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Involving Patients and/or Their Next of Kin in Serious Adverse Event Investigations: A Qualitative Study on Hospital Perspectives

Linda J. Knap, LLM,† Rachel I. Dijkstra-Eijkemans, LLM,‡ Roland D. Friele, PhD,*† and Johan Legemaate, PhD§*

Background: The involvement of patients or next of kin (P/N) after a serious adverse event (SAE) is evolving. Beyond providing mandatory information, there is growing recognition of the need to incorporate their interests. This study explores practical manifestations of P/N involvement and identifies significant considerations for hospitals.

Methods: The data collection involved various qualitative research methods: 7 focus groups with 56 professionals from 37 hospitals, an interview with 2 representatives from the Dutch Association of Hospitals, and an interactive reflection seminar with over 60 participants from 34 hospitals. Before the focus groups, a brief questionnaire was sent out to survey participants' practices regarding into SAE investigations. After the study, another questionnaire was distributed to gather suggestions for future improvements and to identify their lessons learned. Thematic analysis was applied to the gathered data to identify key themes.

Results: Hospitals are increasingly acknowledging the interests and perspectives of P/N, recognizing their potential contributions to organizational learning and improvement. P/N involvement following SAEs includes active participation in different stages of the investigation process, not just passive information dissemination. Important factors influencing involvement are the provision of (emotional) support, identification of needs, and transparency of the SAE investigation.

Conclusions: This study enhances understanding of evolving practices surrounding P/N involvement in the context of SAEs in Dutch hospitals. The findings highlight the importance of promoting meaningful involvement, recognizing the significance of P/N experiences, and fostering a culture of transparency and collaboration. By examining the dynamics of involvement, this research aims to inform policy development and facilitate the implementation of patient-centered approaches to post-SAE care.

Key Words: serious adverse event investigation, involvement of patients and next of kin, hospital policy

Abbreviations: P/N = Patients and/or next of kin, SAE = Serious adverse events, The Inspectorate = Health and Youth Care Inspectorate, Wkkgz = Healthcare Quality, Complaints and Disputes Act

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In healthcare, when a serious adverse event (SAE) occurs, impacting patient care quality and resulting in death or severe harm, hospitals can be mandated to conduct thorough investigations. These investigations aim to identify the contributing factors, extract valuable lessons, and implement preventive measures.

Several countries, such as the Netherlands, Australia, the UK, France, and certain states in the United States (e.g., Maryland and Minnesota), have established mandatory reporting systems for all or specific severe patient harm incidents.[1] However, in the UK, the new national policy, the Patient Safety Incident Response Framework, mandates a shift from the broad approach to focusing on those incidents that provide valuable learning opportunities to enhance patient safety. This targeted approach aims to allocate resources more effectively and prioritize incidents with the greatest potential for learning to improve patient safety.[2]

Research on SAEs has evolved significantly, with a movement toward involving patients and/or their next of kin (P/N) in the investigation process.[3] This study examines hospitals' perspectives on this remarkable movement and explores the potential implications of this new collaborative approach.

Previous research underscores the value of involving P/N in identifying medical errors and improving patient safety,[4] highlighting the importance of exploring new approaches tailored to the specific information and improvement needs of both research authorities and family members.[5] It is crucial for SAE investigations to be flexible and sensitive to both clinical and emotional aspects of care to avoid compounding harm.[6] Integrating P/N in SAE investigations can be achieved in various ways and may offer an untapped reservoir of learning potential.[7]

Several studies have shown that P/N highly value being involved in the process, as it can facilitate reconciliation after a traumatic event and restore their trust in the healthcare system.[8–10]

From the *Netherlands Institute for Health Services Research (Nivel), Utrecht, the Netherlands; †Tranzo Scientific Center for Care and Wellbeing, Tilburg University, Tilburg, the Netherlands; ‡Tilburg Law School, Tilburg University, Tilburg, the Netherlands, and §University of Amsterdam, Law Centre for Health & Life, Amsterdam, the Netherlands.

Correspondence: Linda J. Knap, LLM, Netherlands Institute for Health Services Research (Nivel), PO Box 1568, 3500 BN Utrecht, the Netherlands (e-mail: lindaknap@live.nl).

ORCID: https://orcid.org/0000-0002-2598-5665
ORCID: https://orcid.org/0000-0003-1308-3696
ORCID: https://orcid.org/0000-0002-5602-826X
ORCID: https://orcid.org/0000-0002-7061-3991

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Ethics statement: Ethical approval was obtained from the Tilburg Law School Ethics Review Board. The Medical Ethical Review Committee of the VUmc has declared that this research does not fall under the scope of the Medical Research Involving Human Subjects Act (WMO).

