conveyed to the hospital? How did the management/staff react to the findings?
Process for following up	• What has the hospital done in response to the identified nonconformities? • Who were involved in following up the findings from the inspection?
The role of management	• What are important management tasks related to the inspection?
Contribution to change	• How did the inspection impact the internal quality improvement work? • What factors other than the inspection have had an impact on quality improvement work? • How is the quality of care now, compared with before the inspections?

The focus group interviews lasted from 35 to 105 minutes. After each session, field notes were recorded describing how the interview went and whether there were important contextual factors that should be taken into account in the analysis.

Transcription and analysis

Interviews were digitally recorded and subsequently transcribed and imported to NVivo qualitative data analysis software version 12 (QSR International Pty Ltd.). Participants did not receive copies of transcripts.

We analysed the data using a thematic analytic approach.[26] After the first interview, before analyzing the transcript, EH and GH introduced some preliminary codes (awareness of current and desired practice, leader commitment, use of performance metrics, communication and network, staff engagement, and systems thinking). Other codes were added throughout the interviews and the subsequent coding of the material.

Once GH had done the initial coding of the interview transcriptions, EH and GH identified potential themes from the data material. We grouped the codes we considered relevant for understanding the relationship between inspections and improvement work into these themes. Next, we analysed the interviews, first within each hospital, and then cross-case including all interviews, using the themes as an analytical framework.

As the focus groups were made up of three distinct roles, clinicians, managers, and inspection team, we took extra care to compare and contrast the analyses between these roles. The interviews with clinicians and managers were more specific to the inspection in their hospital, as compared to the interviews with the inspection teams, because the inspection teams could draw on experiences from all inspected hospitals in their region.

We read the transcripts and listened to the recorded interviews numerous times to ensure immersion, and we refined, synthesized, and reorganized the identified themes according to our developing understanding of the material. We also extracted quotations from the material to illustrate themes and analytical points.

GH translated the quotes into English, and the translations were checked by all co-authors.

Patient and public involvement

Patient organizations participated in a reference advisory group for the overall research program, which included this study. They were involved from the planning stage on, but they did not directly participate in developing or framing this specific article. We used their inputs to inform the overall study design. Patient organizations strongly advocated the importance of disseminating the study findings to relevant parties. NBHS has held a national, public conference for hospitals, government agencies, and patient representatives where we presented preliminary study findings.

RESULTS

We identified three themes as central for understanding how the inspections could contribute to clinical improvement in the emergency departments: 1) Increasing awareness about the need to improve the quality of care by providing data on clinical performance 2) Building acceptance for improvement through professional credibility and focus on clinical practice, and 3) Fostering leadership commitment.

Increasing awareness about the need to improve the quality of care by providing data on clinical performance

According to the clinicians, managers, and inspection teams, the discrepancy between guidelines and clinical practice was in part caused by the heterogenous nature of the group of patients with sepsis and by how sepsis can manifest itself through various symptoms. They explained that deciding the course of the patient care is challenging, that the clinical processes of diagnosing and treating sepsis is complex, and that judgments often are being made under quite stressful conditions.

A point that was clearly made during the interviews was that the hospitals lacked systems to monitor the extent to which diagnosis and treatment complied with desired practice and procedures. Though data is entered into patients' electronic health records from the time the patients are admitted to the hospitals, the information is not structured in a way that is easily aggregated so that the hospital can track the performance statistically over time.

One of the members of the inspection team at Hospital C, who had long experience from leading system audits, told that this was the first time she had dared to state that an inspection had saved lives. She pointed to the systematic collection and analysis of patient data as the main reason for why the inspection had made a difference:

> I think what makes a difference, and impacts very strongly, is simply that we have measured, that we have systematised the findings from the electronic health records, [and] presented this using bar charts. The hospital employees were deeply affected by seeing these data. Across-the-board everyone thought they were very good and [in reality] no one were up to the mark.

Some clinicians found that, while they were not exceedingly surprised by the results, the data presented by the inspection team helped frame the challenges they experienced in their day-to-day activities. Describing how the efforts of improving the patient care had changed after the inspection, a clinician from Hospital A referred to how the attention to completing diagnostic procedures quickly

increased after the inspection results were presented. It made them “see through other’s eyes” what they already knew:

> After the inspection, and after [one of the managers] presented the findings in the auditorium, [the diagnostic work] got a lot more focused. It was nice because in a way… we saw through other´s eyes what we in reality knew, and then we focused on that work in a whole other way. So these patients have been given much better treatment after the inspection, compared to before.

Having performance data presented by the inspection team can help managers and clinicians re-evaluate their own experiences and assessment of clinical performance. The inspection team of hospital B described how their presentation of data in a closing meeting at one of the hospitals had encouraged the participants at the meeting to share and discuss recent experiences of challenges in the emergency department:

> We just displayed our own data, but [the managers and clinicians] brought it up on the agenda. And then someone just pointed out: “We heard that there was a surge of patients yesterday as well”. We overheard that a discussion and a dynamic emerged that we could pitch into.

Building acceptance for improvement through professional credibility and focus on clinical practice

Professional credibility was a topic that was underscored by inspection teams, clinicians, and managers. The clinicians and managers expected the inspection teams to include professionals with medical background, and they expected the inspection team to have insight into the requirements and practices of acute functions in hospitals. A manager at hospital A argued that the inclusion of medical experts was important for the legitimacy of the findings from the inspections:

> It is crucial that there is someone [on the inspection team] who comes from clinical practice, and possibly also from clinical research, and sort of knows the details of the issues that they enquire into; and who also is going to have an understanding of what the management component of these issues might be. So I think this is crucial for the legitimacy of this inspection.

The inspection teams also shared this view, that the medical experts' knowledge of sepsis care and experience with the day-to-day operations of emergency departments enhanced the legitimacy of the inspections.

Clinicians and managers stressed the need for the inspection teams to have a clear understanding of the work processes in emergency departments. By focusing on how the different processes were interconnected, the inspections identified system-level weaknesses that could produce barriers to timely diagnosis and treatment. One of the managers from Hospital D pointed out that one of the strengths of the inspection had been how these findings were related to issues critical to patient care:

> The direct effect of the inspection is obvious. In this case one can relate it directly to the patient, even though much is related to systems and how systems are in place to take care of patients presenting with sepsis. But [the inspection] is very efficient, benefiting the patient directly.

A factor that both clinicians and managers pointed out across interviews, is that diagnosing and treating sepsis patients involve several different organizational subunits within the hospitals. As such, there are very real organizational hurdles that need to be overcome in order to achieve the desired improvement in clinical performance. The inspection teams' understanding of complicated care processes was especially important because it enabled them to direct the inspection on how different groups of clinicians worked together. This forced the different organizational subunits to take a more birds-eye view of the patient care processes as a whole. A manager from hospital B explained:

> I believe that it is positive that someone comes from the outside and then points out that you have to have these things up and running. Because […] the workday is so hectic that every department is preoccupied with themselves and their work […] And I think that [the inspection] is a good pry tool, because then we have to cooperate between departments. And you could say that as a hospital we should be able to do this of our own volition, but this has turned out to be difficult.

Fostering leadership commitment

Because of the challenges of making improvements across different subunits within the hospital, hospital management had an important role in the improvement efforts. In this context, leadership commitment refers to the whole chain of command from the executive director on top to the senior nurses in the emergency department.

Both clinicians, managers, and the inspection teams argued that without bringing the clinical managers and leaders on board and making sure that they were invested in this work, it would be exceedingly difficult to achieve successful improvement of the patient care. When discussing experiences with the improvement initiatives that started up after the inspections, a clinician at hospital D commented on the role of managers:

> Of course they nag a bit, but often because they want to get better. They are genuinely concerned with the medical issues, and that makes one want to join in.

Similarly, one of the clinicians at hospital C pointed out that it was important that clinical managers were genuinely interessed in the improvement efforts:

> The clinical managers are actually interested in putting much effort into it, ensuring that one has resources, and that time is allocated to this. And in a way … they join in and look at the results of what is being presented. […] And this holds true both for nurses and for doctors; that one gets motivated to continue working [with improvements] and feel a bit acknowledged for the work one does.

An important function of the inspections was how they precipitated communication between different leadership levels on matters related to patient care. A clinician from hospital B described how the inspection report affected the hierarchy from clinic to department, and how this caused ripple effects throughout the organization:

> An inspection makes an impact on the management. The head of clinic just said: "This is not good, this is not good enough. Now; who takes care of what? Now we have to do something

different." And the head of department joins in. The heads of departments talk together and in a way you get a whole organization joining … This is clearly an effect of the inspection; from the top management and downwards. It feels more momentous: Here we need to do something, to close the nonconformities, we need to … And this has yet more ripple effects. So in that sense, [the inspection] has major consequences, in my opinion.

Facilitating communication networks that also included the managerial level was reported to be an important part of achieving organizational commitment to the issues of the inspection. The inspection facilitated that a large group of decision makers came together to discuss issues related to patient care.

In the period following the initial report from the inspection, hospitals are expected to develop a response and action plan to the NBHS. Many interviewees explained that this was an occasion for mutual learning between different disciplines and different hierarchies of management. A manager from hospital A argued:

Almost nothing happens one-to-one, right? It happens across supporting professions or laboratory professions and radiology and shift teams and positions. So to get some of this reciprocity in the learning process we have tried bringing together these groups and develop a common response [to the NBHS inspection report].

DISCUSSION

In this study, we set out to explore how inspections may foster clinical improvements in hospitals. The first theme we identified was related to how the inspections provided data on the quality of care for patients with sepsis. Our findings suggest that by providing these data, the inspection promotes increasing awareness of clinical performance.

Secondly, we found that there was a need for inspection teams to have a clear understanding of the clinical work and of work processes in the emergency department. Without such knowledge, the legitimacy of the inspection would suffer, and the inspection would be rendered ineffective as a tool for systematic improvements. By directing attention to the interdependencies of the care processes, the inspection could help the hospital to target their efforts on improving the clinical system as a whole.

Lastly, the hospital management seems to be the main conduit through which the inspection team can affect the hospitals´ work on improving a clinically complex task such as sepsis management. Not only do inspection teams engage managers directly; they also play a role in opening up channels of communication between clinical and top-level management and leadership. External inspections could therefore create arenas for discussion and interprofessional reflection between different levels of management on how the hospital as a whole could improve their services to the sepsis patients.

Strengths and limitations

The findings and interpretations of this study are intrinsically linked to the organizational and procedural context in which they are being held. Inspections are complex interventions. Reviewing their effects, we need explanatory analyses that bring to bear both theoretical and practical understanding of the intervention and the contexts within which it is being implemented.[27] The generalizability of the findings should be judged accordingly. We have purposively chosen to study

the experiences of actors involved in presumptively successful inspections within a clinically demanding field of patient care. If we had selected less successful cases within another type of inspection, for instance administrative tasks, one could expect our findings to diverge substantially. However, we are convinced that the cases we have chosen illuminate important aspects of what is needed to make inspections work.

Our focus on change mechanisms related to improvements in quality of care also implies that we have not explored potential costs and adverse side-effects of the inspections. Inspections may impose compliance costs on regulated organizations, including costs related to handling requests for information, consulting the inspection team, and acting as guides on site-visits.[28] If the organization frequently receives inspections, inquiries, or instructions from different regulatory bodies, such costs might add up to a substantial strain, especially on the management and administrative staff. This study should therefore not be considered an exhaustive evaluation of the benefits and disadvantages of the sepsis inspections or inspections in general.

Furthermore, we do not argue that the aspects highlighted in this study are the only mechanisms that might be set in motion during an inspection process. One line of argument worth mentioning in this respect, is that the prospect of being inspected in itself can initiate improvement efforts.[3, 29] Though the search for such anticipatory effects is an important avenue of research, the focus of this study has been on how the findings and recommendations from the inspections, and the interaction with the inspection teams, might influence the hospitals' improvement efforts.

Interpretation in relation to previous studies

Our analyses echo previous research regarding how inspections with a patient-centered focus might promote awareness among clinicians and managers.[30] Furthermore, our analyses lend support to studies highlighting how using data in external assessments of quality of care can help hospitals track improvement.[31] Providing measurable data seems especially pertinent in the case of the sepsis inspections, as previous studies have shown the importance of performance metrics in fostering change in clinical behavior in care for patients with sepsis.[32]

Some authors have argued that if external assessment schemes lead to increased use of data, they do so primarily through a strengthening of the bureaucratic control in the organization.[33] We, however, found that the quality metrics were not considered as being solely within the purview of bureaucratic control; the professionals in the organization viewed the use of data as a necessity for improving quality.

Our analyses nonetheless show that clinical leads played a key role in any improvement effort. Making leaders commit to improving patient care was seen as a *sine qua non* for the inspections to succeed. While this supports an argument for seeing external assessments as a platform from which clinicians can negotiate with senior management,[34] we would add that inspections might empower leaders and managers as well as clinicians.[35] Some important ways in which leaders wield power within organizations are by calling on shared organizational values and by leveraging facts and reasoning.[36] Clinical leaders can facilitate change processes and organizational learning by providing front-line clinicians with an arena for sharing information and a context for reflecting on shared information.[37] The effectiveness of such leadership approaches can be bolstered by the inspections. The sepsis inspections highlight patient safety, which is a laudable and legitimate shared value goal in the emergency departments, and they do so by providing tangible facts for the leaders to leverage vis-à-vis their subordinates and team members.

Recent research has found that educative approaches to regulation can succeed when regulators are able to leverage existing norms and accountability structures in the regulated community.[38] This seems to be the case for the sepsis inspection. They have resulted in an improved understanding of the inherent complexities in the care of sepsis patients, and the improved understanding brings forth organizational commitment and readiness for change, which are pivotal for improvement to take place. These processes also parallel findings from a study of professionals' motivation in hospital accreditation, which showed that external assessment opened up opportunities for collaborative learning and promoted understanding of the whole organization across organizational boundaries.[39] Similarly, the importance of the system perspective runs like a red thread through our interviews, both in terms of the inspection teams' competencies, and in terms of how clinicians and managers address quality challenges in their own organizations.

Policy implications

Even if performance data is key, focusing exclusively on performance data and quantifiable targets might pose a risk by underestimating the measurement problems or risks of health organizations gaming the system.[40] There is a risk that externally imposed standards in external assessment schemes may end up being perceived as a 'tick-box' exercise for the clinicians involved.[41]

When using indicators to assess performance, one needs to choose indicators that carry a clinical relevance to those working in the inspected organizations. It is also necessary to combine the evaluation of the indicators with a thorough understanding of the clinical processes at work. The task of the inspectors is to review the numbers and in additional bring to the table an assessment of why the hospital might fail to meet the standards.

Organizations do of course review their own performance data and make efforts to improve without the help of external inspections. When it is feasible to make improvements through smaller adjustments, it is likely that the hospitals will do so. Addressing the underlying challenges inherent in tasks like sepsis diagnosis and treatment, on the other hand, entails both deeper analysis and more profound structural changes. Here, inspection teams can play a crucial role. Yet, their regulatory responses should allow the management and staff to find flexible solutions for quality improvement.[42] This calls for a refined balancing act on the part of the inspectors: Their goal is to lay the groundwork for the organization to self-improve, but to do so requires a sustained commitment to change that perhaps is unlikely to be achieved without a certain amount of external pressure or expectations.

Acknowledgement

We thank the focus group participants for devoting their time to this study. We also thank the patient organizations for their involvement in the research project, the inspection teams for participating in data collection, and the staff at the Norwegian Board of Health Supervision for developing the sepsis inspection. Professor Geir Sverre Braut translated the inspection report, for which we are most grateful.

