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Next-of-Kin Involvement in Regulatory Investigations of Adverse Events That Caused Patient Death: A Process Evaluation (Part II: The Inspectors' Perspective)

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Objective: The aim of the study was to explore regulatory inspectors' experiences with a new method for next-of-kin involvement in investigation of adverse events causing patient death. A resilient healthcare perspective is used as the theoretical foundation.

Methods: The study design was a qualitative process evaluation of the new involvement method in 2 Norwegian counties. Next of kin, who had lost a close family member in an adverse event, were invited to a 2-hour face-to-face meeting with the inspectors. Data collection involved 3 focus group interviews with regulatory inspectors and observation (20 hours) of the meetings (2017–2018). Data were analyzed by a thematic content analysis.

Results: Next-of-kin involvement informed the investigations by additional and new information about the adverse events and by different versions of the investigators' earlier obtained information, such as time sequences, what happened and how, and who were involved. Inspectors considered next of kin as a key source of information that contributed to improve the quality of the investigation. The downside was that the involvement method increased work load and could challenge the principle of equal treatment in regulatory practice.

Conclusions: Involvement of next of kin in regulatory investigation of adverse events causing patient death contributes to a better understanding of work as done in clinical practice and contributes to strengthen the learning potential in resilience.

Key Words: next of kin, regulatory inspections, adverse events, death

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In this article, we demonstrate the link between regulation and co-creation of resilience in healthcare. We explore how innovation in regulatory investigation methods at the healthcare system macro level can link regulatory inspectors with next of kin at the micro level, in face-to-face meetings. When next of kin are given opportunity to tell their version of the story about how a close relative died because of medical harm, they may contribute with in-depth knowledge of work as done in healthcare, to the regulatory body. Based on this knowledge and interaction between inspectors and next of kin, we are able to study resilience mechanisms in the interface between the regulator and next of kin and how adaptation in regulatory practice takes place to improve processes and outcome.

User Involvement in Regulation and Follow-up After Adverse Events Causing Death

A high number of patients are harmed every year in healthcare,[1–3] and they and their next of kin experience the process after the event as difficult, including neglect, and cover-ups by healthcare organizations.[4] In Norway, a large proportion of the most severe adverse events reported to the Norwegian Board of Health Supervision relate to death due to medical harm.[5,6] In many of these cases, either the Norwegian Board of Health Supervision (regulatory body at the national level) or the County Governor (regulatory body at the regional level) will initiate an investigation to reveal whether healthcare services were provided according to legislation and sound professional practice. The usual approach to collecting information in these investigations is by written information exchange between the service provider (hospital or municipality), the individual healthcare professional, and the regulatory body. There has been critique of the narrow written information exchange and the limited involvement of patients, users, and family members in regulatory activities.[6] There is a growing international interest in involving patients and family in disclosure and analysis of events at the service provider and regulatory level.[5,7–9] Previous research has shown that there is often a mismatch between the perspectives of patients and regulators on healthcare quality and which areas of healthcare that regulators should examine to improve care quality.[10,11] Some studies from the Netherlands describe experiences from using different patient and family involvement methods at the regulatory level, such as web-based surveys, interview with patients, and use of lay persons in the investigation work, resulting in new types of information used by the regulator.[8] However, there is a gap in the literature on involvement of the bereaved next of kin in regulatory activities when patients have died in adverse events.[12]

Resilience and Regulation

Literature within resilient healthcare[13,14] has recently shown how next of kin are key in co-creation of resilience and play an important role in ensuring sound patient care. Resilient healthcare can be defined as "a healthcare system's ability to adjust its functioning before, during, or following changes and disturbances, so that it can sustain required performance under both expected and unexpected conditions."[15p.xxv] Bergerød et al[16] showed that next of kin are important stakeholders in quality and safety in cancer care. Their in-depth knowledge of the patient's history and their observations of the patient over time and during care transitions are key elements of their contribution to co-creation of resilience. However, studies adopting a perspective combining resilient healthcare perspectives and next of kin as co-creators of resilience at the regulatory level are absent in the literature.[17–19] Some

