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Independent safety investigation in Norway – the work of UKOM from a risk management perspective.

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Abstract
The Norwegian Healthcare Investigation Board (UKOM) is a relatively new government body tasked with its mission of conducting independent safety investigation of serious incidents in the healthcare services. This study was developed prior to this proposal and aims to explore how UKOM's work has evolved from a risk management perspective, and how UKOM employees experience the processes of investigation and analysis, resulting in investigation reports. The study also aims to explore how investigators perceive investigations to influencing the healthcare system and contributing to system change and learning. The study employs an explorative design with a qualitative approach including semi-structured individual interviews with 11 participants from UKOM, conducted between January and April 2023. The study revealed that the learning potential from serious incidents is a key factor in selecting issues and events for investigation. Results showed that the composition of interdisciplinary investigator teams is an important resource, bringing diverse perspectives to the process and facilitating mutual learning within the team. The study also demonstrated that the legally mandated focus on learning, not punishment, fosters transparency and a safe space for sharing stories, thoughts, and opinions for both healthcare professionals and next of kin.

Keywords: UKOM, safety investigation, risk management, safety, learning, improvement.

1. Introduction

Each year, numerous patients worldwide suffer harm due to issues like incorrect or delayed diagnosis, improper treatment, infections, technical failures, medication errors (Bates et al, 2023; Directorate of Health, 2024). To gain insights from these incidents, conducting safety investigations constitutes an essential instrument for learning in addition to other ways of collecting and using information to avoid reoccurrence of these situations (Wrigstad et al., 2017; Wiig and Macrae, 2018).

However, the process of investigating and learning from serious adverse events is intricate and faces many challenges (Macrae and Vincent, 2014; Lea et al., 2023; Wiig et al., 2025). The Norwegian Healthcare Investigation Board (UKOM) is a relatively new government body tasked with a mission of conducting independent safety investigation of serious incidents in the healthcare services.

1.1. Public investigation bodies in infrastructural domains

The establishment of UKOM was inspired by the Norwegian Safety Investigation Authority (NSIA), which covers aviation, railway, road traffic, marine, and defense matters (Wiig et al., 2023). The context was partly political, partly professional, with a high risk of patient injuries and serious adverse events necessitating a systemic approach. According to Magnussen (2020), the establishment of UKOM was however a result from a political power struggle, where political control trumped professional recommendations. The Directorate of Health opposed the establishment of UKOM, and neither supervisory authorities nor other state bodies supported such a commission (Magnussen, 2020). It was argued that strengthening the Norwegian Board of Health Supervision (NBHS) was a better alternative than establishing a new commission (MHCS, 2015). Questions were raised about whether it would be a sensible use of resources to establish yet another body (MHCS, 2015; Magnussen, 2020, 2021). Those in favor of

UKOM emphasized lack of independence from the healthcare service as a significant obstacle to uncovering valuable learning points from events handled by the NBHS (MHCS, 2015). A new investigation commission without the authority to sanction was therefore seen as a buffer to the NBHS's lack of independence (Magnussen, 2020). Scholars have pointed to the same argument, by stressing the importance of having separate agencies of safety investigation with no attributions of blame or liability (Macrae and Vincent, 2014; Wiig and Macrae, 2018).

The main purpose of external investigation is to improve patient and user safety through learning and improvement, with healthcare professionals, patients, users, and next of kin being able to report without any risks (MHCS, 2017). UKOM has a system-wide scope, focusing on independent, multi-level, and multidisciplinary investigations to promote learning and patient safety, with no risk of blame, liability, nor sanctions. The patient and user perspectives are pillars in the approach. UKOM is subordinate to the Norwegian Ministry of Health and Care Services (MHCS) but has its own legal framework; the Act of the Norwegian Healthcare Investigation Board (MHCS, 2017).

Different means of external evaluation policies and regulations for quality improvement and safety of health services exist, with external inspection and external investigation being two governmental structures in Norway (Øyri et al., 2023). Although improving the services is the main objective of both structures, inspection and investigation have separate features. External inspection (performed by the NBHS and County Governors) supervises the health and care services to enhance safety and quality. External investigation (performed by UKOM) investigates serious incidents and other serious conditions to improve patient and user safety in health and care services (MHCS, 2017). The purpose of the reporting system to the NBHS (serious incidents for the most) is to quickly identify unacceptable conditions so they can be corrected, thereby improving patient safety (MHCS, 1999). The aim of UKOM investigations on the other hand is to examine the sequence of events, causal factors, and connections to contribute to learning and the prevention of serious incidents (MHCS, 2017). UKOM makes independent decision on which cases to investigate, the scale and scope and can take on cases based on information from multiple sources including patients, families, healthcare professionals, trends, and media to mention a few.

