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Next of Kin Involvement in Regulatory Investigations of Adverse Events That Caused Patient Death: A Process Evaluation (Part I – The Next of Kin's Perspective)

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Objective: The aim of the study was to explore experiences from the next of kin's perspective of a new involvement method in the regulatory investigation process of adverse events causing patient death.

Methods: The study design was a qualitative process evaluation of the new involvement method in two 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 regulatory inspectors to shed light on the event from the next of kin's perspective. Data collection involved 18 interviews with 29 next of kin who had participated in the meeting and observations (20 hours) of meetings from 2017 to 2018. Data were analyzed using a thematic content analysis.

Results: Next of kin wanted to be involved and had in-depth knowledge about the adverse event and the healthcare system. Their involvement extended beyond sharing information, and some experienced it as having a therapeutic effect and contributing to transparency and trust building. The inspectors' professional, social, and human skills determined the experiences of the involvement and were key for next of kin's positive experiences. The meeting was emotionally challenging, and some next of kin found it difficult to understand the regulators' independent role and suggested improving information given to the next of kin before the meeting.

Conclusions: Although the meeting was emotionally challenging, the next of kin had a positive experience of being involved in the investigation and believed that their information contributed to improving the investigation process.

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

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Patient and family involvement has been increasingly focused on in patient safety research and practice in recent years.[1–5] Previous research scans[4,6,7] have shown a growing number of ways to involve patients in patient safety, particularly at the individual level, by monitoring themselves and providing feedback (e.g., incident reports, discharge feedback). The methods mainly relate to how patients can safeguard themselves by, for example, asking healthcare professionals about hand hygiene or checking their medication. Fewer methods exist at the proactive collective level, where patients and families are involved in planning and system improvement.[7]

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Next of Kin as a Source of Resilience

Family members and next of kin play an important role in ensuring quality and safety in services provision.[2,8–10] Next of kin frequently accompany patients during hospital stays, in care transitions, or at home and have in-depth knowledge of the patients' history and condition. They are able to monitor changes in well-being over time and communicate this to service providers. When patients are very ill, the next of kin may take over communication and decision making on their behalf. Bergerød et al[8,10] identified the following nine areas where next of kin are important stakeholders in quality and safety in cancer care: nutrition, observations, transitions, pain treatment, information, palliative and terminal care, motivation, daily care, and rehabilitation. Next of kin functioned as a safety net and an extra resource for healthcare services, ensuring that the patient was safe during hectic periods or at home. Bergerød et al[8] noted this contribution from next of kin as a co-creation of resilience, meaning that next of kin contribute to safe healthcare services under varying conditions when the system faces understaffing, full wards, and time pressure or when the chronically ill patient is at home and out of healthcare professionals' sight. Next of kin monitor the patient, anticipate the health condition and potential risks, respond to deterioration, communicate this tacit knowledge to the healthcare providers, and ensure learning processes across services levels.[8] Similarly, O'Hara et al[5] considered next of kin as a source of resilience and argued, in line with Bergerød et al,[8] that the next of kin are scaffolding the system and act as knowledge brokers between service levels. Such unique insights and knowledge can support safer services through early detection of safety gaps, because next of kin are often involved in the entire patient trajectory.[5]

Next of Kin's Involvement in Investigating Adverse Events Causing Death

Involvement in investigations of adverse events has a large potential to meet both patient and family needs and improve quality and safety.[11] Examples of patients and family involvement occur in analyses of adverse events in hospitals,[1,11] showing that the most common method of involvement is a one-time interview event. Kok et al[1] found that such involvement was important in its own right and contributed new facts and verified technical details. Other studies have shown that patient and family perspectives of the adverse event often differ significantly from those of healthcare professionals[12] and regulatory inspectors.[13,14] At the regulatory level, we have also seen innovation in methods for involving patients and the public in general, such as reviews, surveys, and the inclusion of laypersons on inspection teams[14,15] and in the aftermath of serious adverse events.[15–17] However, involvement of the bereaved next of kin in formal regulatory activities when patients have died in adverse events is lacking in the literature. More

knowledge is needed about ways next of kin are involved in such regulatory follow-up as well as their views of being involved.[1]

Regulatory Methods Innovation in Norway

Norway has a limited tradition of user involvement in regulatory practice. As part of a response to a heavy critique of this insufficient involvement practice, the Norwegian Board of Health Supervision—the national regulatory body in healthcare—developed a user involvement strategy and funded development projects to improve involvement of next of kin in regulatory practice.[17] One project was conducted by one county governor who oversees healthcare services in two counties, accounting for approximately 25% of the total Norwegian population in 2017–2018. This county governor designed a new user involvement method where 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 regulatory inspectors (medical doctor and legal practitioner). Families from a total of 50 patient deaths were included in the project. 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 conducted an independent process evaluation of the new regulatory method and how regulators and next of kin experienced it.