Author's contributions: LK and RF had the original idea for the study and developed the proposal. LK and RF collected the data. LK and RD analyzed the qualitative data. LK wrote the first draft of the paper, and RF contributed significantly through proofreading and commenting on the paper. LK wrote all subsequent drafts of the paper and RF, RD, and JL all commented on these drafts. All authors have read and approved the final manuscript.

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Indeed, the coping process for P/N continues even after the completion of formal procedures related to the SAE process.[11] However, within the Dutch context, prior research has revealed a limitation in P/N involvement—often restricted to a single interview.[12] Regrettably, a prevailing notion persists that the P/N perspective, despite its significance, possesses restricted utility and validity in the realm of SAE investigations, where the professional perspective takes precedence.[12]

The evaluation of Dutch legislation, the Healthcare Quality, Complaints, and Disputes Act (Wkkgz), emphasized that P/N's interest in not only being informed but also being seen and heard.[13] This insight calls for a shift from a ritualistic approach to a more restorative justice-driven involvement of P/N, aligning with global perspectives.[14–16] This evaluation recommendation prompted the Dutch Health and Youth Care Inspectorate (the Inspectorate) to initiate this study, examining P/N involvement in Dutch hospitals. Thus, our central question remains: *How do hospitals involve P/N after a SAE and what drives their decisions?*

Several studies highlight a clear need to develop comprehensive and efficient policies for involving P/N in SAE investigations. O'Connor et al (2010)[17] and Busch et al (2020)[7] both emphasize the importance of patient involvement in these investigations, with O'Connor specifically calling for improved disclosure practices and Busch et al proposing a framework for patient participation.

Therefore, this study aims to contribute to the practice-based learning curve by guiding the integration of P/N into the SAE process. By offering globally relevant insights, this research contributes to the development of comprehensive and efficient policies for involving P/N in SAE processes.

METHODS

Research Design

This study is part of a broader exploratory research project focusing on P/N involvement after a SAE in Dutch hospitals, commissioned by the Inspectorate and assigned to us by ZonMw. Before the research commenced, the research protocol was reviewed and approved by the ethical review board of Tilburg University's Faculty of Law. Additionally, the VUmc Medical Ethical Review Board confirmed that this study does not fall under the Medical Research Involving Human Subjects Act.

The study involved 2 concurrent substudies: one examining the patient perspective and the other exploring the hospital's perspective on involving P/N in SAE investigations. The patient perspective substudy included 11 interviews with a total of 8 patients and 11 next of kin. Additionally, 2 broad consultations were held with 16 chairpersons and members of client councils, and an interview was conducted with a representative of the Netherlands Patients Federation.[18] Further details on the patient substudy are beyond the scope of this article.

This study specifically examines the viewpoint of healthcare professionals and representatives from an umbrella hospital association on the involvement of P/N in a SAE investigation.

The central research question is: *How do hospitals involve P/N after a SAE and what drives their decisions?*

Participant Recruitment

We invited all 74 Dutch hospitals, of which 37 hospitals (50%) participated. These included 4 academic, 13 top clinical, and 20 peripheral hospitals. We used contact information provided by the hospitals to invite specific professionals to participate, sending digital invitations containing information and registration links. Our inclusion criteria specified that participants must be professionally involved in handling SAE investigations within their respective hospital. The exclusion criteria ruled out individuals without such involvement.

Data Collection

The data collection included several qualitative research methods, which are outlined below.

Questionnaire Before Focus Groups

Before conducting the focus groups, a brief questionnaire was sent to all participants (N = 56) to gather data on their hospital's approach for handling SAEs and their awareness of the Wkkgz evaluation's recommendation on this topic (see Appendix 1, http://links.lww.com/JPS/A649). This provided a solid foundation regarding investigation approaches, saving discussion time during the focus groups on organizational details. As researchers of the Wkkgz evaluation, which inspired this follow-up study, we were also interested in participants' familiarity with this evaluation, helping us better contextualize discussions during the focus groups.