1.2. Gaps in knowledge

Research on the role of analytical models in safety investigations of serious adverse events in Norwegian healthcare, has provided insights into methodological and analytical aspects of past investigation reports (Øyri and Berg, 2022). These previous findings indicate various themes and analytical methods and models applied, based on key principles such as autonomy, confidentiality, public disclosure, non-punitive policies. Selection criteria are related to severity, complexity, representativity, relevance, knowledge gap, and learning potential. UKOM reports demonstrate a mix of systemic models, epidemiological models, and non-analytical approaches (Øyri and Berg, 2022). Although previous research has demonstrated limitations in UKOM's work, the body is still in its infancy and empirical studies are still lacking (Wiig and Macrae, 2018; Øyri and Berg, 2022). Our paper presents qualitative findings based on the perspectives of UKOM investigators. From a risk management perspective, this study therefore adds to the gaps in knowledge.

1.3. Aim and research question

This study aims to explore how UKOM's work has evolved from a risk management perspective, and how UKOM employees are experiencing the processes of investigation and analysis, resulting in investigation reports (Aven and Renn, 2010). The study also aims to explore how investigators perceive investigations to influencing the healthcare system and contributing to system change and learning.

2. Methods

The study applies a qualitative exploratory research design using individual interviews. The design was used to gather insights into employees' experiences with independent investigations of serious incidents in the health and care services. The study setting is the establishment and development of UKOM.

UKOM as such was recruited through an open invitation directed at the management level, which accepted the invitation to participate in the study. The recruitment of individual participants for interviews was conducted through email

invitation to employees working in UKOM. The aim was to interview participants with different backgrounds and experiences. A total of 11 participants were recruited. All participants participated in individual interviews conducted by the researchers (NV, SFØ, TBJ). A semi-structured interview guide was developed, focusing on themes such as teamwork, selection of cases and topics, choice of method, conduction of investigations, impact of investigations, competence and training, and frameworks and resources. At the end of the interviews, participants had the opportunity to share information not previously covered. The interviews were conducted between January and April 2023 at the participants' workplace and lasted approximately one hour. All interviews were audio recorded and transcribed.

The transcribed interviews were analysed according to qualitative content analysis (Granheim and Lundman, 2004). The analysis was conducted inductively and consisted of several steps. Transcribed data was carefully reviewed to gain a comprehensive understanding of the content. Subsequently, meaning units in the text were identified and condensed, followed by development of categories and overarching themes. A digital matrix was created for each transcription, manually marked with different themes. Finally, a complete matrix containing overarching themes and subcategories was created. The analysis was led by TBJ and NV. SFØ and SW were involved in discussions, and all agreed on the final themes.

The study was approved by the Norwegian Centre for Research Data (NSD), project nr. 954839. Written informed consent was obtained from all participants prior to the interviews.

3. Results

The analysis identified three categories reflecting the participants' experiences (Table 1). Results are presented thereafter, including quotes from the participants.

Table 1. Categories and subcategories

Categories	Subcategories
The nature of and risk potential of the issue or event is the basic selection criteria for investigation	The decision-making process
	Selection of cases for investigation
The composition of interdisciplinary investigator teams as a resource	Various perspectives
	Internal competence transfer
The legally mandated focus on learning fosters transparency in a safe space	Facilitating open meetings
	Learning and change as main objectives

3.1. The nature of and risk potential of the issue or event is the basic selection criteria for investigation

3.1.1. The decision-making process

The participants explained that many factors are decisive for the choice of cases for investigation**.** According to them, a rotating reception team is sorting incoming alerts, cases, media reports, and concerns. These cases are reviewed at the weekly reception team meeting, where it is decided whether the cases should further proceed to the monthly selection process meeting. At the monthly selection process meeting, the entire organization is represented, and everyone can provide input and discuss the cases from various perspectives. Finally, the cases are presented at the management team meeting, where the management team decides if, and possibly when, an investigation should be initiated. One participant described the decision-making process as follows:

There is a clear thread from receiving an alert to finally making the final decision in the management team meeting. (Participant E)

3.1.2. Selection of cases for investigation

According to the participants, the reception team closely monitors all national media and issues arising in the public debate. Additionally, all employees engage extensively in travelling, and meetings with healthcare services in both municipalities and specialist services, as well as with user organizations and professional organizations, suggesting topics they are concerned about in the context of patient safety.