Objective and Research Question

The aim of this article is to explore experiences from the next of kin's perspective of the new involvement method in the regulatory investigation. The following research question guided the study:

How do next of kin experience being involved in a regulatory investigation of an adverse event in which a close family member died?

METHODS

Design

The study was designed as a qualitative process evaluation.[18] The data collection period lasted 11 months (2017–2018) and involved focus group interviews with regulatory inspectors, observation of meetings, and interviews with next of kin after participation in the meetings.

Data Collection and Analysis

This article focuses on the next of kin's perspective. Eighteen interviews with 29 next of kin were conducted (Table 1 for sample description). Participating next of kin were recruited by the project manager at the county governor's office. The

TABLE 1. Sample Description of the Interviewed Next of Kin, Including Short Case Description

Interview	Next of Kin and Relation to the Patient	Short Case Description	X Means Next of Kin Participated in Both Interview and Observation
1	2 (mother and father)	Patient with extensive care needs due to a former medical error. Found dead in bed one morning at the hospital.	
2	2 (mother and aunt)	Woman committed suicide the same day she was sent home from psychiatric ward.	
3	1 (wife)	Man died due to cerebral hemorrhage; he had a history of evolving symptoms, and multiple stakeholders were involved.	x
4	1 (cousin)	Young woman with dementia in nursing home transferred to the hospital. Lack of information to next of kin that she was terminal.	
5	2 (wife, daughter)	Woman died under unclear circumstances after removal of pacemaker.	
6	3 (mother, sister, aunt)	Young woman with cancer died after chemotherapy. Next of kin had been informed about a possible genetic issue implying that she was intolerant of this medication.	
7	2 (wife and cousin)	Man died due to ileus after diagnostic delay in a local hospital.	
8	1 (mother)	Young woman died after comprehensive cancer surgery – questioning diagnostic delays	x
9	1 (live-in partner)	Man was rapidly deteriorating and died after being transferred from intensive care unit to ward.	
10	1 (brother)	Man died due to heart attack after delayed response from emergency service central.	x
11	2 (mother and father)	Young girl died due to cerebral hemorrhage during exercise. Questioning response from the emergency service central.	
12	2 (wife, daughter)	Man found dead in a parking lot. General practitioner did not suspect heart disease.	x
13	1 (wife)	Man died of cancer – question about treatment.	
14	2 (father and godmother)	Man committed suicide after three meetings with psychologist at local psychiatric hospital.	
15	1 (daughter)	Female resident in nursing home died after falling from bed.	
16	1 (mother)	Man died of drug overdose while hospitalized in a psychiatric ward.	
17	2 (mother, big brother)	Young man committed suicide while hospitalized in psychiatric hospital (under commitment).	x
18	2 (daughter, family friend)	Woman died of cancer. Questioning insufficient follow-up by general practitioner.	
Total	**29**		**5**

interviews were conducted using an interview guide to map next of kin's expectations and experiences when meeting with regulatory inspectors. Themes in the interview guide included experiences from the meeting, advantages/disadvantages, practice, and improvement suggestions. All interviews were conducted by the same researcher, lasted approximately 2 hours each, and were tape recorded and transcribed.

We also conducted observations in eight meetings (approximately 20 hours), during which 15 next of kin were observed. Next of kin from five of the eight observed meetings were also interviewed. In each meeting, an inspection team of one medical doctor (chairperson, the same in all meetings) and one or two legal practitioners participated. The observation included the inspection team's premeetings, the meeting itself, and the inspections team's postmeeting discussion. The county governor project manager asked all next of kin if a researcher could observe the meeting as part of an evaluation. Consent was given both before and during the meeting. An observation guide was developed and focused on how the meeting was conducted, language, interaction, communication patterns, emotional reactions, and power balance. Field notes were taken during observations.

The transcribed data material from the interviews and observations were analyzed using a thematic content analysis.[19] All researchers except EH read the total material and discussed the themes to agree and refine the analysis. The themes were divided into positive experiences, challenging experiences, and suggestions for improvement, as seen from the next of kin's perspective.

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 according to themes. Table 2 provides an overview of results, with quotes.