Contributors

Gunnar Husabø

Conception and design, planning and conducting interviews, initial analysis, interpretation of findings, authoring original draft, making critical revisions, and approving the final version of the manuscript

Inger Lise Teig
Conception and design, interpretation of findings, making critical revisions and approving the final version of the manuscript

Jan C. Frich
Conception and design, interpretation of findings, making critical revisions and approving the final version of the manuscript

Gunnar Tschudi Bondevik
Conception and design, interpretation of findings, making critical revisions and approving the final version of the manuscript

Einar Hovlid
Conception and design, planning and conducting interviews, initial analysis, interpretation of findings, making critical revisions and approving the final version of the manuscript

Funding
This research received no specific grant from any funding agency in the public, commercial or not-for-profit sectors.

Competing interests
All authors have completed the ICMJE uniform disclosure form at www.icmje.org/coi_disclosure.pdf and declare: no support from any organisation for the submitted work; no financial relationships with any organisations that might have an interest in the submitted work in the previous three years; no other relationships or activities that could appear to have influenced the submitted work.

Data availability
This is a qualitative study and therefore the data generated is not suitable for sharing beyond that contained within the report. Further information can be obtained from the corresponding author.

REFERENCES

1. Shaw C, Groene O, Berger E. External institutional strategies: accreditation, certification, supervision. In: Busse R, Klazinga N, Panteli D, et al., eds. Improving healthcare quality in Europe, 2019:203-31.
2. Sutherland K, Leatherman S. *Regulation and quality improvement - A review of the evidence*. London: The Health Foundation, 2006.
3. Smithson R, Richardson E, Roberts J, et al. Impact of the Care Quality Commission on provider performance: Room for improvement?, 2018.
4. Schaefer C, Wiig S. Strategy and practise of external inspection in healthcare services – a Norwegian comparative case study. Safety in Health 2017;3(1):1-9 doi: 10.1186/s40886-017-0054-9.

5. Weiner BJ, Amick H, Lee SY. Conceptualization and measurement of organizational readiness for change: a review of the literature in health services research and other fields. Med Care Res Rev 2008;65(4):379-436 doi: 10.1177/1077558708317802.
6. Nonaka I. A Dynamic Theory of Organizational Knowledge Creation. Organization Science 1994;5(1):14-37.
7. Wesselink SFO, Lingsma HF, Erasmus V, et al. Does Government Supervision Improve Stop-Smoking Counseling in Midwifery Practices? Nicotine & Tobacco Research 2014;17(5):572-79 doi: 10.1093/ntr/ntu190.
8. Wesselink SFO, Lingsma HF, Ketelaars CA, et al. Effects of Government Supervision on Quality of Integrated Diabetes Care: A Cluster Randomized Controlled Trial. Med Care 2015;53(9):784-91.
9. Castro-Avila A, Bloor K, Thompson C. The effect of external inspections on safety in acute hospitals in the National Health Service in England: A controlled interrupted time-series analysis. J Health Serv Res Policy 2019;24(3):182-90 doi: 10.1177/1355819619837288.
10. Allen T, Walshe K, Proudlove N, et al. Measurement and improvement of emergency department performance through inspection and rating: an observational study of emergency departments in acute hospitals in England. Emerg Med J 2019;36(6):326 doi: 10.1136/emermed-2018-207941.
11. Flodgren G, Goncalves-Bradley DC, Pomey MP. External inspection of compliance with standards for improved healthcare outcomes. Cochrane Database Syst Rev 2016;12:Cd008992 doi: 10.1002/14651858.CD008992.pub3.
12. Hovlid E, Braut GS, Hannisdal E, et al. Mediators of change in health care organizations subject to external inspections: a systematic review with narrative synthesis. BMJ Open. Forthcoming., 2020.
13. Norwegian Board of Health Supervision. Introduction to the supervisory authorities and the supervision of child welfare services, social services and health and care services in Norway 2019/08/22/ 2019. https://www.helsetilsynet.no/en/introduction-to-the-supervisory-authorities-and-the-supervision-of-child-welfare-services-social-services-and-health-and-care-services-in-norway.
14. Goodwin A, Srivastava V, Shotton H, et al. Just say sepsis. A review of the process of care received by patients with sepsis London: National Confidential Enquiry into Patient Outcome and Death 2015.
15. Rhodes A, Evans LE, Alhazzani W, et al. Surviving Sepsis Campaign: International Guidelines for Management of Sepsis and Septic Shock: 2016. Intensive Care Med 2017;43(3):304-77 doi: 10.1007/s00134-017-4683-6.

16. Plata-Menchaca EP, Ferrer R, Ruiz Rodríguez JC, et al. Antibiotic treatment in patients with sepsis: a narrative review. Hosp Pract 2020:1-11 doi: 10.1080/21548331.2020.1791541.
17. Gatewood MOK, Wemple M, Greco S, et al. A quality improvement project to improve early sepsis care in the emergency department. BMJ Qual Saf 2015;24(12):787-95 doi: 10.1136/bmjqs-2014-003552.
18. Husabø G, Nilsen RM, Flaatten H, et al. Early diagnosis of sepsis in emergency departments, time to treatment, and association with mortality: An observational study. PLoS One 2020;15(1):e0227652 doi: 10.1371/journal.pone.0227652.
19. ISO. ISO/IEC TS 17022:2012. Conformity Assessment -- Requirements and Recommendations for Content of a Third-Party Audit Report on Management Systems. Geneva: International Organization for Standardization, 2012.
20. National Institute for Health and Care Excellence. Sepsis. Quality standard QS161, 2017.
21. Dellinger RP, Levy MM, Rhodes A, et al. Surviving Sepsis Campaign: international guidelines for management of severe sepsis and septic shock, 2012. Intensive Care Med 2013;39(2):165-228 doi: 10.1007/s00134-012-2769-8.
22. Hovlid E, Frich JC, Walshe K, et al. Effects of external inspection on sepsis detection and treatment: a study protocol for a quasiexperimental study with a stepped-wedge design. BMJ Open 2017;7(9):e016213 doi: 10.1136/bmjopen-2017-016213.
23. Morgan DL. *The Focus Group Guidebook*. Thousand Oaks, CA: SAGE Publications, 1997.
24. Pawson R. *The Science of Evaluation: A Realist Manifesto*. London: SAGE Publications, 2013.
25. O'Brien BC, Harris IB, Beckman TJ, et al. Standards for Reporting Qualitative Research: A Synthesis of Recommendations. Acad Med 2014;89(9):1245-51 doi: 10.1097/acm.0000000000000388.
26. Braun V, Clarke V. Using thematic analysis in psychology. Qual Res Psychol 2006;3(2):77-101 doi: 10.1191/1478088706qp063oa.
27. Pawson R, Greenhalgh T, Harvey G, et al. Realist review - a new method of systematic review designed for complex policy interventions. J Health Serv Res Policy 2005;10(1_suppl):21-34 doi: 10.1258/1355819054308530.
28. Hood C, Scott C, James O, et al. *Regulation inside government: waste watchers, quality police, and sleaze-busters*. Oxford: Oxford University Press, 1999.
29. Walshe K, Phipps D. Developing a strategic framework to guide the Care Quality Commission's programme of evaluation. London: CQC 2013.

30. Åsprang AF, Frich JC, Braut GS. Organizational impact of governmental audit of blood transfusion services in Norway: A qualitative study. Transfus Apher Sci 2015;53(2):228-32 doi: 10.1016/j.transci.2015.04.015.
31. El-Jardali F, Jamal D, Dimassi H, et al. The impact of hospital accreditation on quality of care: perception of Lebanese nurses. Int J Qual Health Care 2008;20(5):363-71 doi: 10.1093/intqhc/mzn023.
32. Levy MM, Rhodes A, Phillips GS, et al. Surviving Sepsis Campaign: association between performance metrics and outcomes in a 7.5-year study. Crit Care Med 2015;43(1):3-12 doi: 10.1097/ccm.0000000000000723.
33. Paccioni A, Sicotte C, Champagne F. Accreditation: a cultural control strategy. Int J Health Care Qual Assur 2008;21(2):146-58 doi: 10.1108/09526860810859012.
34. Baskind R, Kordowicz M, Chaplin R. How does an accreditation programme drive improvement on acute inpatient mental health wards? An exploration of members' views. J Ment Health 2010;19(5):405-11 doi: 10.3109/09638230903531118.
35. Walshe K. *Regulating Healthcare : A Prescription for Improvement?* Berkshire: McGrawHill Education, 2003.
36. Van Wart M, Suino P. *Leadership in public organizations : an introduction*. 2nd ed. ed. Armonk, N.Y.,London: M.E. Sharpe, 2012.
37. Hovlid E, Bukve O, Haug K, et al. Sustainability of healthcare improvement: what can we learn from learning theory? BMC Health Serv Res 2012;12(1):235 doi: 10.1186/1472-6963-12-235.
38. van Erp J, Wallenburg I, Bal R. Performance regulation in a networked healthcare system: From cosmetic to institutionalized compliance. Public Administration 2020;98(1):46-61 doi: 10.1111/padm.12518.
39. Greenfield D, Pawsey M, Braithwaite J. What motivates professionals to engage in the accreditation of healthcare organizations? Int J Qual Health Care 2011;23(1):8-14 doi: 10.1093/intqhc/mzq069.
40. Bevan G, Hood C. What's Measured Is What Matters: Targets and Gaming in the English Public Health Care System. Public Administration 2006;84(3):517-38 doi: 10.1111/j.1467-9299.2006.00600.x.
41. Campbell SM, Chauhan U, Lester H. Primary Medical Care Provider Accreditation (PMCPA): pilot evaluation. Br J Gen Pract 2010;60(576):295-304 doi: 10.3399/bjgp10X514800.
42. Healy J, Braithwaite J. Designing safer health care through responsive regulation. Med J Aust 2006;184(10):S56-S59.

The county governor of Troms

Report from inspection of sepsis treatment

in the emergency department at

University Hospital of Northern Norway, Tromsø

UNOFFICIAL TRANSLATION[1]

Address of the enterprise: 9030 Tromsø

Time span for the inspection: 6. September 2016 – 9. March 2017

Summary

Norwegian Board of Health Supervision (NBHS) has decided that in the period 2016-2017, there will be performed nationwide inspections of the hospitals' emergency departments and their work with recognition and treatment of patients with sepsis.

The county governor of Troms has performed a inspection designed as a system audit at the University Hospital of Northern Norway, Tromsø. This report describes the nonconformities identified within the audited areas. The system audit comprised the following themes:

Identification and initiation of treatment in the emergency department of patients with sepsis or suspected sepsis.

During the inspection we would investigate if the hospital ensures:

- adequate admission, registration and prioritisation (triage) of patients with sepsis or suspected sepsis at the time of admission to the emergency department
- adequate assessment and diagnosis of the patients during their stay in the emergency department
- adequate initiation of treatment of the patients in the emergency department
- adequate observation of the patients in the emergency department
- adequate preparation and discharge of the patients to other departments, supplemented by ordinations/plans for further observation and treatment

The inspection team has 66 health records of patients presenting to the emergency department with sepsis or suspected sepsis.

[1] This report is an unofficial translation of the original report from Norwegian Board of Health Supervision. The original report, along with the reports from the other sepsis inspections, is available on the NBHS website: https://www.helsetilsynet.no/tilsyn/tilsynsrapporter/?w=2016+Sepsis+i+somatiske+akuttmottak

At the inspection, three nonconformities were identified:

Nonconformity 1:

The majority of the patients with sepsis did not receive treatment with antibiotics within the time limits prescribed in nationwide guidelines and in the hospital's own goal statements. Patients with severe sepsis who had to wait more than one hour, did not receive adequate treatment.

Nonconformity 2:

The management has not ensured that there is sufficient medical competence available in the emergency department so that assessments and initiation of treatment of patients with sepsis can be performed within the time limits prescribed in nationwide guidelines and in the hospital's own goal statements.

Nonconformity 3:

The hospital management has been aware that patients with sepsis receive delayed treatment with antibiotics in the emergency department but has not implemented sufficient corrective actions.

Date: 9. March 2017

xxxxx
Lead Auditor

yyyyy
Auditor

1. Introduction

This report is written after a system audit at University Hospital of Northern Norway, Tromsø in the period 6. September 2016 – 9. March 2017. It is a part of a nationwide inspection performed in 2016-2017, and one of the planned inspections to be performed by the County governor of Troms this year. The county governors of Finnmark, Troms and Nordland have appointed a joint inspection team to perform the inspections in these counties.

The county governor is through section 2 of the act on governmental supervision of the health and care services given authority to perform inspections with the provision of health and care services.

The aim of a system audit is to evaluate if the enterprise by means of internal control meets the legal requirements. The audit encompassed the following themes:

- which actions were taken by the enterprise to disclose, correct and prevent infringement of the legal requirements relevant for the analysed issues
- if the prescribed actions were performed in practice and, if necessary, corrected
- if the prescribed actions are sufficient to ensure adherence to the legal requirements

A system audit is performed by analysis of documents, through interviews and by other investigations.

This report deals with the nonconformities identified at the system audit, and thus does not present a complete evaluation of the work of the enterprise relevant for the themes covered by the inspection.

- **Nonconformity** is lack of fulfilment of requirements given by or on basis of acts and regulations

The background for the decision to perform inspection of the sepsis treatment, is, i.a. that NBHS has received several reports according to the requirement [on reporting adverse events] in section 3-3 of the act on specialised health care about serious infections and sepsis, where detection of infection has been too late, and where there has been delayed initiation of treatment with antibiotics.

NBHS has established a research project to gain knowledge on how planned inspection can contribute to improving quality on health services. Data collected from patient files in this inspection will be used to evaluate the effect of inspection on the quality of the service. As part of the inspection and this project, we will perform sampling from relevant health records in 8 months and 14 months from now.

2. Description of the enterprise – particular conditions

The University Hospital of Northern Norway (UNN HF) serves a population of about 190.000 inhabitants and consists of three hospitals, respectively in Tromsø, Harstad and Narvik, in addition to Longyearbyen hospital on Svalbard. The main administrative centre of the hospital is located to Tromsø, and is led by the chief executive director.

The health enterprise is divided into nine clinics, among them the *clinic for acute medicine* and the *clinic for medicine*. Each clinic is led by a director who reports to the chief executive director.

The emergency department at UNN HF Tromsø is a department in the clinic for acute medicine. Head of department reports to the director of the clinic. Head of department is at the moment also acting director of clinic for the clinic for acute medicine. Head of the unit for acute somatic admissions is responsible for the nursing services in this unit and reports to the head of the department. There is a medical consultant, 60% of a full position, adhered to the unit for acute somatic admissions as a medical advisor.

The medical on-duty teams consist of an intern, first line and second line registrars, first line registrar for heart and pulmonary diseases and subspecialised consultants in the different parts of internal medicine. The first line registrar is available 24hrs, the second line registrar is available 8hrs-22hrs on week days and 9hrs-15hrs in the weekends. The intern is not available at night time. The intern shall confer with the second line registrar (or first line registrar) related to all investigated patients.

The physicians working in the unit for acute somatic admissions are employed at different parts of the clinic for medicine or the clinic for heart and lung diseases. All physicians in first line or second line duty are undergoing training as a specialist. Head of department/chief consultant of the department of gastrology and nephrology is responsible for planning the on duty scheme and for arranging regular meetings with the physicians on both levels.

RETTS (Rapid Emergency Triage and Treatment System) is used in the unit for acute somatic admissions. According to activity under algorithm 47 treatment with antibiotics shall be initiated within 1 hour after arrival of the patient.