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high-profile severe adverse events in Norway have marked a call for the development of methods for next-of-kin involvement in regulatory investigation of adverse events causing patient death, to increase understanding of the complex causality, and to take advantage of information from the next of kin.[20,21] Next of kin may have been at the bedside and will have experienced the adverse event from a different perspective than the involved healthcare professionals.[16,17] Therefore, they may have potential valuable information for the regulatory bodies who investigate whether healthcare was provided according to the law. There is also a need to know more about resilience mechanisms at the regulatory level[17–19] including how the regulators adapt their practice to new information and how next of kin can contribute to supplement the inspectors' understanding of how clinical work is done in practice when patients are harmed and die.

Regulatory Methods Innovation in Norway

There is a limited tradition for involving the next of kin in macro level regulatory practice in Norway. As part of a response to a heavy critique of this insufficient involvement practice, the Norwegian Board of Health Supervision developed a user involvement strategy and funded development projects to improve involvement of next of kin in regulatory practice. One of these projects was conducted by one county governor who oversees healthcare services in 2 counties, approximately 25% of the total Norwegian population.[5] This county governor designed a new user involvement method where next of kin from 50 families, who had experienced the loss of a close family member in an adverse event, were invited to a 2-hour face-to-face meeting with the regulatory inspectors (medical doctor and legal practitioner). The meeting took place at the county governor's office as part of the regulatory investigation, to shed light on the event from the next of kin's perspective. Researchers from the University of Stavanger were involved to conduct a process evaluation of the new regulatory method and how it was experienced by the regulators and the next of kin.

Objective and Research Question

The objectives were to explore expectation and experiences from the regulatory inspectors' perspective of the new involvement method and to evaluate whether it contributed to new information about the incident and whether it led to adaptations of the regulatory investigation practice. The results will be discussed using a resilient healthcare perspective.

The following research question guided the study:

1. How do regulatory inspectors expect and experience that next-of-kin involvement in investigations of the most severe adverse events influence the regulatory process?

METHODS

Design

The study was designed as a qualitative process evaluation.[22] The data collection was conducted during 11 months (2017–2018) and involved focus group interviews with regulatory inspectors, observation of the meetings, and interviews with the next of kin who had participated.

Data Collection and Analysis

In this article, we focus on the perspective of the inspectors. A total of 3 focus group interviews were conducted in the early phase of the project in September 2017 (3 informants) and then repeated after 6 months (5 informants) and 10 months (4 informants). We interviewed the same inspectors to map their expectations and experiences over time. The inspectors were recruited by the regulatory project manager at the county governor office. The regulatory project manager did not attend the focus group interview, to prevent participants feeling inhibited about speaking freely. The interviews were conducted according to an interview guide aiming to map the expectations and experiences with the meeting (advantages/disadvantages, change in regulatory practice, improvement suggestions). Two researchers conducted the interviews. All interviews were tape recorded and transcribed.

In addition, we conducted observations in 8 meetings (20 hours) where a total of 16 next of kin participated (Table 1 for information about the observations). In each meeting, an inspection team of 1 doctor (the same inn all meetings) and 1 or 2 legal professionals participated. The observation also included the premeetings held by the inspection team and their discussion after the meeting. All next of kin were asked by the regulatory project manager if a researcher could observe the meeting, as part of an evaluation. All families accepted. An observation guide was developed and focused on how the meeting was conducted, language, interaction, communication patterns, emotional reactions, and power balance. During observation, field notes were taken.

The transcribed data material from the interviews and observations was analyzed according to a thematic content analysis.[23] All researchers read the total material and discussed the themes to agree and refine the analysis. The themes were divided into positive experiences, negative experiences, and suggestions for improvement, as seen from the inspectors' point of view.

Ethical Approval

The study was approved by the Norwegian Centre for Research Data (Reference Number 54865). All participants signed informed consent.

RESULTS

The results are presented theme-wise hereinafter, and an overview with examples is provided in Table 2.