Positive Experiences

Next of Kin Want to be Involved

All the next of kin in our study were positive about being involved in the investigation of the adverse event causing the patient

TABLE 2. Overview of Themes

Theme	Subtheme	Quote
Positive experiences	Next of kin want to be involved	*"I think that the bereaved has information that is important for the regulatory body. Of course, this will vary between cases, but the next of kin can elaborate on issues that the healthcare services are incapable of, as they [next of kin] can explain from their perspective. And that has to be important for the regulatory assessment. If you want to find out what happened, which I guess it the regulator's purpose, then it is important to listen to different stakeholders. And it is [name of the other next of kin in the interview] who has most insight into what went on." (Int. 14)* *"My intention is to help by doing this. And this is not just about myself; this is about the system and that they [the regulator] can investigate the system and see how risky the current system is for the public" (Int. 16)*
	Next of kin's in-depth knowledge about the adverse event and the healthcare system	*"What happened cannot be undone, sadly. But it is possible to do your best to prevent the same mistakes from happening again. Then there has to be a willingness to look into what happened. And looking back to our next of kin meeting at the hospital, there were no signs of willingness, not one millimeter, although there were obvious mistakes (laughter). So, it feels kind of hopeless, I have to admit… So, it is rather a question if they try to protect themselves and then send someone (to the meeting) that is not willing to admit anything." (Int. 6)*
	Involvement means more than sharing information; Therapeutic effect and trust building	*"I felt very comfortable with the two inspectors. It was a good atmosphere and we felt safe" (Int. 6)*
	Inspectors' professional, social, and human skills define the experiences	*"You feel that they see you as a person, and you could feel their empathy. I think that is crucial in such meetings. You are vulnerable, so extremely vulnerable. You can feel the atmosphere, you can look at the persons and notice if they are not interested. Then everything is wrong. But that was not the case at all here in this meeting. They were very empathic and understanding. They said it was nice and well done that we came. Yes, it is those little things, such as saying 'great that you came, we are very grateful for that.' You could think of it as superficial, but it is so important." (Int. 11)*
Challenging experiences	Emotional aspects of involvement	*"A person who meant so much to me is not there anymore. I cannot talk to her anymore (almost crying). I have the same problems today as half a year ago. I think it's going to be some hard months ahead." (Int. 8)*
	Difficulty understanding the regulator's role	*"You should not believe that the dialog with the county governor is neutral. They (the regulator) are part of the case, in a way, and even though they negotiate between those stakeholders, and we (next of kin) are one of these stakeholders." (Int. 4)*
Suggestions for further methods improvement	Strengthen information about involvement and the investigation process	*"Well I think that they could call me in advance and explain that when there is an unexpected death they would investigate it. Then you are a bit prepared when you receive the letter." (Int. 16)*

death. They were pleased to receive the meeting invitation and wanted to participate in informing the investigation. The involvement made them feel that the regulator was engaged in their case and really wanted to identify what happened. All informants agreed that next of kin's involvement is important for a thorough regulatory investigation. They listed specific reasons related to their knowledge of the causal chain and the involved healthcare personnel. Several asserted that their contribution provided new information to the investigation, implying that the regulator had to collect additional information from the stakeholders already involved and from new stakeholders identified by the next of kin during the meeting.

The next of kin were recruited in several ways. They received a meeting invitation because they had filed a formal complaint to the county governor, the police had reported the death, or a hospital in the county had reported a serious adverse event, causing the patient death, to the Norwegian Board of Health Supervision. The latter is mandatory for all hospitals, and the Norwegian Board of Health Supervision delegates follow-up for most cases to county governors at the regional level. The next of kin who had filed a complaint indicated that being invited to a meeting confirmed that the formal complaint was appropriate.

The next of kin had strong opinions about the healthcare system, and many argued that it has major flaws. Their motivation for being involved largely related to their desire to share their experiences with the regulator, thereby contributing to system change. Overall, next of kin preferred a face-to-face meeting instead of a written information exchange. They argued that the regulator would get a better understanding of their experiences during a dialog compared with written information exchange. After each meeting, inspectors provided meeting minutes to all next of kin, who could indicate whether information was missing or wrong. The minutes were considered useful for both parts.