3. Execution

The system audit consisted of the following activities:

Notice/information regarding the inspection was sent 6. September 2016.

Overview over documents presented by the enterprise is to be found in the chapter on Documents.

Analysis of patient files were performed 7. November 2016 and 5. January 2017.

Opening meeting was arranged 25. January 2017.

Interviews

15 persons were interviewed.

On site visit in the unit for acute somatic admissions was performed 25. January 2017.

Closing meeting was arranged 26. January 2017.

4. What the inspection comprised

In the inspection, we have investigated if the health enterprise governs and controls that patients admitted with sepsis or suspected sepsis are identified and treated according to the requirements laid down in the legislation related to health care.

The inspection was limited to the unit for acute somatic admissions, and activities that are planned and ordered from the unit for acute somatic admissions.

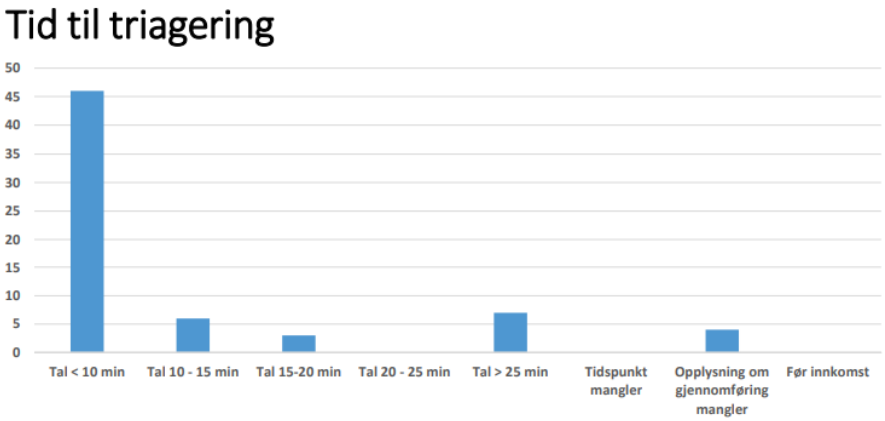
In particular we investigated if the University Hospital of Northern Norway had:

- prudent admission, registration and prioritisation (triage) of patients with sepsis or suspected sepsis at the time of admission to the emergency department
- prudent investigation and diagnosis of the patients during their stay in the emergency department
- prudent initiation of treatment of the patients in the emergency department
- prudent observation of the patients in the emergency department
- prudent preparation and transferral of the patients to other departments, supplemented by ordinations/plans for further observation and treatment

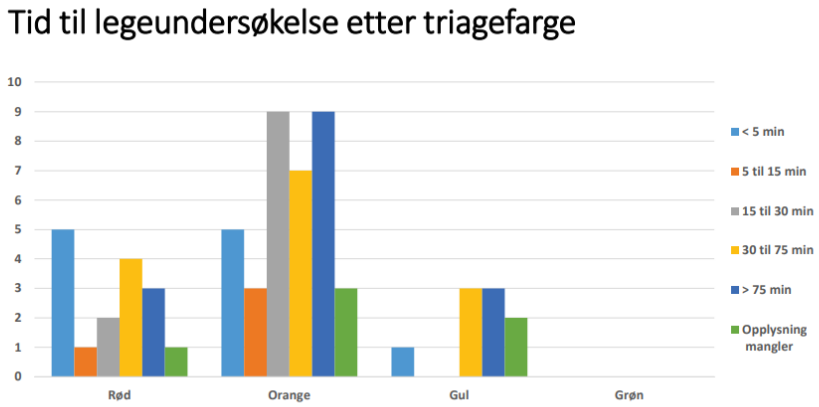
5. Findings

The inspection team has analysed patient files from patients admitted to the unit for acute somatic admissions with sepsis or suspected sepsis. The 66 patients included had an infection and fulfilled at least two of four SIRS-criteria. 33 patient files were from 1. October 2015 and immediately before (called P0), and 33 from 1. December 2016 and immediately before (called P1).

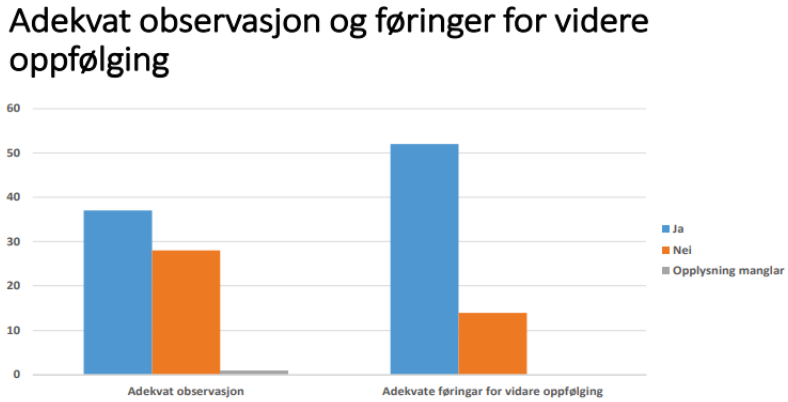
In the graphics below P0 and P1 are combined. The analysis showed:



(Time till triage, in minutes)



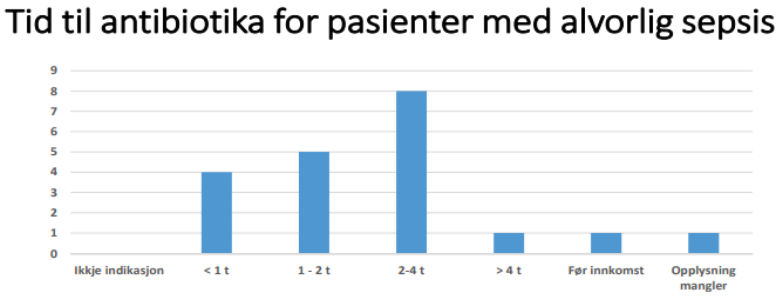
(Time until investigation by physician in minutes, according to triage colour)



(Adequate observation and instructions for further treatment, Yes (ja), No (nei), Lacking information (grey))

(Time till treatment with antibiotics in hours, all patients.

No indication, < 1 hr ….. > 4 hrs, Before admission, Lacking information)



(Time till treatment with antibiotics in hours, patients with severe sepsis.

No indication, < 1 hr ….. > 4 hrs, Before admission, Lacking information)

Three nonconformities were indicated.

Nonconformity 1:

The majority of the patients with sepsis did not receive treatment with antibiotics within the time limits prescribed in nationwide guidelines and in the hospital's own goal statements. Patients with severe sepsis who had to wait more than one hour, did not receive adequate treatment.

This is a deviation from the requirement in section 2-2 of the act on specialised health care and sections 6 to 9 in the regulation on governance and quality improvement in the health and care services.

Justification of this claim:

- The analysis of 66 patient files shoved that:
  - 9 of 16 patients with triage colour red were investigated by a physician more than 15 minutes after admission to the hospital
  - 24 of 49 patients with sepsis got their first treatment with antibiotics more than two hours after admission to the hospital
  - 9 of 18 patients with severe sepsis had to wait over two hours before treatment with antibiotics was initiated, 14 of 18 had to wait over one hour. One patient waited more than four hours
- None of the directors of the clinics (clinic for medicine and clinic for acute medicine) have determined specific routines or practice for treatment of sepsis in the unit for acute somatic admissions. Instead, there are several different, older versions of written procedures in Docmap. These are not known for the health personnel, and their status remains unclear. There is also a non-dated flow chart with unclear status. This is presented as wall charts in the unit for acute somatic admissions.
- The health personnel is unsure about which procedures that are currently valid and they have different opinions about if and when treatment with antibiotics shall be initiated.
- Inexperienced physicians use much time for investigating the patients and decide upon treatment with antibiotics. Front line physicians do not always get a go-signal to initiate treatment when searching for support on decisions, even when related to patients with sepsis that according to national guidelines should get treatment.
- The management of the hospital and the directors of the clinics (clinic for medicine and clinic for acute medicine) do not follow up if the hospital achieves the goal specifying that patients with sepsis should get treatment with antibiotics within one hour.
- Conflicts of simultaneity and problems with vacant beds in the unit for acute somatic admissions arise several times every week and this is leading to delayed initiation of treatment with antibiotics.
- Observation of vital parameters of patients with sepsis are not always documented after triage when the patient still is in the unit for acute somatic admissions.
- Physicians and nurses work to a low degree in teams related to the sepsis patients.
- The bed wards often have low capacity and need a long time before being able to accept new patients, and the intensive care unit for internal medicine is often full. This leads to congestion in the unit for acute somatic admissions of patients that are ready for transferral to a bed ward. The capacity of rooms thus is reduced, and leads to new patients with sepsis not always are investigated by a physician when the physician is available. This in turn leads to delayed initiation of treatment with antibiotics.
- The day of the on-site visit we were informed that a patient with severe sepsis had to wait three hours before initiation of treatment with antibiotics, and had to wait more than nine hours before transferral to a bed ward.

Nonconformity 2:

The management has not ensured that there is sufficient medical competence available in the emergency department so that assessments and initiation of treatment of patients with sepsis can be performed within the time limits prescribed in nationwide guidelines and in the hospital's own goal statements.

This is a deviation from sections 6 to 9 in the regulation on governance and quality improvement in the health and care services.

Justification of this claim:

- It is not planned for the physicians in the unit for acute somatic admissions to investigate and treat all patients in accordance with the national guidelines and the hospital's own goals, cfr. nonconformity 1.
- Interns in some occasions are left alone with a higher degree of responsibility than planned due to first line registrars are occupied with telephone calls from physicians outside the hospital and for distributing patients from the unit for acute somatic admissions to the bed wards of the hospital. The second line registrar often is occupied at the observation unit.
- Training of subordinate physicians in treatment of sepsis is failing, and characterised of lacking procedures for this activity.

Nonconformity 3:

The hospital management has been aware that patients with sepsis receive delayed treatment with antibiotics in the emergency department but has not implemented sufficient corrective actions.

This is a deviation from sections 8 and 9 in the regulation on governance and quality improvement in the health and care services.

Justification of this claim:

- Statistics and other instruments are scarcely used to follow up results and objectives.
- The management demands few data on results from the unit of acute somatic admissions, e.g. on waiting time for investigation by a physician and time till initiation of treatment with antibiotics.
- The health personnel has reported nonconformities related to delayed treatment of sepsis in the unit for acute somatic admissions but sufficient actions have not been taken.
- The chief executive officer as well as the directors of the clinics have been aware of the long waiting times for the patients in the unit for acute somatic admissions.
- It remains unclear who is responsible for developing av implementation of joint procedures for nurses and physicians in the unit for acute somatic admissions. The management scarcely has an overview of which procedures that are currently valid.

6. Evaluation of the system of governance of the enterprise

The management scarcely has an overview of which goals that are established for the treatment of sepsis in the unit for acute somatic admissions and if these goals are achieved. It remains unclear who is responsible for ensuring unambiguous procedures for treatment of sepsis unit for acute somatic admissions that is known for everyone. It is known for the management that patients risk to be waiting in the unit for acute somatic admissions to be transferred to a bed ward, but efficient actions have not been taken. The health enterprise thus has not arranged for the health personnel enabling them to take care of their duties in a way that ensures that patients with sepsis at the unit for acute somatic admissions are treated according to national guidelines and the hospital's own goals.

7. Legislation

- Act of 2. July 1999 no. 61 relating to specialised health care.
- Act of 2. July 1999 no. 64 relating to health personnel.
- Regulation of 21. December 2000 no. 1385 relating to patient files.
- Regulation of 28.October 2016 no 1250 relating to on governance and quality improvement in the health and care services.

8. Documentation

Documentation from the enterprise related to management of the services, provided by the enterprise during the preparation of the audit:

- Information in letter from the head of the unit dated 22. September 2016
- Organisational mapping for the health enterprise and the unit for acute somatic admissions
- Overview of physicians taking part in the on-duty scheme in the unit for acute somatic admissions
- Overview of first line and second line registrars, with information on length of service
- Overview of anaesthesiologists
- Overview of nurses in the unit for acute somatic admissions
- Overview of nurses functioning as coordinators in the unit for acute somatic admissions
- Work tasks for coordinator at the unit for acute somatic admissions in Tromsø
- Work tasks for responsible for the waiting room in Tromsø
- Work tasks for the triaging nurse at the unit for acute somatic admissions in Tromsø
- On-duty-order intern (FB1485)
- On-duty-order first line registrar (FB1484)
- On-duty-order second line registrar (FB1483)
- Admission of patients from the ambulance service.
- Algorithm 47 from the RETTS-manual
- Blood sampling routine sepsis

- Joint patient file for acute admissions UNN HF
- Flow chart treatment and monitoring at intermediary and/or intensive care units
- Transferral of patients with internal medical conditions from the unit for acute somatic admissions when lacking places at medical bed wards
- Procedure for handling of deviations UNN
- Copy of reports of deviations
- Minutes of meeting. Sepsis 1 – patient flow 11. April 2013
- Terms of reference, follow up of Sepsis 1 – 29. May 2013
- Minutes of meeting, Quality Commission UNN HF 3. June 2014
- Minutes of meeting, Quality Commission UNN HF 11. May 2016
- Plan for training for newly engaged health personnel in the units for acute somatic admissions and observations
- "Welcome to the physicians department, Clinic of medicine" (Valid from 9. December 2011)
- Check list newly engaged physicians (valid from 21. January 2013)
- Check list – joint plan for training for newly engaged employees in the units for acute somatic admissions and observations
- Agenda internal education internal medicine spring term 2016
- Agenda internal education internal medicine autumn term 2016

Documentation analysed during the inspection:

- Admission of adult patients with infection and suspected sepsis and serious sepsis/septic shock, common part (elaborated 8. February 2010)
- Admission of the patient with serious sepsis and septic shock (elaborated 11. January 2010)
- Admission of the patient with sepsis (SIRS score 2 or above and no symptoms of organic failure) (elaborated 4. March 2010)
- Placing [in bed wards] of patients with sepsis (elaborated 2. February 2010)
- Flow chart admission of adult patients with infection and suspected sepsis (19. February 2010)
- Sepsis-algorithm for physicians in in the unit for acute somatic admissions (valid from 28. October 2011)

Correspondence between the enterprise and the county governor:

- Notification of the inspection in letter dated 6. September 2016
- Documentation from the enterprise dated 22. September 2016
- Additional information/documentation from the enterprise in e-mail 31. October 2016, 4. November 2016 and 13. December 2016
- Agenda sent in letter dated 2. January 2017, revised 10. January 2017

9. Participants at the inspection

[In the original report participants are presented by name and position. Here only position is presented.]

In this table the participants from the enterprise and their type of participation is presented.

Function/position	*Opening meeting*	*Interview*	*Closing meeting*
Nurse, responsible for nuring development, unit for acute somatic admissions	x	x	x
Registrar, internal medicine	x	x	x
Specialist nurse, unit for acute somatic admissions		x	x
Nurse, unit for acute somatic admissions		x	x
Registrar, internal medicine	x	x	
Nurse, unit for acute somatic admissions	x	x	
Registrar, internal medicine		x	
Leading nurse, unit for acute somatic admissions	x	x	x
Consultant, infection medicine	x	x	
Consultant, unit for acute somatic admissions	x	x	x
Head of department, gastrology & nephrology	x	x	x
Director of clinic, medical clinic	x	x	x
Head of department & acting director of clinic (acutemedicine)	x	x	x
Deputy chief executive officer	x	x	x
Chief executive officer	x	x	
Director for quality and development	x		x
Deputy head of department, unit for acute somatic medicine			x

From the inspection authority these took part:

Chief county medical officer, lead auditor

Dep. chief county medical officer, auditor

Senior advisor, auditor

Advisor, auditor

Consultant (anaesthesiologist), medical auditor

Senior advisor, observer

Inspection findings

Reported in the table below are the main findings from the inspections at the three hospitals, a description of key measures implemented by the hospitals after the inspections, and the percentages before and after the inspection of patients with sepsis who had antibiotic administration within one hour. Time to antibiotics was an important performance measurement included in the inspections' review of electronic health records (EHR). A previous study from this project lists all indicators that were included in the EHR review.[1]

The data for the main findings are based on the focus group interviews and the publicly available inspection reports.