The participants emphasized that they always keep severity, scope and learning potential in mind when selecting issues and events for investigation. Moreover, great emphasis is placed on ensuring that the adverse events have cross-learning value: that it can happen frequently and anywhere in the country. Other criteria for initiating an investigation are if the case is being considered severe for those affected; there is a

need for more knowledge, including fertile ground for initiating a learning process. As explained by one of the participants:

The event must be serious, common, and important, and it must be possible to do something about it. (Participant D)

3.2. The composition of interdisciplinary investigator teams as a resource

3.2.1. Various perspectives

There is a deliberate search for individuals with expertise in health sciences, safety sciences, and patient and user experience during team composition. The participants revealed that the leadership team assembles the individual investigation team, considering the topic of the investigation, employees' availability, expertise, and experiences.

All participants highlighted the advantages of having an interdisciplinary composition of competence within the teams. An interdisciplinary team composition helps ensuring a comprehensive professional assessment and various perspectives going into the investigations**.** The importance of being able to view a case from different angles was important, as well as avoiding "tribal language". One participant pointed out that if the team is too familiar with the professional environment they are investigating, the assessments can be very one-sided. By including other professional groups than healthcare professionals, other questions are being asked. It was also stressed that multidisciplinary teams ensure that specialized and expert knowledge are utilized in the best possible way. Participants emphasized that the teams, in all phases of the investigation, could bring in the expertise they need. This provided flexibility. One participant described it as follows:

We are looking at complex and difficult issues, meaning that we are completely dependent on having employees who can bring in different perspectives. (Participant H)

One participant pointed out that a key success factor for a good team is having a strong team leader who can engage and delegate. However, it was also explained that professional backgrounds and personalities in teamwork can be challenging. Participants noted that situations where investigators were involved in many teams simultaneously**,** could be challenging, as it could become difficult to structure the workday. Key to ensuring good teamwork, was thus to be patient and generous with the other team members.

3.2.2. Internal competence transfer

There was agreement among the participants that interdisciplinary teams are beneficial for knowledge transfer *within* the teams:

We are a learning organization, so at the end of the investigation process we should reflect on what we have done to be an effective team. We must also have learned something new and developed ourselves further. (Participant J)

3.3. The legally mandated focus on learning fosters transparency in a safe space

3.3.1. Facilitating open meetings

The fact that UKOM does not have the authority to impose formal sanctions, unlike the NBHS, was considered a strength. The participants experienced that UKOM's non-sanctioning and independent role makes people feeling safe when talking to investigators. According to the participants, this also allows them to delve deeper into the stories being told. The participants stated that this non-sanctioning approach provides more room for various perspectives and experiences, leading to greater transparency and better communication between investigators and those being interviewed. Topics that might be challenging to address without fear of supervision and possible sanctions, are easier to discuss when sanctions are unavailable. Several participants, however, emphasized that having supervisory authorities with different approaches than UKOM, is useful:

We absolutely need both, but I believe they need to be quite separate. (Participant F)

The participants experienced varying levels of maturity in the healthcare services regarding improvement competence at the system level. Familiarity with UKOM as a government body, varied, they claimed. However, participants explained that UKOM's non-sanctioning and independent role resulted in them being well-received by the healthcare services when conducting interviews. They also found participants to be honest during talks. However, one participant remarked that it is probably part of the human nature to show "the better side of things".