Next of Kin's In-depth Knowledge About the Adverse Event and the Healthcare System

Although there were exceptions, most next of kin described a disheartening picture of how the healthcare service providers treated them after the adverse event leading to the patient death. Examples showed that service providers had insufficient routines for taking care of next of kin, and healthcare personnel tried to hide information and cover up for each other. Several next of kin did not receive information from the involved healthcare personnel and still had unanswered questions. Both the observations and interviews revealed that the information in the medical records was often not in accordance with the next of kin's experiences of the event. Several next of kin present during the event had a clear memory of what happened but did not find the medical record to match their experiences. Key information was omitted, and descriptions were inaccurate, which implied an even stronger need for a meeting to explain their perspective. The next of kin were particularly frustrated about information being kept from them, and they argued that the most important aspect was to admit that errors had occurred so healthcare personnel could learn from them.

Involvement Means More Than Sharing Information: Therapeutic Effect and Trust Building

The next of kin had positive experiences sharing their story with somebody who listened. Some said that the meeting almost had a therapeutic effect and helped them process grief. They also related this to the inspectors, who were characterized as empathic, listening, and taking the next of kin seriously during the meeting. However, the next of kin also indicated that the therapeutic effect was subordinate; the main reason for attending the meeting was to inform the investigation of the adverse event causing the patient death. Indeed, some argued that it was difficult to evaluate the involvement method before their case was concluded and closed.

The issue of trust related to both the healthcare services and the regulator varied greatly. Some questioned the role of the regulator as a neutral actor and did not consider the regulator as an independent body in the healthcare system. Others questioned the regulator's ability to solve the case. However, the main finding was that being involved in a face-to-face meeting contributed to transparency and trust building.

Inspectors' Professional, Social, and Human Skills Define the Experiences

The next of kin had positive involvement experiences, and inspectors' competence seemed to determine the quality of the conversation. One inspector per team had a medical background and experience conducting difficult conversations with people going through the grief process. The medical doctor involved in this project was the same in every meeting and had extensive experience as an oncologist. The next of kin underscored the importance of meeting inspectors able to adapt to their needs in the situation and show empathy and interest in the way they communicated, both verbally and nonverbally. Such skills were a prerequisite for being able to share event details.

Challenging Experiences

Emotional Aspects of Involvement

Attending the meeting was a challenging emotional situation. Within our sample, next of kin were traumatized and they struggled with aftereffects, such as anger, grief, concentration problems, guilt, and distrust in the healthcare system, implying that they were in a vulnerable situation during the meeting. Many were not only dealing with their own grief and emotional reactions but also taking care of other family members. The results indicate that it was a large mental strain to be part of the entire investigation process. It was difficult for the next of kin to comprehend the different phases of the investigation, gain insights into all the documents, develop an overview, and conceptualize the complex medical and legal information. The documents received also repeatedly reminded them of the adverse event that led to the death, which complicated the experience, and several had to take long-term sick leaves.

Difficulty Understanding the Regulator's Role

The results indicate the importance of clarifying and understanding the regulator's role. Several next of kin struggled to understand the regulator's role and purpose of the meeting. They wondered about the meeting agenda and questions they were asked, as well as whether they helped the investigation, as they intended. Some next of kin found that the inspector's agenda and their own agenda did not fully match. Some cases were characterized as conflicts between the service provider/healthcare personnel and the next of kin. The inspectors collected information from both sides before drawing any conclusions, and next of kin argued that the regulator should clearly explain this to them.

Suggestions for Further Methods Improvement

Strengthen Information About Involvement and the Investigation Process

The next of kin had several suggestions for further improvement. They suggested improving the information letter to include

a clearer purpose of the meeting, attendees, and a timeline for the investigation process. One informant explained that she did not know about the adverse event causing the patient death until she got the letter from the regulator; she would have liked to have been informed in another way. A final suggestion related to the emotional stress. Inspectors should prepare suggestions for further follow-up in case the meeting turned out to be too challenging for the next of kin.

DISCUSSION

This article explored how innovative regulatory methods to improve user involvement in regulatory investigation have been developed and tested in Norway.[20,21] The drive for stronger user involvement in regulation is similar to that in other countries (e.g., Adams et al[15]). In our study, we directed attention to the next of kin's voices and how they experienced being involved in the regulatory investigation of a fatal adverse event.

Although involvement was emotionally challenging and it could be difficult to understand the role of the regulator, the next of kin had positive experiences of being involved. They held unique knowledge and insights that often made significant contributions to the investigation by identifying problems in care.[5,8,22] The inspectors' professional, social, and human skills (empathy, taking time, listening carefully, legal and medical knowledge) were key determinants for the positive next of kin experience from being involved. This issue is an important lesson for other regulatory bodies initiating user involvement in regulation.