The data on the percentages of patients with antibiotic administration within one hour were collected by the inspection teams. Patients presenting to the emergency department with an International Classification of Diseases, 10th Revision (ICD-10) diagnostic code classifying sepsis or infection were identified through the Norwegian Patient Registry. The EHR and included patients with clinically suspected infection and two systemic inflammatory response syndrome signs (not including high leukocyte count) were included.[2] Patients were sampled from four time periods specific to each hospital: two before the inspection and two after. Records from the two pre-inspection time periods were reviewed during the inspection, and records from the post-inspection periods were reviewed at 8 and 14 months after the inspection, using records from the most recent patients. For each time period, 33 patients were sampled, though the number of patients included in the analyses in some cases ended up being slightly smaller due to duplicate records.

References

1. Husabø G, Nilsen RM, Flaatten H, et al. Early diagnosis of sepsis in emergency departments, time to treatment, and association with mortality: An observational study. PLoS One 2020;15(1):e0227652 doi: 10.1371/journal.pone.0227652.
2. Dellinger RP, Levy MM, Rhodes A, et al. Surviving Sepsis Campaign: international guidelines for management of severe sepsis and septic shock, 2012. Intensive Care Med 2013;39(2):165-228 doi: 10.1007/s00134-012-2769-8.

Supplementary table 1 Main findings from the inspections

Hospital	Population*	Main findings from the inspection	Follow-up by hospital	Percent of patients with antibiotic administration within one hour		
				Before insp.	After insp.	n
Hospital A	350 000	The inspection found that for a substantial proportion of patients, time from presentation to examination by physician and administration of antibiotics was delayed.	In response to the inspection, the hospital evaluated their procedures in inter-professional meetings and implemented changes in procedure and training initiatives.	22%	49%†	123
Hospital B	100 000	Some of the main findings from the inspection were delays in examination by physician and antibiotic administration. There were also inadequacies in documentation of responsibility and medical procedures. The emergency department in Hospital B had already started an improvement project for sepsis care prior to the inspection. The inspection nevertheless found deficiencies that the hospital had not been aware of.	The inspection led to a deepened commitment by the top-level management for the ongoing improvement project.	35%	59%†	122
Hospital C	50 000	The inspection found that for many patients, antibiotic treatment started too late. Furthermore, there were at times not enough available physicians to attend to patients in emergency department and not clear designation of responsibility for treatment between interns and resident physicians.	Following the inspection, the hospital started measuring indicators related to treatment in the emergency department, and clinicians and managers used these measurements for quality improvement purposes. In addition, there was a change in prehospital practice where more patients were administered antibiotics before being sent to the hospital.	18%	41%‡	77
Hospital D	300 000	The inspection found delays in antibiotic treatment and inadequate triage and observation of patients in emergency department.	After the inspection the hospital has implemented several initiatives, including training, revised procedures, and stand-up improvement board meetings.	15%	43%†	121
All hospitals§				25%	43%†	2869

* The hospitals are publicly owned and run institutions with responsibilities for specialized acute somatic care for all inhabitants in their local area. "Population" figures reported here are (rounded off and) based on information from the governments National plan for hospitals Meld. St. 11 (2015–2016).

† P-value < 0.01 (chi square test for difference between before and after inspection)

‡ P-value < 0.05 (chi square test for difference between before and after inspection)

§ All hospitals = all 24 hospitals included in the nation-wide inspection, including hospitals A - D.

Reporting checklist for qualitative study.

Based on the SRQR guidelines.

Instructions to authors

Complete this checklist by entering the page numbers from your manuscript where readers will find each of the items listed below.

Your article may not currently address all the items on the checklist. Please modify your text to include the missing information. If you are certain that an item does not apply, please write "n/a" and provide a short explanation.

Upload your completed checklist as an extra file when you submit to a journal.

In your methods section, say that you used the SRQRreporting guidelines, and cite them as:

O'Brien BC, Harris IB, Beckman TJ, Reed DA, Cook DA. Standards for reporting qualitative research: a synthesis of recommendations. Acad Med. 2014;89(9):1245-1251.

	Reporting Item	Page Number
Title		
#1	Concise description of the nature and topic of the study identifying the study as qualitative or indicating the approach (e.g. ethnography, grounded theory) or data collection methods (e.g. interview, focus group) is recommended	1

Abstract			
	#2	Summary of the key elements of the study using the abstract format of the intended publication; typically includes background, purpose, methods, results and conclusions	2
Introduction			
Problem formulation	#3	Description and signifcance of the problem / phenomenon studied: review of relevant theory and empirical work; problem statement	3
Purpose or research question	#4	Purpose of the study and specific objectives or questions	3-4
Methods			
Qualitative approach and research paradigm	#5	Qualitative approach (e.g. ethnography, grounded theory, case study, phenomenolgy, narrative research) and guiding theory if appropriate; identifying the research paradigm (e.g. postpositivist, constructivist / interpretivist) is also recommended; rationale. The rationale should briefly discuss the justification for choosing that theory, approach, method or technique rather than other options available; the assumptions and limitations implicit in those choices and how those choices influence study conclusions and transferability. As appropriate the rationale for several items might be	4

		discussed together.	
Researcher characteristics and reflexivity	#6	Researchers' characteristics that may influence the research, including personal attributes, qualifications / experience, relationship with participants, assumptions and / or presuppositions; potential or actual interaction between researchers' characteristics and the research questions, approach, methods, results and / or transferability	5
Context	#7	Setting / site and salient contextual factors; rationale	4-5/7
Sampling strategy	#8	How and why research participants, documents, or events were selected; criteria for deciding when no further sampling was necessary (e.g. sampling saturation); rationale	5
Ethical issues pertaining to human subjects	#9	Documentation of approval by an appropriate ethics review board and participant consent, or explanation for lack thereof; other confidentiality and data security issues	5
Data collection methods	#10	Types of data collected; details of data collection procedures including (as appropriate) start and stop dates of data collection and analysis, iterative process, triangulation of sources / methods, and modification of procedures in response to evolving study findings; rationale	4-5
Data collection	#11	Description of instruments (e.g. interview guides,	4-5

instruments and technologies		questionnaires) and devices (e.g. audio recorders) used for data collection; if / how the instruments(s) changed over the course of the study	
Units of study	#12	Number and relevant characteristics of participants, documents, or events included in the study; level of participation (could be reported in results)	5
Data processing	#13	Methods for processing data prior to and during analysis, including transcription, data entry, data management and security, verification of data integrity, data coding, and anonymisation / deidentification of excerpts	5
Data analysis	#14	Process by which inferences, themes, etc. were identified and developed, including the researchers involved in data analysis; usually references a specific paradigm or approach; rationale	6-7
Techniques to enhance trustworthiness	#15	Techniques to enhance trustworthiness and credibility of data analysis (e.g. member checking, audit trail, triangulation); rationale	6-7
Results/findings			
Syntheses and interpretation	#16	Main findings (e.g. interpretations, inferences, and themes); might include development of a theory or model, or integration with prior research or theory	7-10
Links to empirical data	#17	Evidence (e.g. quotes, field notes, text excerpts, photographs) to substantiate analytic findings	7-10

Discussion			
Intergration with prior work, implications, transferability and contribution(s) to the field	#18	Short summary of main findings; explanation of how findings and conclusions connect to, support, elaborate on, or challenge conclusions of earlier scholarship; discussion of scope of application / generalizability; identification of unique contributions(s) to scholarship in a discipline or field	10-12
Limitations	#19	Trustworthiness and limitations of findings	10-11
Other			
Conflicts of interest	#20	Potential sources of influence of perceived influence on study conduct and conclusions; how these were managed	13
Funding	#21	Sources of funding and other support; role of funders in data collection, interpretation and reporting	13

None The SRQR checklist is distributed with permission of Wolters Kluwer © 2014 by the Association of American Medical Colleges. This checklist can be completed online using https://www.goodreports.org/, a tool made by the EQUATOR Network in collaboration with Penelope.ai

BMJ Open

Promoting leadership and quality improvement through external inspections of management of sepsis in Norwegian hospitals: a focus group study

Journal:	*BMJ Open*
Manuscript ID	bmjopen-2020-041997.R2
Article Type:	Original research
Date Submitted by the Author:	20-Oct-2020
Complete List of Authors:	Husabø, Gunnar; Høgskulen på Vestlandet, Department of Social Science; Universitetet i Bergen, Department of Global Public Health and Primary Care Teig, Inger Lise; Universitetet i Bergen, Department of Global Public Health and Primary Care Frich, Jan; Universitetet i Oslo, Institute of Health and Society Bondevik, Gunnar; Universitetet i Bergen, Department of Global Public Health and Primary Care; NORCE Norwegian Research Centre AS Hovlid, Einar; Høgskulen på Vestlandet, Department of Social Science; Universitetet i Bergen, Department of Global Public Health and Primary Care
Primary Subject Heading:	Health services research
Secondary Subject Heading:	Emergency medicine, Health policy
Keywords:	Quality in health care < HEALTH SERVICES ADMINISTRATION & MANAGEMENT, Organisational development < HEALTH SERVICES ADMINISTRATION & MANAGEMENT, Clinical governance < HEALTH SERVICES ADMINISTRATION & MANAGEMENT

I, the Submitting Author has the right to grant and does grant on behalf of all authors of the Work (as defined in the below author licence), an exclusive licence and/or a non-exclusive licence for contributions from authors who are: i) UK Crown employees; ii) where BMJ has agreed a CC-BY licence shall apply, and/or iii) in accordance with the terms applicable for US Federal Government officers or employees acting as part of their official duties; on a worldwide, perpetual, irrevocable, royalty-free basis to BMJ Publishing Group Ltd ("BMJ") its licensees and where the relevant Journal is co-owned by BMJ to the co-owners of the Journal, to publish the Work in this journal and any other BMJ products and to exploit all rights, as set out in our licence.

The Submitting Author accepts and understands that any supply made under these terms is made by BMJ to the Submitting Author unless you are acting as an employee on behalf of your employer or a postgraduate student of an affiliated institution which is paying any applicable article publishing charge ("APC") for Open Access articles. Where the Submitting Author wishes to make the Work available on an Open Access basis (and intends to pay the relevant APC), the terms of reuse of such Open Access shall be governed by a Creative Commons licence – details of these licences and which Creative Commons licence will apply to this Work are set out in our licence referred to above.

Other than as permitted in any relevant BMJ Author's Self Archiving Policies, I confirm this Work has not been accepted for publication elsewhere, is not being considered for publication elsewhere and does not duplicate material already published. I confirm all authors consent to publication of this Work and authorise the granting of this licence.

Promoting leadership and quality improvement through external inspections of management of sepsis in Norwegian hospitals: a focus group study

Corresponding author
Gunnar Husabø: gunnar.husabo@hvl.no
tel +47 971 82 327

Authors
Gunnar Husabø: Department of Social Science, Western Norway University of Applied Sciences, Sogndal, Norway; Department of Global Public Health and Primary Care, University of Bergen, Bergen, Norway

Inger Lise Teig: Department of Global Public Health and Primary Care, University of Bergen, Bergen, Norway

Jan C. Frich: Institute of Health and Society, University of Oslo, Oslo, Norway

Gunnar Tschudi Bondevik: Department of Global Public Health and Primary Care, University of Bergen, Bergen, Norway; National Centre for Emergency Primary Health Care, NORCE Norwegian Research Centre, Bergen, Norway

Einar Hovlid: Department of Social Science, Western Norway University of Applied Sciences, Sogndal, Norway; Department of Global Public Health and Primary Care, University of Bergen, Bergen, Norway

Word count
5128

ABSTRACT

Objective Inspections and other forms of external assessment may contribute to positive changes in the health services, but the mechanisms of such change remains unclear. We did a study to explore how external inspections may foster clinical improvement in hospitals.

Design Focus group study.

Setting Statutory inspections of sepsis treatment in hospital emergency departments in Norway.

Participants Clinicians, managers, and inspection teams involved with the inspections of sepsis treatment in emergency departments at four different hospitals. Twelve focus groups interviews were carried out, with a total of 47 participants.

Results Three themes emerged as central for understanding how the inspections could contribute to clinical improvement in the emergency departments: 1) increasing awareness about the need to improve the quality of care by providing data on clinical performance, 2) building acceptance for improvement through professional credibility and focus on clinical practice, and 3) fostering leadership commitment.

Conclusions Our findings suggest that the inspections have the potential to enhance hospital management and staff's understanding of complicated care processes and help strengthen the organizational commitment to bring about systematic quality improvements.

STRENGTHS AND LIMITATIONS OF THIS STUDY

- Focus group interviews in hospitals that had achieved improvement in key clinical procedures following an inspection provided information-rich cases of how inspections can contribute to quality improvement.
- The interviews elicited new insights into how inspections can enhance understanding of the clinical system and promote leadership in quality improvement efforts.
- We did not explore change mechanisms related to anticipatory effects resulting from the announcement of upcoming inspections.
- The generalizability of our findings and interpretations are dependent on the organizational and procedural context in which inspections are being held.

INTRODUCTION

External inspection, also referred to as statutory supervision, is an external assessment strategy that is used to evaluate if healthcare providers meet accepted quality standards. Compared to other forms of external assessment, such as certification and accreditation, external inspections differ in that they are run by government bodies and subject to country-specific regulations.[1] While the subject and scope vary greatly from one inspection to another, most inspections have in common the goal of improving the quality of care provided by the organizations subject to the inspection.[2]

The rationale for why external assessment strategies could lead to improved quality, is that managers will review the results of assessments and implement changes that are necessary for better and safer healthcare.[1] Such effects might function through directive steps, in which the inspectors guide or force the health organization to act in a specific way. They can also be a result of 'softer' mechanisms, such as if inspections lead to a shift in focus and organizational objectives at the service provider.[3] In either case, the inspectors themselves cannot directly affect the quality of care being provided. As such, they must find ways to improve the quality of care through influencing the care processes and internal controls at the hospitals. External inspection can thus be seen as a way of boosting the internal quality and patient safety improvement work.[4]

Following the argument above, the effectiveness of inspections would likely depend on the degree to which they support organizational attributes and work processes associated with successful improvement. The literature describes readiness for change as a main dimension influencing the chance of success when implementing improvement efforts in healthcare organizations.[5] This view is rooted in a notion of organizations as communities that contribute to the amplification and development of knowledge, rather than merely entities of hierarchical information processing.[6]

Research has shown mixed effects of inspections on improvement in healthcare organizations. Some studies have found care practices to improve following inspections, but not been able to fully establish the association between the inspections and the improvements.[7, 8] Other studies have not found any improvements following inspections at all.[9, 10] Gaining a deeper insight into the mechanisms of change in connection with external inspections is needed in order to understand how and under what circumstances inspections might lead to substantial, long-lasting improvement.[11, 12]

Our overall aim was to study how external inspections may foster clinical improvement, using the case of a nationwide inspection of sepsis treatment in emergency departments at Norwegian hospitals. We sought to explore clinicians', managers', and inspection teams' experiences of being involved in the inspection process, and to explore their views on how inspections can affect the quality of care.