Positive Experiences

Next-of-kin Involvement Informs the Investigation

The results showed that meeting bereaved family members face-to-face differed significantly from ordinary regulatory investigation that the inspectors were familiar with. Usual regulatory practice is based on written information exchange between the involved stakeholders. The observation showed that the next of kin were given time to tell their side of the story to the inspectors, without interruptions. The inspectors could, if needed, explain the content of medical or juridical information in written documents, such as patient records, letters, and statements sent to the next of kin as part of the ongoing investigation. The need to explain the content of the often large amount of written information to the next of kin was frequently observed and mentioned by the inspectors in the interviews. Before each new meeting, the inspectors conducted a premeeting where they went into the details in each case (e.g., medical record, letters, complaints) and ensured that they were well prepared and agreed on the agenda. The medical doctor (regulatory project manager) chaired the meeting and the legal professional supplemented and asked follow-up questions. They never rushed the agenda and always took the time needed to talk to and listen, although the meeting could last longer than the intended 2 hours.

The inspectors were able to gain additional and new information about the adverse event causing the patient's death, and different versions of earlier obtained information, such as time sequences and how and what happened, and who were involved

TABLE 1. Observation of Meeting and Short Description of Case

Observation of Meeting Number	Next of kin Present at Meeting and Relation to the Patient	Short Case Description	No. Inspectors Present at Meeting
1	1 (wife)	Man died of cerebral hemorrhage, he had a history of evolving symptoms, and multiple stakeholders were involved.	2
2	2 (mother and father)	Young woman died after comprehensive cancer surgery – questioning the diagnostic delays.	2
3	3 (mother, brother, sister)	Man died because of heart attack after delayed response from emergency service central.	2
4	2 (wife and daughter)	Man found dead in a parking lot. General practitioner did not suspect heart disease.	2
5	2 (mother and father)	Baby died before birth – questioning follow-up	2
6	2 (mother and big brother)	Young man committed suicide when hospitalized in psychiatric hospital (under commitment).	2
7	1 (son)	Woman using anticoagulant was sent home after consultation and died after a fall of cerebral hemorrhage consultation in emergency department.	2
8	3 (wife, son, daughter)	Man died of multiorgan failure after perforation of coronary artery during cardiac surgery.	2

both in terms of healthcare professionals, but also different institutions and services levels. The inspectors considered the meeting as a method where they got detailed explanations of conditions around the patient, which were often not included in the medical records or in documents and statements sent from the healthcare professionals or the institutions. The observation showed that the next of kin could elaborate on their experiences of the event, causal chain, and give details about who had been involved at different stages and time of the patient journey, which the inspectors found to be crucial information for their investigation. The meeting often resulted in additional information gathering from the involved service providers and from new services providers that next of kin identified for the inspectors in the meeting.

The inspectors considered next of kin as a key source of information that contributed to improve the quality of the investigation. They considered the method as being adaptive and flexible in what kind of questions that could be asked to the different next of kin. Inspectors had to be sensitive to each next of kin and their emotional state in the meeting. However, usually, inspectors were surprised of how well next of kin handled the meeting and the difficult situation of going into details about the event when the patient died. The inspectors experienced that they could adapt follow-up questions to be more targeted to their needs, to inform the investigation. In particular, they argued that the meeting is helpful and works well when cases are complex and involve multiple stakeholders, because information provided by the next of kin contributed to a more holistic picture of the adverse event and the involved stakeholders.

Involvement is Emotionally Challenging but in Accordance With Political Expectation

The inspectors experienced the meetings as a way of acting more in accordance with political expectations for user involvement in healthcare—also at the regulatory level. Some argued that the regulatory body should be more open to the users in general than current practice, whereas others were more skeptical because it may raise too high expectations for involvement in all cases. The inspectors experienced the method as a safe space for the next of kin, who often had been in heavy conflicts with the service providers. Inspectors could read about frustration, anger, and rage of not being heard, in the medical records and the complaints. In addition, someone then took the time to listen and explain which had a resemblance to a therapeutic effect for the next of kin, although that was not the purpose of the meeting. The grief and the emotional aspects were handled at the end of every observed meeting. The inspectors asked how the next of kin felt and whether they needed professional follow-up. The meeting was also an emotionally challenging situation for the inspectors themselves, because they were sometimes worried about attending beforehand and continued to think about it after the meeting. However, they argued that it was a positive experience to be a support, help, and being able to clarify misunderstandings or questions from next of kin in the meeting. The inspection team conducted a short debriefing session after the meeting. A lecture from a psychologist about emotional reactions and response was the only training session before the project start up. The observations showed a strong collegial support to deal with emotional reactions among the inspectors.