To date, we have lacked knowledge about next of kin's involvement in such regulatory investigations. Informing investigations of adverse events causing death by involving next of kin is innovative regulation-wise,[20,23] and it is important to map and learn from next of kin's experiences. Similar to other studies,[1,12,13] we found that next of kin had different conceptualizations of the event compared with what was presented in the written information. Next of kin found that vital information was lacking or hidden, and they wanted to be involved because sharing their experiences filled a gap in the regulatory investigation, especially because they were the stakeholders with the most complete picture of the event. Although the meeting as a method was designed for the adverse events causing deaths, we argue that it would also be applicable in investigation of adverse events in general, in particular when the causality is complex. However, in these cases, we argue that the patient should be involved too. Perspectives from patients and next of kin might supplement each other.

Our findings support those of Kok et al,[1] who argued that the literature has two main lines of rationale for family involvement in investigations: (*a*) moral justification of being involved from an ethical perspective and (*b*) epistemological justification arguing that the family are experts in their own and can foster valuable learning information. Kok et al[1] found that such involvement was mainly conceptualized as useful when the family informed the investigation; therefore, the family's experiences and perspectives should be recognized as valuable in their own right and considered as the core of the investigation process. In our study, the next of kin perceived the meeting and opportunity to share their experiences as a good way of strengthen investigators' knowledge base when assessing compliance with regulations. Next of kin often added knowledge that implied the need for inspectors to collect additional information to get a more comprehensive understanding of the event. However, more research is needed to understand how patients and next of kin can be the core of regulatory investigations.[1]

The effects of regulation and compliance with standards in improving healthcare are complex and often focus on improving healthcare organizations' behavior, healthcare professionals' behavior, or patient outcomes.[24–26] Our study of user involvement in regulation illustrates the need to develop regulatory methods and shift approaches in conceptualizing the quality and voices that determine what is a relevant outcome in regulation processes. Patient experiences, next of kin experiences, and the conceptualization of quality and safety[27] should be integrated as relevant outcomes and criteria when assessing effects of regulatory activities—not only at the service provider level but also at the regulatory level.

In a resilient healthcare perspective, our study shows that next of kin are a vital source of understanding work carried out in healthcare practice.[5,8,28] Regulatory inspectors normally rely on written information from the involved stakeholders when healthcare fails, but important aspects are potentially lacking if next of kin's perspective is omitted. Involving next of kin contributed not only to informing the investigation but also to transparency and trust building at the individual level and potentially to the restoration of resilience at a systemic level because next of kin changed the way regulators investigated and generated new information that could be used for system improvement.[29]

Limitations

This study examined a project implemented by one county governor in Norway, and the sample could have been larger. However, we conducted in-depth interviews with 29 next of kin and observed 20 hours of meetings for a period of almost 1 year, thereby giving our study high information richness.[30] The sample has a potential selection bias because some of the most traumatized next of kin attending the meetings were considered to be too depressed and unstable to participate in the evaluation interviews. A pilot test was not conducted, but we changed order of some of the interview questions based on experiences in the first interview with the next of kin. The main data collection was also conducted by one researcher, creating consistency in the data gathered; the analysis was strengthened through collaborations among a team of researchers.[18] The perspective of the regulatory inspectors (not covered here) is included in Part II of the evaluation.[31]

Conclusions and Recommendations

When a close family member dies because of an adverse event and a regulatory investigation is initiated, next of kin expect to be involved and listened to; they also expect their information about the adverse event and the healthcare system to be considered. Despite the challenging situation, the next of kin had positive experiences when involved in the investigation and found that their information contributed to the investigation process by integrating additional information, new stakeholders, and a more correct understanding of the adverse event causing the patient's death. Meeting with inspectors was emotionally challenging, but the inspectors' adaptable professional, emotional, and human skills enabled next of kin to share their experiences with the inspectors. The rationale for being involved was to prevent the reoccurrence of similar events and ensure system improvements. Future research should examine the long-term effects of next of kin's involvement in regulatory investigations and compare the findings across different regulatory regimes in cross-country studies.

We recommend that regulatory bodies develop methods to collect information from next of kin in a dialog-based way when patients die because of adverse events. We recommend a stronger acknowledgement of the potential knowledge contribution from next of kin in informing the regulatory investigation. Being involved in such an investigation can be a very challenging emotional situation and the regulators should take time, explain

carefully the purpose and content of the involvement, and emphasize that the involvement is volunteer.

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