METHODS

Study design

The study is a part of an ongoing research on the impact of external inspection of sepsis diagnosis and treatment in emergency departments in Norwegian hospitals. The study protocol has been described previously.[13] The inspections were planned and directed by the Norwegian Board of Health Supervision (NBHS) at 24 hospitals with acute care functions.

For this study, we chose a qualitative approach, conducting focus group interviews with clinicians, managers, and inspectors. We found this to be a well suited method of inquiry, as the focus group

discussion can provide interpretive insights into the participants experiences and opinions.[14] Our approach is informed by a realist paradigm, its concept of causal mechanisms providing a framework for understanding the conditions under which inspections may foster clinical improvement. [15] The study follows Standards for Reporting Qualitative Research (SRQR) guidelines.[16]

The research project was reviewed and approved by the Regional Ethics Committee of Norway North (Identifier: 2015/2195) and the Norwegian Data Protection Authority (Identifier: 15/01559).

The sepsis inspections

In Norway, health services are publicly funded and based on the principle of universal and equitable access. They are mandated by legislation to be safe, effective, and provided in accordance with sound professional standards. NBHS is responsible for ensuring that health services meet these requirements. One of their main supervision approaches is nationwide thematic inspections of services, prioritized on the basis of information about risk and vulnerability. During these inspections, NBHS or the County Governors, who are local representatives of the central government, investigate services and report any identified nonconformities. While NBHS can impose its authority on healthcare organizations and individual healthcare workers through a wide range of responses and sanctions, the reactions issued after nationwide inspections are normally limited to instructing the organizations to correct the situation. The inspectors will then follow up the organization until the nonconformity is considered satisfactorily corrected.[17]

NBHS chose diagnosis and treatment of sepsis in hospital emergency departments as a subject of a thematic inspection starting in 2016 because patients presenting to emergency departments with sepsis often receive substandard care.[18] Delayed treatment is a major challenge, as time is of paramount importance in treatment of sepsis.[19, 20] Because early treatment depends on early diagnosis and recognition,[21, 22] the failures in expediting the treatment often come down to failures in recognizing the diagnosis at an early stage.[18]

There were six regional inspection teams. Each team included three to four inspectors from the County Governors with prior training and experience from either healthcare or law. Additionally, each team had an external medical specialist who had extensive clinical experience from working with sepsis diagnosis and treatment.

Methodologically, the inspections were system audits.[23] NBHS used existing guidelines and conferred with experts to formulate a set of quantitative criteria for recommended diagnosis and treatment of sepsis.[24, 25] At inspection, which typically lasted for two days, the team gathered data from the electronic health records of a set of 66 patients with sepsis and evaluated the care given against the criteria. As is customarily done in system audits, the inspection teams also reviewed documentation of relevant procedures and interviewed clinicians and managers responsible for the care of patients with sepsis. At the final day of inspection, the main findings were presented to the hospital management and staff in a closing meeting. Afterwards, the inspection team wrote up a report that included findings and a list of nonconformities. The report was sent as a draft to the hospital's executive management for comments and eventually finalized and released to the public via the Internet. A translated version of the report from one of the inspections is provided as supplementary file 1, and an overview of the findings from the four inspections included in this study is provided as supplementary file 2.

Participants and data collection

This study draws on data from twelve focus group interviews with clinicians, managers, and inspection teams involved in the inspection of four of the hospitals (designated A, B, C, and D). The interviews were conducted after the initial inspection, in the period from March 2017 to November 2018. Analyses that included all inspected hospitals found that, on average, the inspection had a positive effect on several care process measures.[26] We chose to include these four hospitals in the present study because they were among the hospitals that showed substantial improvements following the inspection. An overview of the improvements in a key indicator, time to antibiotic treatment, is provided in supplementary file 2.

We conducted separate focus group interviews with clinicians, managers, and the inspection teams at each hospital. The focus groups were sized from three to five participants and included in total 47 interviewees: 15 clinicians, 16 managers, and 16 inspection team members.

The groups of clinicians consisted of physicians and nurses who had diagnosis and treatment of sepsis patients in the emergency department as a part of their daily tasks. The managers were either head nurses at emergency departments, chief physicians, or heads of clinics. As such, the manager focus groups had a mix of interviewees in managerial roles and interviewees with combined responsibility for management and patient care. Clinicians and managers were recruited to the focus groups via contact persons with responsibility for quality management in the hospitals. We recruited all members currently on the inspection team who were available to attend the interview. As the members of the inspection teams changed over time, some inspection team interviewees had not participated in the inspections at the specific hospitals included in our study. The participants were informed beforehand about the purpose of the interviews and they signed a form agreeing to participate in the study. No compensation was given for participation in the study.

The interviews were conducted by GH (male, M.Sc.), except for two interviews that were conducted in collaboration with EH (male, M.D. /Ph.D.). GH had no previous affiliation with the NBHS but had experience from performance audit work in healthcare organizations. EH had a part-time position as a researcher in NBHS and had previously participated in NBHS inspections. He was acquainted with some of the interviewees from his work in NBHS.

For hospitals A, B, and C, the interviews with clinicians and managers were conducted at the respective hospitals. The interviews with the inspection teams were conducted at County Governors' offices. For hospital D, all interviews were conducted by conference call, due to vast travel distances and logistical challenges with convening the inspection team to a physical meeting. The interviewers and the participants were the only ones attending the interviews.

We used three different interview guides, one for each of the three types of groups. The interview guides focused on the impact of the inspections on the quality of care, and the interviews were centered on the experiences from the sepsis inspections (see Table 1). Additionally, time was devoted to discussing sepsis care in general and specific issues surrounding the organization of work in emergency departments.

Table 1 Interview topics

Topic	Probes (sample items)
General experience of the inspection process	
Relevance	• What was the focus of the inspection?

	• Are the themes covered in the inspection relevant for clinical practice?
Dialog between inspection team and hospital	• How were findings conveyed to the hospital? How did the management/staff react to the findings?
Process for following up	• What has the hospital done in response to the identified nonconformities? • Who were involved in following up the findings from the inspection?
The role of management	• What are important management tasks related to the inspection?
Contribution to change	• How did the inspection impact the internal quality improvement work? • What factors other than the inspection have had an impact on quality improvement work? • How is the quality of care now, compared with before the inspections?

The focus group interviews lasted from 35 to 105 minutes. After each session, field notes were recorded describing how the interview went and whether there were important contextual factors that should be taken into account in the analysis.

Transcription and analysis

Interviews were digitally recorded and subsequently transcribed and imported to NVivo qualitative data analysis software version 12 (QSR International Pty Ltd.). Participants did not receive copies of transcripts.

We analysed the data using a thematic analytic approach.[27] After the first interview, before analyzing the transcript, EH and GH introduced some preliminary codes (awareness of current and desired practice, leader commitment, use of performance metrics, communication and network, staff engagement, and systems thinking). Other codes were added throughout the interviews and the subsequent coding of the material.

Once GH had done the initial coding of the interview transcriptions, EH and GH identified potential themes from the data material. We grouped the codes we considered relevant for understanding the relationship between inspections and improvement work into these themes. Next, we analysed the interviews, first within each hospital, and then cross-case including all interviews, using the themes as an analytical framework.

As the focus groups were made up of three distinct roles, clinicians, managers, and inspection team, we took extra care to compare and contrast the analyses between these roles. The interviews with clinicians and managers were more specific to the inspection in their hospital, as compared to the interviews with the inspection teams, because the inspection teams could draw on experiences from all inspected hospitals in their region.

We read the transcripts and listened to the recorded interviews numerous times to ensure immersion, and we refined, synthesized, and reorganized the identified themes according to our developing understanding of the material. We also extracted quotations from the material to illustrate themes and analytical points.

GH translated the quotes into English, and the translations were checked by all co-authors.

Patient and public involvement

Patient organizations participated in a reference advisory group for the overall research program, which included this study. They were involved from the planning stage on, but they did not directly participate in developing or framing this specific article. We used their inputs to inform the overall study design. Patient organizations strongly advocated the importance of disseminating the study findings to relevant parties. NBHS has held a national, public conference for hospitals, government agencies, and patient representatives, where we presented preliminary study findings.

RESULTS

We identified three themes as central for understanding how the inspections could contribute to clinical improvement in the emergency departments: 1) increasing awareness about the need to improve the quality of care by providing data on clinical performance, 2) building acceptance for improvement through professional credibility and focus on clinical practice, and 3) fostering leadership commitment.

Increasing awareness about the need to improve the quality of care by providing data on clinical performance

According to the clinicians, managers, and inspection teams, the discrepancy between guidelines and clinical practice was in part caused by the heterogenous nature of the group of patients with sepsis and by how sepsis can manifest itself through various symptoms. They explained that deciding the course of the patient care is challenging, that the clinical processes of diagnosing and treating sepsis is complex, and that judgments often are being made under quite stressful conditions.

A point that was clearly made during the interviews was that the hospitals lacked systems to monitor the extent to which diagnosis and treatment complied with desired practice and procedures. Though data is entered into patients' electronic health records from the time the patients are admitted to the hospitals, the information is not structured in a way that is easily aggregated so that the hospital can track the performance statistically over time.

One of the members of the inspection team at Hospital C, who had long experience from leading system audits, told that this was the first time she had dared to state that an inspection had saved lives. She pointed to the systematic collection and analysis of patient data as the main reason for why the inspection had made a difference:

> I think what makes a difference, and impacts very strongly, is simply that we have measured, that we have systematised the findings from the electronic health records, [and] presented this using bar charts. The hospital employees were deeply affected by seeing these data. Across-the-board everyone thought they were very good and [in reality] no one were up to the mark.

Some clinicians found that, while they were not exceedingly surprised by the results, the data presented by the inspection team helped frame the challenges they experienced in their day-to-day activities. Describing how the efforts of improving the patient care had changed after the inspection, a clinician from Hospital A referred to how the attention to completing diagnostic procedures quickly increased after the inspection results were presented. It made them "see through other's eyes" what they already knew:

> After the inspection, and after [one of the managers] presented the findings in the auditorium, [the diagnostic work] got a lot more focused. It was nice because in a way… we saw through other´s eyes what we in reality knew, and then we focused on that work in a whole other way. So these patients have been given much better treatment after the inspection, compared to before.

Having performance data presented by the inspection team can help managers and clinicians re-evaluate their own experiences and assessment of clinical performance. The inspection team of hospital B described how their presentation of data in a closing meeting at one of the hospitals had encouraged the participants at the meeting to share and discuss recent experiences of challenges in the emergency department:

> We just displayed our own data, but [the managers and clinicians] brought it up on the agenda. And then someone just pointed out: "We heard that there was a surge of patients yesterday as well". We overheard that a discussion and a dynamic emerged that we could pitch into.

Building acceptance for improvement through professional credibility and focus on clinical practice

Professional credibility was a topic that was underscored by inspection teams, clinicians, and managers. The clinicians and managers expected the inspection teams to include professionals with medical background, and they expected the inspection team to have insight into the requirements and practices of acute functions in hospitals. A manager at hospital A argued that the inclusion of medical experts was important for the legitimacy of the findings from the inspections:

> It is crucial that there is someone [on the inspection team] who comes from clinical practice, and possibly also from clinical research, and sort of knows the details of the issues that they enquire into; and who also is going to have an understanding of what the management component of these issues might be. So I think this is crucial for the legitimacy of this inspection.

The inspection teams also shared this view, that the medical experts' knowledge of sepsis care and experience with the day-to-day operations of emergency departments enhanced the legitimacy of the inspections.

Clinicians and managers stressed the need for the inspection teams to have a clear understanding of the work processes in emergency departments. By focusing on how the different processes were interconnected, the inspections identified system-level weaknesses that could produce barriers to timely diagnosis and treatment. One of the managers from Hospital D pointed out that one of the strengths of the inspection had been how these findings were related to issues critical to patient care:

> The direct effect of the inspection is obvious. In this case one can relate it directly to the patient, even though much is related to systems and how systems are in place to take care of patients presenting with sepsis. But [the inspection] is very efficient, benefiting the patient directly.

A factor that both clinicians and managers pointed out across interviews, is that diagnosing and treating sepsis patients involve several different organizational subunits within the hospitals. As such, there are very real organizational hurdles that need to be overcome in order to achieve the desired improvement in clinical performance. The inspection teams' understanding of complicated care processes was especially important because it enabled them to direct the inspection on how different groups of clinicians worked together. This forced the different organizational subunits to take a more birds-eye view of the patient care processes as a whole. A manager from hospital B explained:

> I believe that it is positive that someone comes from the outside and then points out that you have to have these things up and running. Because […] the workday is so hectic that every department is preoccupied with themselves and their work […] And I think that [the inspection] is a good pry tool, because then we have to cooperate between departments. And you could say that as a hospital we should be able to do this of our own volition, but this has turned out to be difficult.

Fostering leadership commitment

Because of the challenges of making improvements across different subunits within the hospital, hospital management had an important role in the improvement efforts. In this context, leadership commitment refers to the whole chain of command from the executive director on top to the senior nurses in the emergency department.

Both clinicians, managers, and the inspection teams argued that without bringing the clinical managers and leaders on board and making sure that they were invested in this work, it would be exceedingly difficult to achieve successful improvement of the patient care. When discussing experiences with the improvement initiatives that started up after the inspections, a clinician at hospital D commented on the role of managers:

> Of course they nag a bit, but often because they want to get better. They are genuinely concerned with the medical issues, and that makes one want to join in.

Similarly, one of the clinicians at hospital C pointed out that it was important that clinical managers were genuinely interested in the improvement efforts:

> The clinical managers are actually interested in putting much effort into it, ensuring that one has resources, and that time is allocated to this. And in a way … they join in and look at the results of what is being presented. […] And this holds true both for nurses and for doctors; that one gets motivated to continue working [with improvements] and feel a bit acknowledged for the work one does.

An important function of the inspections was how they precipitated communication between different leadership levels on matters related to patient care. A clinician from hospital B described how the inspection report affected the hierarchy from clinic to department, and how this caused ripple effects throughout the organization:

> An inspection makes an impact on the management. The head of clinic just said: "This is not good, this is not good enough. Now; who takes care of what? Now we have to do something different." And the head of department joins in. The heads of departments talk together and

> in a way you get a whole organization joining … This is clearly an effect of the inspection; from the top management and downwards. It feels more momentous: Here we need to do something, to close the nonconformities, we need to … And this has yet more ripple effects. So in that sense, [the inspection] has major consequences, in my opinion.

Facilitating communication networks that also included the managerial level was reported to be an important part of achieving organizational commitment to the issues of the inspection. The inspection facilitated that a large group of decision makers came together to discuss issues related to patient care.

In the period following the initial report from the inspection, hospitals are expected to develop a response and action plan to the NBHS. Many interviewees explained that this was an occasion for mutual learning between different disciplines and different hierarchies of management. A manager from hospital A argued:

> Almost nothing happens one-to-one, right? It happens across supporting professions or laboratory professions and radiology and shift teams and positions. So to get some of this reciprocity in the learning process we have tried bringing together these groups and develop a common response [to the NBHS inspection report].

DISCUSSION

In this study, we set out to explore how inspections may foster clinical improvements in hospitals. The first theme we identified was related to how the inspections provided data on the quality of care for patients with sepsis. Our findings suggest that by providing these data, the inspection promoted increasing awareness of clinical performance.

Secondly, we found that there was a need for inspection teams to have a clear understanding of the clinical work and of work processes in the emergency department. Without such knowledge, the legitimacy of the inspection would suffer, and the inspection would be rendered ineffective as a tool for systematic improvements. By directing attention to the interdependencies of the care processes, the inspection could help the hospital to target their efforts on improving the clinical system as a whole.