3.3.2. Learning and change as main objectives

The participants perceived UKOM to contributing to learning and improvement in the healthcare services. Some highlighted that an important part of UKOMS's impact is to increase the awareness

and debate about safety issues. Several participants reported that more and more examples exist of UKOM reports being applied in in the services: having real influence, seeing traces of their impact in various debates and cases. The participants noted that published reports are often revisited long after publication:

It is especially impactful when they address the learning points we have mentioned in our reports and arrange seminars and meetings to discuss (…). It spreads like ripples in water, and we see many examples of this. (Participant I)

However, some stressed that it could be challenging to measure the specific effect of what those involved have learned, how much change has really taken place, especially in bigger investigations. Therefore, the importance of developing good recommendations, enabling the services to implement real changes, was portrayed essential. Changes in regulations and the like was however explained to be processes of structural changes with a much longer time frame. Small steps would eventually be making a difference:

Will we ever going to have zero suicides in Norway? No. If the numbers go down, do we know what caused it? No. However, if we have a good debate around certain issues we can hope for a better and more ethically correct treatment. (Participant G)

Several of the participants explained how dissemination and evaluation of the reports were important, including participation at national conferences as a key part of the dissemination strategy. One participant stressed the importance of directing UKOM's recommendations towards the highest system-level possible:

I always aim to make recommendations as high up the system as possible, preferably to the ministry and lawmakers. It's about changing the framework conditions and redesigning the system. (Participant A)

The participants found that next of kin and patients who had experienced adverse events reported to UKOM as a way of preventing similar incidents from happening again, and thereby helping others.

4. Discussions and implications

The overall findings are discussed by the structure of two main aspects in a risk management perspective:

1) Fostering transparency by the means of non-sanctioning authority.

2) Facilitating learning potential through interdisciplinary and multilevel investigations.

4.1. Transparency and non-sanctioning authority

UKOM is governed by a designated act (MHCS, 2017), ensuring its independence. Our participants stressed this as an important structural feature to their job and the analytical process. Macrae and Vincent (2014) highlight that independent investigations in healthcare can be ensured through impartial authority. In the context of establishing an independent investigation institution in the UK, key aspects were independence, authority, transparency in its practices and recommendations. Investigations should be trusted, impartial, credible, and lead to practical changes. The agency must have the authority and expertise to investigate all aspects of the healthcare system and access all relevant information and parties (Macrae and Vincent, 2014). Although UKOM is independent with regards to selecting cases for investigation, the literature points to one clear criteria for intervention: it should cover serious patient safety incidents, major healthcare disasters, and emerging systemic risks (Macrae and Vincent, 2014). Despite both our results and previous results showing the cruciality of an independent investigation structure, there is currently a hearing to repeal UKOM's regulatory framework and incorporate the organization and its mission into the NBHS (MHCS, 2024). The outcome of this hearing will have major impact on the role of UKOM, and our results may therefore give substantial feedback to the government initiating the hearing.

Our results clearly highlight the value of UKOM having a sanction-free mandate, both in terms of administrative reactions and other types of sanctions. Based on our study's results regarding the UKOM mandate, it fosters transparency and offers a safe space for healthcare professionals, patients, and next of kin. The idea of a blame-free approach, as part of the culture of safety is not a new one and emphasized by Bruun Jensen (2008) and Behr and colleagues (2015).

A committee ("Varselutvalget"), appointed to assess the reporting systems of adverse events in the Norwegian healthcare system, acknowledges that a non-punitive reporting system for healthcare professionals may face resistance in the public due to the widespread

expectation that 'someone must be held accountable': “However, data from the NBHS and UKOM shows that serious incidents rarely involve 'ill will' from individuals (Ytterdahl et al., 2023). These incidents typically occur due to multiple simultaneous failures or poorly designed systems, procedures, and routines. Assigning blame to individual employees does not lead to improvement, therefore, system-focused improvement should be the basis for a new reporting system for serious incidents. Besides, incidents involving unfit personnel should be handled by supervisory authorities through other established arrangements (Ytterdahl et al., 2023). Support is found in research prior to our study, demonstrating how learning links with transparency and disclosure, which in turn links with a culture of improvement (Øyri et al., 2023; UKOM, 2023, Øyri and Wiig, 2023; Wiig et al., 2024).

Considering the proposed merge of UKOM and the NBHS, the MHCS de facto proposes to discontinue a sanction-free reporting system (Ytterdahl et al., 2023; MHCS, 2024). The MHCS refers to UKOM’s previous statements to “Varselutvalget” where UKOM stressed that incident reports as such do not provide learning, sanction-free investigations do (Ytterdahl et al., 2023). In contrast to the MHCS and “Varselutvalget”, UKOM advocates for upholding two separate systems (MHCS, 2024). The latter is consistent with our results.