Negative Experiences

Involvement Increases Work Load and Challenges the Principle of Equal Treatment

The results were consistent over time, and although the inspectors expected that some cases would take less time, their experience was that the meetings added more work. Their organization had not supported them with additional resources, except from the regulatory project manager who was partly funded and exempted from other work tasks. Therefore, the inspectors argued that although the investigation quality was improved by next-of-kin involvement, it cannot be justified as a regular practice, unless additional resources are allocated to the office.

According to the inspectors, there was a need to develop criteria for judging when a meeting would be helpful. The meeting has much to offer in the most complex adverse events, but at the same time, an individual assessment of utility for a meeting in each case would challenge the principle for equal treatment in

TABLE 2. Overview of Themes

Theme	Subtheme	Quote
Positive experiences	Next-of-kin involvement informs the investigation	*"I think we have gained much more relevant information in the meetings, than I anticipated before we started… The next of kin has been very structured, I think. We get a lot of additional information when we talk with them, and can ask follow-up questions. We get the entire time line in a new way. It is about what happened, when, what kind of symptoms, and you can ask about more details…. For example the patient history, the procedures, and one patient had been to several other service providers, than the doctors said, and we had to request additional information. In that case, our investigation was expanded to cover additional service providers, after the meeting. The next of kin did not include this information in the original complaint, because they did not think it was important, but then we could ask about it* [in the meeting]*" (Int. 1).* *"We use more time in these cases. I have only been involved in one case, but we got an entire new understanding of the event, and expanded the investigation to additional service providers, and it became much more comprehensive. I think it is very good, because I want us to be thorough in our approach and not just close the case. I think it is a good project, and it contributes to improve our investigation quality, but not efficiency, like it was anticipated when we started the project." (Int. 1).*
	Involvement is emotionally challenging, but in accordance with political expectation	*"In the first meeting I attended, a couple had lost their 1.5-year-old daughter. It was horrible. And also the meeting last week, when I sat there and tried not to cry…. I have been in the same situation with my child at the same hospital, and I really worried about the meeting beforehand and I didn't have any training. I'm just a legal professional." (Int. 2).* *"All the next of kin have told us it felt good for them to meet us, and that is a very positive experience for me." (Int.1)*
Negative experiences	Involvement increases work load and challenges the principle of equal treatment	*"If you ask one of us, do we want this (meeting), we will think that we have a certain amount of hours available, because we have lots of work, and then we think what will we have to sacrifice? It perhaps improves investigation quality in some cases, but at the same time we think of those who will not get a response from us in their case…" (Int. 3)* *"When we start the case we send the invitation and I have experienced several rejects…" (Int. 1)* *"I am worried, that it is only the most resourceful next of kin who accept the invitation…" (Int.1)*
Suggestions for improvement	Improve selection criteria and allow differentiation	*"I have thought several times that it didn't really inform the legal investigation. I think it is because in the suicide cases it is not so much medical details as in acute hospitals, so it is quite different, so speaking from a resource perspective I don't think the suicide cases should be prioritized." (Int.3)*

regulation. The inspectors, therefore, argued that it is easier to refuse a request for face-to-face meetings with the argument that the regulatory practice applies written information exchange only. They also worried that the most resourceful next of kin (high education, strong family relations, and salary) would accept the meeting invitation, whereas other groups would tend to decline, as experienced in some of their cases.