Lastly, the hospital management seems to be the main conduit through which the inspection team can affect the hospital's work on improving a clinically complex task such as sepsis management. Not only do inspection teams engage managers directly; they also play a role in opening up channels of communication between clinical and top-level management and leadership. External inspections could therefore create arenas for discussion and interprofessional reflection between different levels of management on how the hospital as a whole could improve their services to the sepsis patients.

Strengths and limitations

The findings and interpretations of this study are intrinsically linked to the organizational and procedural context in which they are being held. Inspections are complex interventions. Reviewing their effects, we need explanatory analyses that bring to bear both theoretical and practical understanding of the intervention and the contexts within which it is being implemented.[28] The generalizability of the findings should be judged accordingly. We have purposively chosen to study the experiences of actors involved in presumptively successful inspections within a clinically

demanding field of patient care. If we had selected less successful cases or studied inspections of another type of theme, for instance administrative tasks, one could expect our findings to diverge substantially. It is also worth noting that the selection of successful inspections was based on disease-specific indicators. Therefore, we do not know whether the inspections had any significant effect on hospital-level performance.[29]

Our focus on change mechanisms related to improvements in quality of care also implies that we have not explored potential costs and adverse side-effects of the inspections. Inspections may impose compliance costs on regulated organizations, including costs related to handling requests for information, consulting the inspection team, and acting as guides on site-visits.[30] If the organization frequently receives inspections, inquiries, or instructions from different regulatory bodies, such costs might add up to a substantial strain, especially on the management and administrative staff. This study should therefore not be considered an exhaustive evaluation of the benefits and disadvantages of the sepsis inspections or inspections in general.

Furthermore, we do not argue that the aspects highlighted in this study are the only mechanisms that might be set in motion during an inspection process. One line of argument worth mentioning in this respect, is that the prospect of being inspected in itself can initiate improvement efforts.[3, 31] Though the search for such anticipatory effects is an important avenue of research, the focus of this study has been on how the findings and recommendations from the inspections, and the interaction with the inspection teams, might influence the hospitals' improvement efforts.

Interpretation in relation to previous studies

Our analyses echo previous research regarding how inspections with a patient-centered focus might promote awareness among clinicians and managers.[32] Furthermore, our analyses lend support to studies highlighting how using data in external assessments of quality of care can help hospitals track improvement.[33] Providing measurable data seems especially pertinent in the case of the sepsis inspections, as previous studies have shown the importance of performance metrics in fostering change in clinical behavior in care for patients with sepsis.[34]

Some authors have argued that if external assessment schemes lead to increased use of data, they do so primarily through a strengthening of the bureaucratic control in the organization.[35] We, however, found that the quality metrics were not considered as being solely within the purview of bureaucratic control; the professionals in the organization viewed the use of data as a necessity for improving quality.

Our analyses nonetheless show that clinical leads played a key role in any improvement effort. Making leaders commit to improving patient care was seen as a *sine qua non* for the inspections to succeed. While this supports an argument for seeing external assessments as a platform from which clinicians can negotiate with senior management,[36] we would add that inspections might empower leaders and managers as well as clinicians.[37] Some important ways in which leaders wield power within organizations are by calling on shared organizational values and by leveraging facts and reasoning.[38] Clinical leaders can facilitate change processes and organizational learning by providing front-line clinicians with an arena for sharing information and a context for reflecting on shared information.[39] The effectiveness of such leadership approaches can be bolstered by the inspections. The sepsis inspections highlighted patient safety, which is a laudable and legitimate shared value goal in the emergency departments, and they did so by providing tangible facts for the leaders to leverage vis-à-vis their subordinates and team members.

Recent research has found that educative approaches to regulation can succeed when regulators are able to leverage existing norms and accountability structures in the regulated community.[40] This seems to be the case for the sepsis inspection. They have resulted in an improved understanding of the inherent complexities in the care of sepsis patients, and the improved understanding brings forth organizational commitment and readiness for change, which are pivotal for improvement to take place. These processes also parallel findings from a study of professionals' motivation in hospital accreditation, which showed that external assessment opened up opportunities for collaborative learning and promoted understanding of the whole organization across organizational boundaries.[41] Similarly, the importance of the system perspective runs like a red thread through our interviews, both in terms of the inspection teams' competencies, and in terms of how clinicians and managers address quality challenges in their own organizations.

It should be noted that this argument presupposes the existence of norms and accountability structures in the inspected organization that can be harnessed for quality improvement. If the management and staff are not amenable to the inspection team's suggestions, the learning process will likely flounder. Whether the organization responds to the inspection with organizational commitment is not only dependent on which organization is being inspected but also on the theme of the inspection. The way the clinical, patient-centered focus provided a legitimization for the sepsis inspections, is a case in point.

Other contextual factors are also important. If the healthcare organization already performs at a high level, the inspection might not be able to contribute significantly to further improvement.[29] Furthermore, healthcare organizations often require financial resources to initiate improvement efforts, and in some cases they also need external improvement support.[3, 29] Consequently, our findings cannot be extrapolated as universally applicable for all types of inspections within all types of organizations.

Policy implications

Even if performance data is key, focusing exclusively on performance data and quantifiable targets might pose a risk by underestimating the measurement problems or risks of health organizations gaming the system.[42] There is a risk that externally imposed standards in external assessment schemes may end up being perceived as a 'tick-box' exercise for the clinicians involved.[43]

When assessing performance within a specific area of patient care, the inspection authorities should use indicators that carry a clinical relevance for those working in the inspected organizations. To achieve this, they need to operationalize clinical standards into indicators that are well-suited for identifying subpar services and sensitive for improvement. It is also necessary to combine the evaluation of the indicators with a thorough understanding of the clinical processes at work. The task of the inspectors is to review the numbers and bring to the table an assessment of why the hospital might fail to meet the standards. This might necessitate prioritizing regulatory resources so that external clinical experts are extensively involved both in the preparation stages, when relevant indicators are identified, and during the on-site inspections.

Organizations do of course review their own performance data and make efforts to improve without the help of external inspections. When it is feasible to make improvements through smaller adjustments, it is likely that the hospitals will do so. Addressing the underlying challenges inherent in tasks like sepsis diagnosis and treatment, on the other hand, entails both deeper analysis and more

profound systemic changes. Here, the clinical data and asessments provided by the inspection team can be of great value for the management and staff in their search for flexible solutions for quality improvement. Here, however, we also see the limits of this approach to inspections: For the inspection to succeed, the organization must have sufficient personnel and resources that can be mobilized for a sustained commitment to quality improvement.

Acknowledgement
We thank the focus group participants for devoting their time to this study. We also thank the patient organizations for their involvement in the research project, the inspection teams for participating in data collection, and the staff at the Norwegian Board of Health Supervision for developing the sepsis inspection. Professor Geir Sverre Braut translated the inspection report, for which we are most grateful.

Contributors
Gunnar Husabø
Conception and design, planning and conducting interviews, initial analysis, interpretation of findings, authoring original draft, making critical revisions, and approving the final version of the manuscript

Inger Lise Teig
Conception and design, interpretation of findings, making critical revisions and approving the final version of the manuscript

Jan C. Frich
Conception and design, interpretation of findings, making critical revisions and approving the final version of the manuscript

Gunnar Tschudi Bondevik
Conception and design, interpretation of findings, making critical revisions and approving the final version of the manuscript

Einar Hovlid
Conception and design, planning and conducting interviews, initial analysis, interpretation of findings, making critical revisions and approving the final version of the manuscript

Funding
This research received no specific grant from any funding agency in the public, commercial or not-for-profit sectors.

Competing interests
All authors have completed the ICMJE uniform disclosure form at www.icmje.org/coi_disclosure.pdf and declare: no support from any organisation for the submitted work; no financial relationships with any organisations that might have an interest in the submitted work in the previous three years; no other relationships or activities that could appear to have influenced the submitted work.

Data availability
This is a qualitative study and therefore the data generated is not suitable for sharing beyond that contained within the report. Further information can be obtained from the corresponding author.

References

1. Shaw CD, Groene O, Berger E. External institutional strategies: accreditation, certification, supervision. In: Busse R, Klazinga N, Panteli D, et al., eds. Improving healthcare quality in Europe, 2019:203-31.
2. Sutherland K, Leatherman S. *Regulation and quality improvement - A review of the evidence*. London: The Health Foundation, 2006.
3. Smithson R, Richardson E, Roberts J, et al. Impact of the Care Quality Commission on provider performance: Room for improvement?, 2018.
4. Schaefer C, Wiig S. Strategy and practise of external inspection in healthcare services – a Norwegian comparative case study. Safety in Health 2017;3(1):1-9 doi: 10.1186/s40886-017-0054-9.
5. Weiner BJ, Amick H, Lee SY. Conceptualization and measurement of organizational readiness for change: a review of the literature in health services research and other fields. Med Care Res Rev 2008;65(4):379-436 doi: 10.1177/1077558708317802.
6. Nonaka I. A Dynamic Theory of Organizational Knowledge Creation. Organization Science 1994;5(1):14-37.
7. Wesselink SFO, Lingsma HF, Erasmus V, et al. Does Government Supervision Improve Stop-Smoking Counseling in Midwifery Practices? Nicotine & Tobacco Research 2014;17(5):572-79 doi: 10.1093/ntr/ntu190.
8. Wesselink SFO, Lingsma HF, Ketelaars CA, et al. Effects of Government Supervision on Quality of Integrated Diabetes Care: A Cluster Randomized Controlled Trial. Med Care 2015;53(9):784-91 doi: 10.1097/Mlr.0000000000000399.
9. Castro-Avila A, Bloor K, Thompson C. The effect of external inspections on safety in acute hospitals in the National Health Service in England: A controlled interrupted time-series analysis. J Health Serv Res Policy 2019;24(3):182-90 doi: 10.1177/1355819619837288.
10. Allen T, Walshe K, Proudlove N, et al. Measurement and improvement of emergency department performance through inspection and rating: an observational study of emergency departments in acute hospitals in England. Emerg Med J 2019;36(6):326 doi: 10.1136/emermed-2018-207941.
11. Flodgren G, Goncalves-Bradley DC, Pomey MP. External inspection of compliance with standards for improved healthcare outcomes. Cochrane Database Syst Rev 2016;12:Cd008992 doi: 10.1002/14651858.CD008992.pub3.

12. Hovlid E, Braut GS, Hannisdal E, et al. Mediators of change in healthcare organisations subject to external assessment: a systematic review with narrative synthesis. BMJ Open 2020 doi: 10.1136/bmjopen-2020-038850.
13. Hovlid E, Frich JC, Walshe K, et al. Effects of external inspection on sepsis detection and treatment: a study protocol for a quasiexperimental study with a stepped-wedge design. BMJ Open 2017;7(9):e016213 doi: 10.1136/bmjopen-2017-016213.
14. Morgan DL. *The Focus Group Guidebook*. Thousand Oaks, CA: SAGE Publications, 1997.
15. Sayer A. *Realism and Social Science*. Thousand Oaks: Sage, 2000.
16. O'Brien BC, Harris IB, Beckman TJ, et al. Standards for Reporting Qualitative Research: A Synthesis of Recommendations. Acad Med 2014;89(9):1245-51 doi: 10.1097/acm.0000000000000388.
17. Norwegian Board of Health Supervision. Introduction to the supervisory authorities and the supervision of child welfare services, social services and health and care services in Norway 2019. https://www.helsetilsynet.no/en/introduction-to-the-supervisory-authorities-and-the-supervision-of-child-welfare-services-social-services-and-health-and-care-services-in-norway.
18. Goodwin A, Srivastava V, Shotton H, et al. Just say sepsis. A review of the process of care received by patients with sepsis London: National Confidential Enquiry into Patient Outcome and Death 2015.
19. Rhodes A, Evans LE, Alhazzani W, et al. Surviving Sepsis Campaign: International Guidelines for Management of Sepsis and Septic Shock: 2016. Intensive Care Med 2017;43(3):304-77 doi: 10.1007/s00134-017-4683-6.
20. Plata-Menchaca EP, Ferrer R, Ruiz Rodríguez JC, et al. Antibiotic treatment in patients with sepsis: a narrative review. Hosp Pract 2020:1-11 doi: 10.1080/21548331.2020.1791541.
21. Gatewood MOK, Wemple M, Greco S, et al. A quality improvement project to improve early sepsis care in the emergency department. BMJ Qual Saf 2015;24(12):787-95 doi: 10.1136/bmjqs-2014-003552.
22. Husabø G, Nilsen RM, Flaatten H, et al. Early diagnosis of sepsis in emergency departments, time to treatment, and association with mortality: An observational study. PLoS One 2020;15(1):e0227652 doi: 10.1371/journal.pone.0227652.
23. ISO. ISO/IEC TS 17022:2012. Conformity Assessment -- Requirements and Recommendations for Content of a Third-Party Audit Report on Management Systems. Geneva: International Organization for Standardization, 2012.
24. National Institute for Health and Care Excellence. Sepsis. Quality standard QS161, 2017.

25. Dellinger RP, Levy MM, Rhodes A, et al. Surviving Sepsis Campaign: international guidelines for management of severe sepsis and septic shock, 2012. Intensive Care Med 2013;39(2):165-228 doi: 10.1007/s00134-012-2769-8.
26. Husabø G, Nilsen RM, Solligård E, et al. Effects of external inspections on sepsis detection and treatment: a stepped-wedge study with cluster-level randomization. Forthcoming. BMJ Open 2020.
27. Braun V, Clarke V. Using thematic analysis in psychology. Qual Res Psychol 2006;3(2):77-101 doi: 10.1191/1478088706qp063oa.
28. Pawson R, Greenhalgh T, Harvey G, et al. Realist review - a new method of systematic review designed for complex policy interventions. J Health Serv Res Policy 2005;10(Suppl 1):21-34 doi: 10.1258/1355819054308530.
29. Castro AC. Evaluating the effect of external inspections of the Care Quality Commission of acute NHS hospitals in England. University of York, 2018.
30. Hood C, Scott C, James O, et al. *Regulation inside government: waste watchers, quality police, and sleaze-busters*. Oxford: Oxford University Press, 1999.
31. Walshe K, Phipps D. Developing a strategic framework to guide the Care Quality Commission's programme of evaluation. London: CQC 2013.
32. Åsprang AF, Frich JC, Braut GS. Organizational impact of governmental audit of blood transfusion services in Norway: A qualitative study. Transfus Apher Sci 2015;53(2):228-32 doi: 10.1016/j.transci.2015.04.015.
33. El-Jardali F, Jamal D, Dimassi H, et al. The impact of hospital accreditation on quality of care: perception of Lebanese nurses. Int J Qual Health Care 2008;20(5):363-71 doi: 10.1093/intqhc/mzn023.
34. Levy MM, Rhodes A, Phillips GS, et al. Surviving Sepsis Campaign: association between performance metrics and outcomes in a 7.5-year study. Crit Care Med 2015;43(1):3-12 doi: 10.1097/ccm.0000000000000723.
35. Paccioni A, Sicotte C, Champagne F. Accreditation: a cultural control strategy. Int J Health Care Qual Assur 2008;21(2):146-58 doi: 10.1108/09526860810859012.
36. Baskind R, Kordowicz M, Chaplin R. How does an accreditation programme drive improvement on acute inpatient mental health wards? An exploration of members' views. J Ment Health 2010;19(5):405-11 doi: 10.3109/09638230903531118.
37. Walshe K. *Regulating Healthcare: A Prescription for Improvement?* Berkshire: McGrawHill Education, 2003.
38. Van Wart M, Suino P. *Leadership in public organizations : an introduction*. 2nd ed. ed. Armonk, N.Y.,London: M.E. Sharpe, 2012.