4.2. Learning through interdisciplinary and multilevel investigations

Our results highlight the benefits of UKOM's interdisciplinary teams in investigations. The MHCS supports this, noting that UKOM's multidisciplinary environment and experiences with system-focused tools can enhance the methods of UKOM (MHCS, 2024). Macrae and Vincent (2014) emphasize that investigators must have a deep understanding of healthcare practice and policy, for effectively being able to conduct investigations. Others emphasize that diversity in investigation perspectives is beneficial as variability is considered a resource rather than a threat (Wrigstad et al., 2017).

Research by Øyri and colleagues (2024) suggests that external bodies can help adjusting routines and raising awareness about internal quality and safety issues, provided they possess relevant competence and knowledge. The presence of multiple external bodies can however create complex interconnections, with potential of putting health professionals under significant pressure (Øyri et al., 2024).

According to Macrae and Vincent (2014), the goal of an investigation is not only to uncover what occurred but also to identify improvements and involve relevant organizations from the beginning. Learning is a collaborative process that starts with the investigation, where experts must excel in relationship-building, network management, and effective communication, alongside their expertise in safety analysis (Macrae and Vincent, 2014).

Wiig and Macrae (2018) emphasize that recommendations in the investigation reports should aim for systemic changes. A key strength of UKOM is that each investigation produces a public report with safety recommendations, which should foster system-wide learning and publicly assign responsibility for improvements to key stakeholders. Our findings suggest that UKOM might not have fully realized its potential in this regard.

Our results indicate that independent investigations can reveal non-linear relationships. Previous findings support this (Dekker, 2014; Øyri and Berg, 2022). Dekker (2014) argues that attributing suffering to individual choices oversimplifies systemic failures, which often lack clear causes or linear relationships. Leveson and colleagues (2020) confirm, by emphasizing the need for a systems approach to prevent adverse events in hospitals.

Øyri and colleagues (2024) highlight the benefits of involving various stakeholders, such as patients and next of kin, in the evaluation process. Their involvement can provide valuable insights into the complexity of cases and enhance the inspectors' decision-making process (Øyri et al., 2024). Extensive stakeholder involvement may subsequently breed organizational learning (Øyri and Berg, 2022; Øyri et al., 2024; Wiig et al., 2021, 2021). Our study suggests that UKOM's approaches and reports can motivate healthcare organizations to identifying learning points. This is supported by the MHCS (2024), which emphasizes the importance of using serious incident reports for cross-learning. The MHCS (2024) highlights that if UKOM and the NBHS

become merged, the objective would still be to systematizing and identifying risk areas, disseminating knowledge, and contributing to overall learning and improvement in the healthcare services.

The legitimacy of external evaluations has shown to affiliate with communication skills (Hovlid et al., 2020, 2022; Øyri et al., 2024, 2024). Øyri and colleagues (2024) found that while some individuals had negative experiences with inspectors, others appreciated the professional dialogue focused on structural and systemic aspects. A lack of competence among inspectors was seen as a major issue, undermining trust in their decisions. As UKOM initially was suggested by families who lost their loved ones to an adverse event and afterwards experiences these to be covered up, UKOM promotes a clear patient and user voice in their work. However, as shown in the literature it is challenging, with both emotional and clinical aspects that need to be considered in a meaningful way for all stakeholders (Ramsey et al., 2022).

5. Conclusion

This study explored how the work of UKOM has evolved from a risk management perspective. It displays how UKOM employees experience the investigative, analytical process. Overall findings showed that UKOM's attention to multilevel safety issues and its cross-professional team composition, learning-oriented, non-punitive approach collaboratively play parts in promoting systemic change and learning and enhancing healthcare safety, whilst offering a safe space for healthcare professionals, patients and next of kin. UKOM works according to various models of risk management and draws inspiration from system safety thinking, having the goal of promoting comprehensive understanding of accidents and learning from patients, users, next of kin, personnel, and other system actors. UKOM's recommendations however, are largely directed at the organizational system as such and may therefore have less influence on the clinical and practical challenges in the healthcare system. Future research should explore how investigation outcomes are implemented and if these are lasting. Comparing UKOM's approach with other national and international safety investigation models may serve as one way of identifying best practices and potential areas for improvement. Furthermore, future studies could benefit from exploring how healthcare professionals and managers perceive safety investigation in comparison to external inspection to better understand the pros and cons of independent safety investigation in healthcare.

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