Suggestions for Further Methods Improvement

Improve Selection Criteria and Allow Differentiation

Based on the experiences of the meeting, the inspectors argued that the method could be further improved by allowing for a better differentiation of cases of patient deaths, implying that more flexible but high threshold selection criteria were needed. Some experienced that the meeting did not provide so much additional information in the suicide cases and argued that resources should be prioritized to other areas. In addition, they argued that the inspectors should not indicate anything about the conclusion of the case during meetings. Finally, the inspectors suggested to include a medical doctor trained with a primary care background. Currently, a doctor with oncology and hospital background chaired all meetings, but the regulatory follow-up process would involve a doctor (inspector) working with primary care as work area but who was not part of the project.

DISCUSSION

In this article, we have seen how regulatory methods innovation is developed and tested as a response to a public pressure for user involvement at all levels in healthcare (e.g., Adams et al[8]). Our study focused on how next-of-kin involvement contributes to improve regulatory investigations of adverse events causing patient death, as seen from the regulatory inspectors' perspective. The main finding was that the inspectors experienced next-of-kin involvement as method that informed and improved quality of the investigations by adding new and important information. The downsides were added workload and lack of resources to follow up the new information and stakeholders identified in the meeting. In the following, we discuss the findings in a resilient healthcare perspective.

There are several lessons learned from our study in a resilient healthcare perspective.[13,15,24] First, most studies of resilient healthcare take place at the micro level.[17,25–27] However, studies of empirical practices or innovative methods that bridge the micro and the macro level and integrate the patient or next of kin are required to ensure that the perspective of resilient healthcare is

theoretically and practically developed.[14,17,19] Resilient healthcare is a multilevel phenomenon,[17,18,25,28] and as seen in our study, it needs to expand beyond a micro level approach in the healthcare system. Our study showed that a simple method for next-of-kin involvement in regulatory investigation of fatal adverse events fostered an increased information richness for the regulatory inspectors that exceeded their expectations. To promote the learning potential in resilience,[15] information about what actually happened (work as done) is key during regulatory investigations. The stories from next of kin complemented the inspectors' picture and often differed from the written information collected about the adverse event before the meeting (work as imagined). We argue that this involvement method also has the potential to provide additional information in investigation of nonfatal adverse events, but then, the patient should also be involved. By increasing the information richness in investigations, we argue that the next-of-kin involvement contributes to co-creating resilience at the regulatory level. Our study corroborates Bergerød et al's[16] study, showing that next-of-kin involvement is a "stakeholder potential," which strengthens or supports the 4 resilience potentials (anticipation, monitoring, responding, and learning). In the regulatory investigations of adverse events, the learning potential is most relevant, and the next-of-kin involvement strengthened the learning information that inspectors use in their assessment and final report, which is fed back to the services. Adverse events (fatal and nonfatal) are examples of system failure and often cause distrust. Involvement, listening, and learning from the next of kin are therefore mechanisms that bridge system levels in resilience and may also contribute to restoration of trust in the healthcare system.

Second, the meeting is supplementing the regulatory tool kit by being more responsive to the views of next of kin than current practice.[29,30] The meeting could be adapted to different types of contexts (hospital, primary care, psychiatry) and identified problems that were not only associated with clinical standards.[11] Next of kin identified, for example, that additional stakeholders were involved or that the problem had a longer time line or different sequence. The dialog contributed to a more holistic conceptualization of the event. Previous studies[31,32] have suggested that regulatory bodies should take more advantage of people-to-people approaches to knowledge management[33] (e.g., meeting, face-to-face dialog, interviews), instead of relying solely on people-to-documents approaches (letters, medical records, databases) to foster better learning processes. Such meetings contribute to bridging a gap in regulatory methods and should be further tested in a larger scale. However, to succeed, further development of adaptive selection criteria is needed in addition to leadership priority and funding.

Third, we argue that this innovation in regulatory practice illustrates that regulation and resilience are two concepts that can be linked and should not only be conceptualized as counterparts. It also shows that resilience mechanisms exist at the regulatory level when the regulator adapts to external pressure, improves their own methods by testing a new involvement arena, and starts seeing next of kin as an important information source improving investigation quality.[18] We recommend further research to explore both resilience mechanisms within the regulatory body and in the interface between regulators, regulated organizations, and the public (next of kin, patients, stakeholders). Flexibility, adaptations, and responsiveness are mechanisms of interest for both regulation and resilience to improve service performance[18] and should be approached in a multilevel perspective to build new knowledge.[17]

Limitations

The sample size is a limitation. However, we interviewed all inspectors involved in the project and our observations supplement the perspective of how the method contributed to inform the investigation.[34] We did not conduct a pilot test; however, we interviewed the same inspectors over time, which gave us opportunity to make adjustments and ask follow-up questions. The next of kin' experience is not covered in this article but will be in an additional publication,[35] which is necessary to evaluate the method.