39. Hovlid E, Bukve O, Haug K, et al. Sustainability of healthcare improvement: what can we learn from learning theory? BMC Health Serv Res 2012;12(1):235 doi: 10.1186/1472-6963-12-235.

40. van Erp J, Wallenburg I, Bal R. Performance regulation in a networked healthcare system: From cosmetic to institutionalized compliance. Public Administration 2020;98(1):46-61 doi: 10.1111/padm.12518.

41. Greenfield D, Pawsey M, Braithwaite J. What motivates professionals to engage in the accreditation of healthcare organizations? Int J Qual Health Care 2011;23(1):8-14 doi: 10.1093/intqhc/mzq069.

42. Bevan G, Hood C. What's Measured Is What Matters: Targets and Gaming in the English Public Health Care System. Public Administration 2006;84(3):517-38 doi: 10.1111/j.1467-9299.2006.00600.x.

43. Campbell SM, Chauhan U, Lester H. Primary Medical Care Provider Accreditation (PMCPA): pilot evaluation. Br J Gen Pract 2010;60(576):295-304 doi: 10.3399/bjgp10X514800.

The county governor of Troms

Report from inspection of sepsis treatment

in the emergency department at

University Hospital of Northern Norway, Tromsø

UNOFFICIAL TRANSLATION[1]

Address of the enterprise: 9030 Tromsø

Time span for the inspection: 6. September 2016 – 9. March 2017

Summary

Norwegian Board of Health Supervision (NBHS) has decided that in the period 2016-2017, there will be performed nationwide inspections of the hospitals' emergency departments and their work with recognition and treatment of patients with sepsis.

The county governor of Troms has performed a inspection designed as a system audit at the University Hospital of Northern Norway, Tromsø. This report describes the nonconformities identified within the audited areas. The system audit comprised the following themes:

Identification and initiation of treatment in the emergency department of patients with sepsis or suspected sepsis.

During the inspection we would investigate if the hospital ensures:

- adequate admission, registration and prioritisation (triage) of patients with sepsis or suspected sepsis at the time of admission to the emergency department
- adequate assessment and diagnosis of the patients during their stay in the emergency department
- adequate initiation of treatment of the patients in the emergency department
- adequate observation of the patients in the emergency department
- adequate preparation and discharge of the patients to other departments, supplemented by ordinations/plans for further observation and treatment

The inspection team has 66 health records of patients presenting to the emergency department with sepsis or suspected sepsis.

[1] This report is an unofficial translation of the original report from Norwegian Board of Health Supervision. The original report, along with the reports from the other sepsis inspections, is available on the NBHS website: https://www.helsetilsynet.no/tilsyn/tilsynsrapporter/?w=2016+Sepsis+i+somatiske+akuttmottak

At the inspection, three nonconformities were identified:

Nonconformity 1:

The majority of the patients with sepsis did not receive treatment with antibiotics within the time limits prescribed in nationwide guidelines and in the hospital's own goal statements. Patients with severe sepsis who had to wait more than one hour, did not receive adequate treatment.

Nonconformity 2:

The management has not ensured that there is sufficient medical competence available in the emergency department so that assessments and initiation of treatment of patients with sepsis can be performed within the time limits prescribed in nationwide guidelines and in the hospital's own goal statements.

Nonconformity 3:

The hospital management has been aware that patients with sepsis receive delayed treatment with antibiotics in the emergency department but has not implemented sufficient corrective actions.

Date: 9. March 2017

xxxxx
Lead Auditor

yyyyy
Auditor

1. Introduction

This report is written after a system audit at University Hospital of Northern Norway, Tromsø in the period 6. September 2016 – 9. March 2017. It is a part of a nationwide inspection performed in 2016-2017, and one of the planned inspections to be performed by the County governor of Troms this year. The county governors of Finnmark, Troms and Nordland have appointed a joint inspection team to perform the inspections in these counties.

The county governor is through section 2 of the act on governmental supervision of the health and care services given authority to perform inspections with the provision of health and care services.

The aim of a system audit is to evaluate if the enterprise by means of internal control meets the legal requirements. The audit encompassed the following themes:

- which actions were taken by the enterprise to disclose, correct and prevent infringement of the legal requirements relevant for the analysed issues
- if the prescribed actions were performed in practice and, if necessary, corrected
- if the prescribed actions are sufficient to ensure adherence to the legal requirements

A system audit is performed by analysis of documents, through interviews and by other investigations.

This report deals with the nonconformities identified at the system audit, and thus does not present a complete evaluation of the work of the enterprise relevant for the themes covered by the inspection.

- **Nonconformity** is lack of fulfilment of requirements given by or on basis of acts and regulations

The background for the decision to perform inspection of the sepsis treatment, is, i.a. that NBHS has received several reports according to the requirement [on reporting adverse events] in section 3-3 of the act on specialised health care about serious infections and sepsis, where detection of infection has been too late, and where there has been delayed initiation of treatment with antibiotics.

NBHS has established a research project to gain knowledge on how planned inspection can contribute to improving quality on health services. Data collected from patient files in this inspection will be used to evaluate the effect of inspection on the quality of the service. As part of the inspection and this project, we will perform sampling from relevant health records in 8 months and 14 months from now.

2. Description of the enterprise – particular conditions

The University Hospital of Northern Norway (UNN HF) serves a population of about 190.000 inhabitants and consists of three hospitals, respectively in Tromsø, Harstad and Narvik, in addition to Longyearbyen hospital on Svalbard. The main administrative centre of the hospital is located to Tromsø, and is led by the chief executive director.

The health enterprise is divided into nine clinics, among them the *clinic for acute medicine* and the *clinic for medicine*. Each clinic is led by a director who reports to the chief executive director.

The emergency department at UNN HF Tromsø is a department in the clinic for acute medicine. Head of department reports to the director of the clinic. Head of department is at the moment also acting director of clinic for the clinic for acute medicine. Head of the unit for acute somatic admissions is responsible for the nursing services in this unit and reports to the head of the department. There is a medical consultant, 60% of a full position, adhered to the unit for acute somatic admissions as a medical advisor.

The medical on-duty teams consist of an intern, first line and second line registrars, first line registrar for heart and pulmonary diseases and subspecialised consultants in the different parts of internal medicine. The first line registrar is available 24hrs, the second line registrar is available 8hrs-22hrs on week days and 9hrs-15hrs in the weekends. The intern is not available at night time. The intern shall confer with the second line registrar (or first line registrar) related to all investigated patients.

The physicians working in the unit for acute somatic admissions are employed at different parts of the clinic for medicine or the clinic for heart and lung diseases. All physicians in first line or second line duty are undergoing training as a specialist. Head of department/chief consultant of the department of gastrology and nephrology is responsible for planning the on duty scheme and for arranging regular meetings with the physicians on both levels.

RETTS (Rapid Emergency Triage and Treatment System) is used in the unit for acute somatic admissions. According to activity under algorithm 47 treatment with antibiotics shall be initiated within 1 hour after arrival of the patient.

3. Execution

The system audit consisted of the following activities:

Notice/information regarding the inspection was sent 6. September 2016.

Overview over documents presented by the enterprise is to be found in the chapter on Documents.

Analysis of patient files were performed 7. November 2016 and 5. January 2017.

Opening meeting was arranged 25. January 2017.

Interviews

15 persons were interviewed.

On site visit in the unit for acute somatic admissions was performed 25. January 2017.

Closing meeting was arranged 26. January 2017.

4. What the inspection comprised

In the inspection, we have investigated if the health enterprise governs and controls that patients admitted with sepsis or suspected sepsis are identified and treated according to the requirements laid down in the legislation related to health care.

The inspection was limited to the unit for acute somatic admissions, and activities that are planned and ordered from the unit for acute somatic admissions.

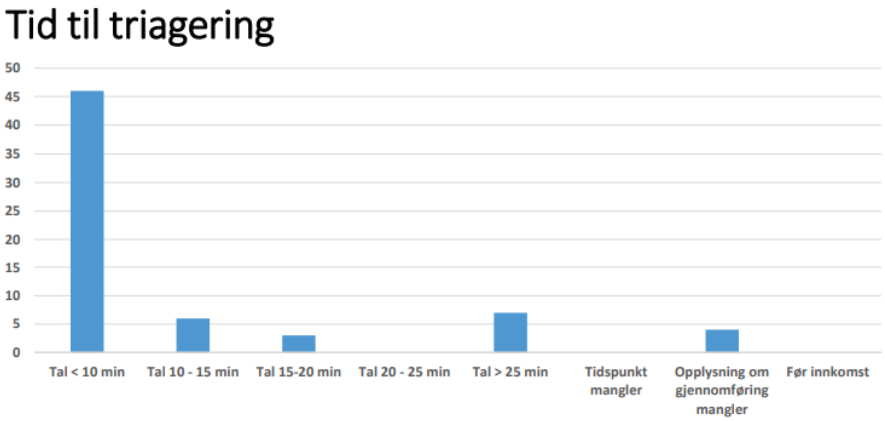
In particular we investigated if the University Hospital of Northern Norway had:

- prudent admission, registration and prioritisation (triage) of patients with sepsis or suspected sepsis at the time of admission to the emergency department
- prudent investigation and diagnosis of the patients during their stay in the emergency department
- prudent initiation of treatment of the patients in the emergency department
- prudent observation of the patients in the emergency department
- prudent preparation and transferral of the patients to other departments, supplemented by ordinations/plans for further observation and treatment

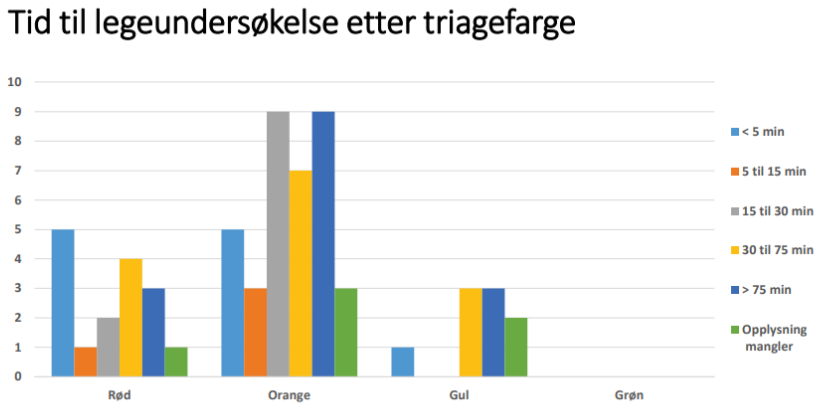
5. Findings

The inspection team has analysed patient files from patients admitted to the unit for acute somatic admissions with sepsis or suspected sepsis. The 66 patients included had an infection and fulfilled at least two of four SIRS-criteria. 33 patient files were from 1. October 2015 and immediately before (called P0), and 33 from 1. December 2016 and immediately before (called P1).

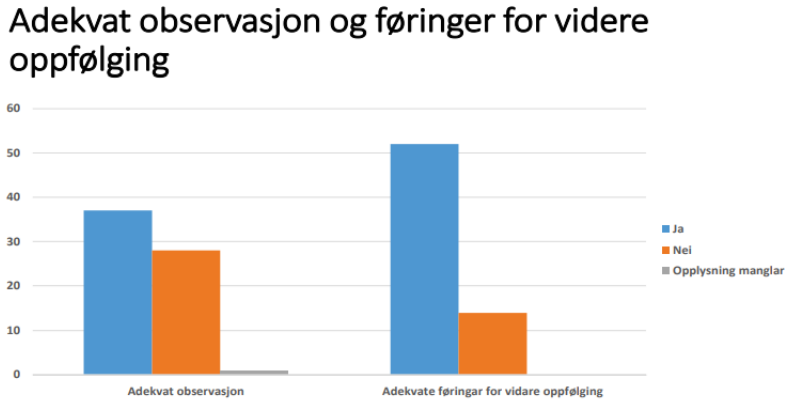
In the graphics below P0 and P1 are combined. The analysis showed:



(Time till triage, in minutes)



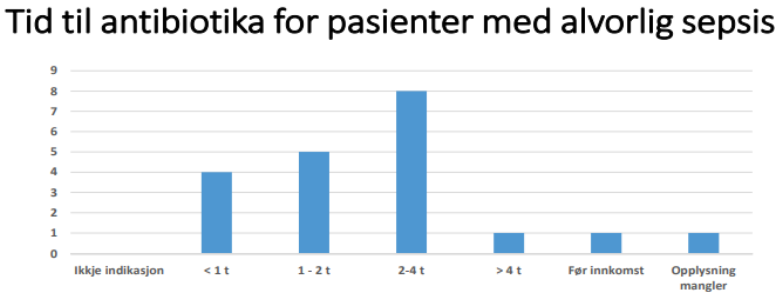
(Time until investigation by physician in minutes, according to triage colour)



(Adequate observation and instructions for further treatment, Yes (ja), No (nei), Lacking information (grey))

(Time till treatment with antibiotics in hours, all patients.

No indication, < 1 hr ….. > 4 hrs, Before admission, Lacking information)



(Time till treatment with antibiotics in hours, patients with severe sepsis.

No indication, < 1 hr ….. > 4 hrs, Before admission, Lacking information)

Three nonconformities were indicated.

Nonconformity 1:

The majority of the patients with sepsis did not receive treatment with antibiotics within the time limits prescribed in nationwide guidelines and in the hospital's own goal statements. Patients with severe sepsis who had to wait more than one hour, did not receive adequate treatment.

This is a deviation from the requirement in section 2-2 of the act on specialised health care and sections 6 to 9 in the regulation on governance and quality improvement in the health and care services.

Justification of this claim:

- The analysis of 66 patient files shoved that:
  - 9 of 16 patients with triage colour red were investigated by a physician more than 15 minutes after admission to the hospital
  - 24 of 49 patients with sepsis got their first treatment with antibiotics more than two hours after admission to the hospital
  - 9 of 18 patients with severe sepsis had to wait over two hours before treatment with antibiotics was initiated, 14 of 18 had to wait over one hour. One patient waited more than four hours
- None of the directors of the clinics (clinic for medicine and clinic for acute medicine) have determined specific routines or practice for treatment of sepsis in the unit for acute somatic admissions. Instead, there are several different, older versions of written procedures in Docmap. These are not known for the health personnel, and their status remains unclear. There is also a non-dated flow chart with unclear status. This is presented as wall charts in the unit for acute somatic admissions.
- The health personnel is unsure about which procedures that are currently valid and they have different opinions about if and when treatment with antibiotics shall be initiated.
- Inexperienced physicians use much time for investigating the patients and decide upon treatment with antibiotics. Front line physicians do not always get a go-signal to initiate treatment when searching for support on decisions, even when related to patients with sepsis that according to national guidelines should get treatment.
- The management of the hospital and the directors of the clinics (clinic for medicine and clinic for acute medicine) do not follow up if the hospital achieves the goal specifying that patients with sepsis should get treatment with antibiotics within one hour.
- Conflicts of simultaneity and problems with vacant beds in the unit for acute somatic admissions arise several times every week and this is leading to delayed initiation of treatment with antibiotics.
- Observation of vital parameters of patients with sepsis are not always documented after triage when the patient still is in the unit for acute somatic admissions.
- Physicians and nurses work to a low degree in teams related to the sepsis patients.
- The bed wards often have low capacity and need a long time before being able to accept new patients, and the intensive care unit for internal medicine is often full. This leads to congestion in the unit for acute somatic admissions of patients that are ready for transferral to a bed ward. The capacity of rooms thus is reduced, and leads to new patients with sepsis not always are investigated by a physician when the physician is available. This in turn leads to delayed initiation of treatment with antibiotics.
- The day of the on-site visit we were informed that a patient with severe sepsis had to wait three hours before initiation of treatment with antibiotics, and had to wait more than nine hours before transferral to a bed ward.

Nonconformity 2:

The management has not ensured that there is sufficient medical competence available in the emergency department so that assessments and initiation of treatment of patients with sepsis can be performed within the time limits prescribed in nationwide guidelines and in the hospital's own goal statements.

This is a deviation from sections 6 to 9 in the regulation on governance and quality improvement in the health and care services.

Justification of this claim:

- It is not planned for the physicians in the unit for acute somatic admissions to investigate and treat all patients in accordance with the national guidelines and the hospital's own goals, cfr. nonconformity 1.
- Interns in some occasions are left alone with a higher degree of responsibility than planned due to first line registrars are occupied with telephone calls from physicians outside the hospital and for distributing patients from the unit for acute somatic admissions to the bed wards of the hospital. The second line registrar often is occupied at the observation unit.
- Training of subordinate physicians in treatment of sepsis is failing, and characterised of lacking procedures for this activity.

Nonconformity 3:

The hospital management has been aware that patients with sepsis receive delayed treatment with antibiotics in the emergency department but has not implemented sufficient corrective actions.

This is a deviation from sections 8 and 9 in the regulation on governance and quality improvement in the health and care services.

Justification of this claim:

- Statistics and other instruments are scarcely used to follow up results and objectives.
- The management demands few data on results from the unit of acute somatic admissions, e.g. on waiting time for investigation by a physician and time till initiation of treatment with antibiotics.
- The health personnel has reported nonconformities related to delayed treatment of sepsis in the unit for acute somatic admissions but sufficient actions have not been taken.
- The chief executive officer as well as the directors of the clinics have been aware of the long waiting times for the patients in the unit for acute somatic admissions.
- It remains unclear who is responsible for developing av implementation of joint procedures for nurses and physicians in the unit for acute somatic admissions. The management scarcely has an overview of which procedures that are currently valid.

6. Evaluation of the system of governance of the enterprise

The management scarcely has an overview of which goals that are established for the treatment of sepsis in the unit for acute somatic admissions and if these goals are achieved. It remains unclear who is responsible for ensuring unambiguous procedures for treatment of sepsis unit for acute somatic admissions that is known for everyone. It is known for the management that patients risk to be waiting in the unit for acute somatic admissions to be transferred to a bed ward, but efficient actions have not been taken. The health enterprise thus has not arranged for the health personnel enabling them to take care of their duties in a way that ensures that patients with sepsis at the unit for acute somatic admissions are treated according to national guidelines and the hospital's own goals.

7. Legislation

- Act of 2. July 1999 no. 61 relating to specialised health care.
- Act of 2. July 1999 no. 64 relating to health personnel.
- Regulation of 21. December 2000 no. 1385 relating to patient files.
- Regulation of 28.October 2016 no 1250 relating to on governance and quality improvement in the health and care services.

8. Documentation

Documentation from the enterprise related to management of the services, provided by the enterprise during the preparation of the audit:

- Information in letter from the head of the unit dated 22. September 2016
- Organisational mapping for the health enterprise and the unit for acute somatic admissions
- Overview of physicians taking part in the on-duty scheme in the unit for acute somatic admissions
- Overview of first line and second line registrars, with information on length of service
- Overview of anaesthesiologists
- Overview of nurses in the unit for acute somatic admissions
- Overview of nurses functioning as coordinators in the unit for acute somatic admissions
- Work tasks for coordinator at the unit for acute somatic admissions in Tromsø
- Work tasks for responsible for the waiting room in Tromsø
- Work tasks for the triaging nurse at the unit for acute somatic admissions in Tromsø
- On-duty-order intern (FB1485)
- On-duty-order first line registrar (FB1484)
- On-duty-order second line registrar (FB1483)
- Admission of patients from the ambulance service.
- Algorithm 47 from the RETTS-manual
- Blood sampling routine sepsis

- Joint patient file for acute admissions UNN HF
- Flow chart treatment and monitoring at intermediary and/or intensive care units
- Transferral of patients with internal medical conditions from the unit for acute somatic admissions when lacking places at medical bed wards
- Procedure for handling of deviations UNN
- Copy of reports of deviations
- Minutes of meeting. Sepsis 1 – patient flow 11. April 2013
- Terms of reference, follow up of Sepsis 1 – 29. May 2013
- Minutes of meeting, Quality Commission UNN HF 3. June 2014
- Minutes of meeting, Quality Commission UNN HF 11. May 2016
- Plan for training for newly engaged health personnel in the units for acute somatic admissions and observations
- "Welcome to the physicians department, Clinic of medicine" (Valid from 9. December 2011)
- Check list newly engaged physicians (valid from 21. January 2013)
- Check list – joint plan for training for newly engaged employees in the units for acute somatic admissions and observations
- Agenda internal education internal medicine spring term 2016
- Agenda internal education internal medicine autumn term 2016

Documentation analysed during the inspection:

- Admission of adult patients with infection and suspected sepsis and serious sepsis/septic shock, common part (elaborated 8. February 2010)
- Admission of the patient with serious sepsis and septic shock (elaborated 11. January 2010)
- Admission of the patient with sepsis (SIRS score 2 or above and no symptoms of organic failure) (elaborated 4. March 2010)
- Placing [in bed wards] of patients with sepsis (elaborated 2. February 2010)
- Flow chart admission of adult patients with infection and suspected sepsis (19. February 2010)
- Sepsis-algorithm for physicians in in the unit for acute somatic admissions (valid from 28. October 2011)

Correspondence between the enterprise and the county governor:

- Notification of the inspection in letter dated 6. September 2016
- Documentation from the enterprise dated 22. September 2016
- Additional information/documentation from the enterprise in e-mail 31. October 2016, 4. November 2016 and 13. December 2016
- Agenda sent in letter dated 2. January 2017, revised 10. January 2017

9. Participants at the inspection

[In the original report participants are presented by name and position. Here only position is presented.]

In this table the participants from the enterprise and their type of participation is presented.

Function/position	*Opening meeting*	*Interview*	*Closing meeting*
Nurse, responsible for nuring development, unit for acute somatic admissions	x	x	x
Registrar, internal medicine	x	x	x
Specialist nurse, unit for acute somatic admissions		x	x
Nurse, unit for acute somatic admissions		x	x
Registrar, internal medicine	x	x	
Nurse, unit for acute somatic admissions	x	x	
Registrar, internal medicine		x	
Leading nurse, unit for acute somatic admissions	x	x	x
Consultant, infection medicine	x	x	
Consultant, unit for acute somatic admissions	x	x	x
Head of department, gastrology & nephrology	x	x	x
Director of clinic, medical clinic	x	x	x
Head of department & acting director of clinic (acutemedicine)	x	x	x
Deputy chief executive officer	x	x	x
Chief executive officer	x	x	
Director for quality and development	x		x
Deputy head of department, unit for acute somatic medicine			x

From the inspection authority these took part:

Chief county medical officer, lead auditor

Dep. chief county medical officer, auditor

Senior advisor, auditor

Advisor, auditor

Consultant (anaesthesiologist), medical auditor

Senior advisor, observer

Inspection findings

Reported in the table below are the main findings from the inspections at the three hospitals, a description of key measures implemented by the hospitals after the inspections, and the percentages before and after the inspection of patients with sepsis who had antibiotic administration within one hour. Time to antibiotics was an important performance measurement included in the inspections' review of electronic health records (EHR). A previous study from this project lists all indicators that were included in the EHR review.[1]

The data for the main findings are based on the focus group interviews and the publicly available inspection reports.

The data on the percentages of patients with antibiotic administration within one hour were collected by the inspection teams. Patients presenting to the emergency department with an International Classification of Diseases, 10th Revision (ICD-10) diagnostic code classifying sepsis or infection were identified through the Norwegian Patient Registry. The EHR and included patients with clinically suspected infection and two systemic inflammatory response syndrome signs (not including high leukocyte count) were included.[2] Patients were sampled from four time periods specific to each hospital: two before the inspection and two after. Records from the two pre-inspection time periods were reviewed during the inspection, and records from the post-inspection periods were reviewed at 8 and 14 months after the inspection, using records from the most recent patients. For each time period, 33 patients were sampled, though the number of patients included in the analyses in some cases ended up being slightly smaller due to duplicate records.

References

1. Husabø G, Nilsen RM, Flaatten H, et al. Early diagnosis of sepsis in emergency departments, time to treatment, and association with mortality: An observational study. PLoS One 2020;15(1):e0227652 doi: 10.1371/journal.pone.0227652.
2. Dellinger RP, Levy MM, Rhodes A, et al. Surviving Sepsis Campaign: international guidelines for management of severe sepsis and septic shock, 2012. Intensive Care Med 2013;39(2):165-228 doi: 10.1007/s00134-012-2769-8.

Supplementary table 1 Main findings from the inspections

Hospital	Population*	Main findings from the inspection	Follow-up by hospital	Percent of patients with antibiotic administration within one hour		
				Before insp.	After insp.	n
Hospital A	350 000	The inspection found that for a substantial proportion of patients, time from presentation to examination by physician and administration of antibiotics was delayed.	In response to the inspection, the hospital evaluated their procedures in inter-professional meetings and implemented changes in procedure and training initiatives.	22%	49%†	123
Hospital B	100 000	Some of the main findings from the inspection were delays in examination by physician and antibiotic administration. There were also inadequacies in documentation of responsibility and medical procedures. The emergency department in Hospital B had already started an improvement project for sepsis care prior to the inspection. The inspection nevertheless found deficiencies that the hospital had not been aware of.	The inspection led to a deepened commitment by the top-level management for the ongoing improvement project.	35%	59%†	122
Hospital C	50 000	The inspection found that for many patients, antibiotic treatment started too late. Furthermore, there were at times not enough available physicians to attend to patients in emergency department and not clear designation of responsibility for treatment between interns and resident physicians.	Following the inspection, the hospital started measuring indicators related to treatment in the emergency department, and clinicians and managers used these measurements for quality improvement purposes. In addition, there was a change in prehospital practice where more patients were administered antibiotics before being sent to the hospital.	18%	41%‡	77
Hospital D	300 000	The inspection found delays in antibiotic treatment and inadequate triage and observation of patients in emergency department.	After the inspection the hospital has implemented several initiatives, including training, revised procedures, and stand-up improvement board meetings.	15%	43%†	121
All hospitals§				25%	43%†	2869

* The hospitals are publicly owned and run institutions with responsibilities for specialized acute somatic care for all inhabitants in their local area. "Population" figures reported here are (rounded off and) based on information from the governments National plan for hospitals Meld. St. 11 (2015–2016).

† P-value < 0.01 (chi square test for difference between before and after inspection)

‡ P-value < 0.05 (chi square test for difference between before and after inspection)

§ All hospitals = all 24 hospitals included in the nation-wide inspection, including hospitals A - D.

Reporting checklist for qualitative study.

Based on the SRQR guidelines.

Instructions to authors

Complete this checklist by entering the page numbers from your manuscript where readers will find each of the items listed below.

Your article may not currently address all the items on the checklist. Please modify your text to include the missing information. If you are certain that an item does not apply, please write "n/a" and provide a short explanation.

Upload your completed checklist as an extra file when you submit to a journal.

In your methods section, say that you used the SRQRreporting guidelines, and cite them as:

O'Brien BC, Harris IB, Beckman TJ, Reed DA, Cook DA. Standards for reporting qualitative research: a synthesis of recommendations. Acad Med. 2014;89(9):1245-1251.

	Reporting Item	Page Number
Title		
#1	Concise description of the nature and topic of the study identifying the study as qualitative or indicating the approach (e.g. ethnography, grounded theory) or data collection methods (e.g. interview, focus group) is recommended	1

Abstract			
	#2	Summary of the key elements of the study using the abstract format of the intended publication; typically includes background, purpose, methods, results and conclusions	2
Introduction			
Problem formulation	#3	Description and signifcance of the problem / phenomenon studied: review of relevant theory and empirical work; problem statement	3
Purpose or research question	#4	Purpose of the study and specific objectives or questions	3
Methods			
Qualitative approach and research paradigm	#5	Qualitative approach (e.g. ethnography, grounded theory, case study, phenomenolgy, narrative research) and guiding theory if appropriate; identifying the research paradigm (e.g. postpositivist, constructivist / interpretivist) is also recommended; rationale. The rationale should briefly discuss the justification for choosing that theory, approach, method or technique rather than other options available; the assumptions and limitations implicit in those choices and how those choices influence study conclusions and transferability. As appropriate the rationale for several items might be	3-4

		discussed together.	
Researcher characteristics and reflexivity	#6	Researchers' characteristics that may influence the research, including personal attributes, qualifications / experience, relationship with participants, assumptions and / or presuppositions; potential or actual interaction between researchers' characteristics and the research questions, approach, methods, results and / or transferability	5
Context	#7	Setting / site and salient contextual factors; rationale	4-5
Sampling strategy	#8	How and why research participants, documents, or events were selected; criteria for deciding when no further sampling was necessary (e.g. sampling saturation); rationale	5
Ethical issues pertaining to human subjects	#9	Documentation of approval by an appropriate ethics review board and participant consent, or explanation for lack thereof; other confidentiality and data security issues	4
Data collection methods	#10	Types of data collected; details of data collection procedures including (as appropriate) start and stop dates of data collection and analysis, iterative process, triangulation of sources / methods, and modification of procedures in response to evolving study findings; rationale	5
Data collection	#11	Description of instruments (e.g. interview guides,	6

instruments and technologies		questionnaires) and devices (e.g. audio recorders) used for data collection; if / how the instruments(s) changed over the course of the study	
Units of study	#12	Number and relevant characteristics of participants, documents, or events included in the study; level of participation (could be reported in results)	5
Data processing	#13	Methods for processing data prior to and during analysis, including transcription, data entry, data management and security, verification of data integrity, data coding, and anonymisation / deidentification of excerpts	6
Data analysis	#14	Process by which inferences, themes, etc. were identified and developed, including the researchers involved in data analysis; usually references a specific paradigm or approach; rationale	6-7
Techniques to enhance trustworthiness	#15	Techniques to enhance trustworthiness and credibility of data analysis (e.g. member checking, audit trail, triangulation); rationale	6-7
Results/findings			
Syntheses and interpretation	#16	Main findings (e.g. interpretations, inferences, and themes); might include development of a theory or model, or integration with prior research or theory	7-10
Links to empirical data	#17	Evidence (e.g. quotes, field notes, text excerpts, photographs) to substantiate analytic findings	7-10

Discussion			
Intergration with prior work, implications, transferability and contribution(s) to the field	#18	Short summary of main findings; explanation of how findings and conclusions connect to, support, elaborate on, or challenge conclusions of earlier scholarship; discussion of scope of application / generalizability; identification of unique contributions(s) to scholarship in a discipline or field	10-13
Limitations	#19	Trustworthiness and limitations of findings	10-11
Other			
Conflicts of interest	#20	Potential sources of influence of perceived influence on study conduct and conclusions; how these were managed	13
Funding	#21	Sources of funding and other support; role of funders in data collection, interpretation and reporting	13

None The SRQR checklist is distributed with permission of Wolters Kluwer © 2014 by the Association of American Medical Colleges. This checklist can be completed online using https://www.goodreports.org/, a tool made by the EQUATOR Network in collaboration with Penelope.ai