CONCLUSIONS AND RECOMMENDATIONS

There has been a call for methods development to improve user involvement in regulatory practice. Our study indicates that there is a need for face-to-face meeting opportunities between the next of kin and regulatory inspectors in selected cases, such as part of the follow-up of the most complex adverse events. There is a need to refine the selection criteria for such meetings, and further research should explore the extent of cases that changed direction and possible conclusion based on the next-of-kin involvement in the investigations of adverse events causing death. Face-to-face communication enables richer information and supplements current methods of data collection and user involvement in regulatory practice. Involvement of next of kin in regulatory investigation contributes to a better understanding of work as done in clinical practice and contributes to strengthen the learning potential in resilience.

We recommend a potential further implementation of involvement methods in regulatory investigations of both fatal and nonfatal adverse events to have sound leadership anchoring, because our study showed that new involvement methods require proper resources, training, and time to be meaningful to both inspectors and next of kin.

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REFERENCES

1. *Pasientskader i Norge* [in Norwegian]. Oslo, Norway: Directorate of Health; 2018.
2. Ministry of Health Foundation. Research scan: levels of harm in primary care. London: 2013. Available at: https://www.health.org.uk/sites/default/files/LevelsOfHarmInPrimaryCare.pdf. Accessed January 8, 2019.
3. Jha AK, Prasopa-Plaizier N, Larizgoitia I, et al. Research Priority Setting Working Group of the WHO World Alliance for Patient Safety. Patient safety research: an overview of the global evidence. *Qual Saf Health Care*. 2010;19:42–47.
4. Hågensen G, Nilsen G, Mehus G, et al. The struggle against perceived negligence. A qualitative study of patients' experiences of adverse events in Norwegian hospitals. *BMC Health Serv Res*. 2018;18:302.
5. Lippestad JW. *Rapport: Følgeevaluering av prosjketet Styrket involvering av pasienter, brukere og pårørende i tilsyn [in Norwegian]*. Oslo, Norway: SINTEF Digital; 2018.
6. Ministry of Health and Care Services. NOU 2015:11 Med åpne kort [in Norwegian]. Oslo, Norway: Ministry of Health and Care Services; 2015.
7. Etchegaray JM, Ottosen MJ, Burress L, et al. Structuring patient and family involvement in medical error event disclosure and analysis. *Health Aff*. 2014;33:46–52.
8. Adams SA, van de Bovenkamp H, Robben P. Including citizens in institutional reviews: expectations and experiences from the Dutch Healthcare Inspectorate. *Health Expect*. 2015;18:1463–1473.
9. Bouwman R, de Graaff B, De Beurs D, et al. Involving patients and families in the analysis of suicides, suicide attempts, and other sentinel events in mental healthcare: a qualitative study in the Netherlands. *Int J Environ Res Public Health*. 2018;15:E1104.
10. Bouwman R, Bomhoff M, Robben P, et al. Is there a mismatch between the perspectives of patients and regulators on healthcare quality? A survey study. *J Patient Saf*. 2017:1. doi: 10.1097/pts.0000000000000413.

11. Bouwman R, Bomhoff M, Robben P, et al. Patients' perspectives on the role of their complaints in the regulatory process. *Health Expect*. 2016;19: 483–496.
12. Haraldseid C, Schibevaag L, Wiig S. Involvement of the bereaved in supervisory investigation of severe adverse events: a literature review. In: *NSQH*. Copenhagen, Denmark: Copenhagen NSQH Proceedings; 2018.
13. Bergerød IJ, Braut GS, Wiig S. Resilience from a stakeholder perspective: the role of next of kin in cancer care. *J Patient Saf*. 2018.
14. O'Hara JK, Aase K, Waring J. Scaffolding our systems? Patients and families 'reaching in' as a source of healthcare resilience. *BMJ Qual Saf*. 2019;28:3–6.
15. Hollnagel E. *Safety-II in Practice: Developing the Resilience Potentials*. New York: Taylor and Francis; 2017.
16. Bergerød IJ, Gilje B, Braut GS, et al. Next-of-kin involvement in improving hospital cancer care quality and safety – a qualitative cross-case study as basis for theory development. *BMC Health Serv Res*. 2018;18:324.
17. Berg SH, Akerjordet K, Ekstedt M, et al. Methodological strategies in resilient health care studies: an integrative review. *Saf Sci*. 2018;110: 300–312.
18. Macrae C, Wiig S. Resilience: from practice to theory and back again. In: Wiig S, Fahlbruch B, eds. *Exploring Resilience: A Scientific Journey From Practice to Theory*. Cham: Springer International Publishing; 2019: 121–128.
19. Wiig S, Fahlbruch B. *Exploring Resilience A Scientific Journey From Practice to Theory*. Cham, Switzerland: Springer Open; 2018.
20. Wiig S, Aase K, Bourrier M, et al. Transparency in health care: disclosing adverse events to the public. In: Bourrier M, Bieder C, eds. *Risk Communication for the Future: Towards Smart Risk Governance and Safety Management*. Cham: Springer International Publishing; 2018: 111–125.
21. Wiig S, Braut GS. *Developments in Analysis of Adverse Events in Healthcare - Policy and Practice in Norway. I: Prevention of Accidents at Work*. Leiden, Netherlands: CRC Press; 2018:39–45.
22. Patton M. *Qualitative Research and Evaluation Methods*. Thousand Oaks: Sage; 2002.
23. Pope C, Ziebland S, Mays N. Analysing qualitative data. In: Pope C, Mays N, eds. *Qualitative Research in Health Care*. Oxford: BMJ Books; 2006: 63–82.
24. Hollnagel E. *Safety-I and Safety-II: the Past and Future of Safety Management*. Surrey, Canada: CRC Press; 2014.
25. Righi AW, Saurin TA, Wachs P. A systematic literature review of resilience engineering: research areas and a research agenda proposal. *Reliability Eng Syst Saf*. 2015;141:142–152.
26. Anderson J, Ross AJ, Back J, et al. Implementing resilience engineering for healthcare quality improvement using the CARE model: a feasibility study protocol. *Pilot Feasibility Stud*. 2016;2:61.
27. Laugaland KA. *Transitional Care of the Elderly From a Resilience Perspective [dissertation no. 259]*. Stavanger: University of Stavanger; 2015.
28. Patriarca R, Bergström J, Di Gravio J, et al. Resilience engineering: current status of the research and future challenges. *Saf Sci*. 2018;102: 79–100.
29. Ayres I, Braithwaite J. *Responsive Regulation*. New York: Oxford University Press; 1992.
30. Walshe K. *Regulating Healthcare: A Prescription for Improvement?* Glaskow: Open University Press; 2003.
31. Wiig S. *Contributions to Risk Management in the Public Sector [dissertation no. 48]*. Stavanger: University of Stavanger; 2008.
32. Wiig S, Aase K. Fallible humans in infallible systems? Learning from errors in health care. *Saf Sci Monitor*. 2007;11:1–13.
33. Hansen MT, Nohria N, Tierney T. What's your strategy for managing knowledge? In: Woods JA, Cortada J, eds. *The Knowledge Management Yearbook*. Boston: Butterworth-Heinemann; 1999.
34. Malterud K, Siersma VD, Guassora AD. Sample size in qualitative interview studies: guided by information power. *Qual Health Res*. 2016;26: 1753–1760.
35. Wiig S, Haraldseid-Driftland C, Tvete Zachrisen R, et al. *Next of kin involvement in regulatory investigations of adverse events that caused patient death - a process evaluation (part I – the next of kins' perspective)*. J Pat Saf. 2019.