Focus Groups

We expanded our focus groups from 5 to 7 due to high registration, including professionals like quality and safety employees, complaints officers, patient representatives, and SAE investigators from Dutch hospitals. A total of 56 participants from 37 hospitals took part (Table 1), averaging 8 participants per group to ensure effective discussions.[19,20] Led by the same researcher for consistency, each session started with a standardized opening question about P/N involvement in hospitals, aligned with the research question (Appendix 2, http://links.lww.com/JPS/A650). All focus groups lasted 1 hour, were conducted digitally, recorded with consent, and transcribed for summarization. Summaries were then shared with participants for feedback within a two-week window.

Interview With the Dutch Association of Hospitals

An interview with 2 representatives from the Dutch Association of Hospitals provided a national-level perspective. Conducted digitally, it mirrored the questions used in the focus groups and was recorded with participants' consent. The transcription and summary of the interview were shared with participants for verification and approval.

Interactive Reflection Seminar

An interactive reflection seminar engaged over 60 professionals from 34 hospitals to discuss preliminary research findings and promote mutual learning. Participants included healthcare professionals and patient council chairs from all hospitals, including those not involved in the initial study. Reflecting on our findings, we sought to understand the general consensus, implementation of shared views, and remaining challenges. Following the seminar, participants received a digital questionnaire to provide feedback and insights for implementing in their work, completed by 18 participants. This feedback provided valuable suggestions for future improvements and identified key lessons learned from the study.

Analysis

To ensure a comprehensive analysis, data from multiple sources were systematically integrated. The initial questionnaire established

TABLE 1. Overview of Focus Groups

	Date	No. Participants	No. Hospitals Represented
Focus group 1	25 October 2022	8	5
Focus group 2	31 October 2022	7	5
Focus group 3	8 November 2022	9	7
Focus group 4	9 November 2022	10	6
Focus group 5	15 November 2022	8	6
Focus group 6	21 November 2022	6	4
Focus group 7	22 November 2022	8	6
Total		**56**	**39***

*Participants from 2 hospitals were divided into 2 focus groups making a total of 37 hospitals represented.

baseline practices and awareness levels, guiding subsequent focus groups. The focus groups offered qualitative insights into hospital approaches and considerations to P/N involvement in SAE investigations. An interview with the Dutch Association of Hospitals broadened the perspective to national policies. By integrating data from these different sources, a robust analysis of challenges and strategies around P/N involvement was achieved.

The analytical procedures involved open coding, categorization, and interpretation of qualitative data to thoroughly explore the research aims. Anonymous transcripts from all focus groups were initially open-coded using MAXQDA software by the primary author, with significant themes abstracted by the secondary author. Both authors adhered to Braun and Clarke's 6 phases of thematic analysis, incorporating input from the tertiary author to identify major themes.[21,22] The results were reported following SRQR standards and discussed during the reflection seminar.[23]

RESULTS

Since this research was prompted, in part, by a recommendation from the Wkkgz evaluation, we were interested in understanding its awareness and impact within hospital settings. The prefocus group questionnaire, sent to the participants (N = 56), was completed by 12 individuals (21.43%). Half of the respondents (n = 6) were unaware that the Wkkgz had been evaluated. The remaining respondents had either heard about it (n = 4) or discussed some results with colleagues (n = 2). Interestingly, all respondents indicated that the evaluation had no impact on hospital policies (n = 8) or were unsure of any impact (n = 4). A similar pattern emerged from the focus groups, where most respondents had heard about the evaluation but had not taken any concrete actions in practice, despite the evaluation containing a focused recommendation in this regard.

Our analysis of the questionnaire, focus groups, and the interview with the Dutch Association of Hospitals, showed that hospitals have long considered P/N involvement after SAEs, implementing diverse approaches shaped by multiple considerations. Our data identified the following 3 distinct stages in this process: (1) at the start of the investigation, (2) during the investigation, and (3) after the investigation. Each stage addresses unique focus points, detailed below.

(1) Shaping patient involvement at the start of the investigation

- Classification of a SAE

  Hospitals have the autonomy to determine whether an incident qualifies as a SAE, as this designation carries certain obligations such as reporting to the Inspectorate within 3 days and conducting an investigation within 6 weeks. We have noticed that hospitals tend to adopt a cautious approach to ensure accuracy, often organizing multidisciplinary discussions to make well-informed determinations. However, this cautiousness can result in delays in the decision-making process and in informing the P/N about categorizing the incident as a SAE.

  Considerations: Early classification can potentially harm the patient-provider relationship if it turns out afterward that the situation is not classified as a SAE. To prevent implausible scenarios and false expectations for the P/N, hospitals are taking careful measures through preliminary exam. By doing so, they aim to avoid inconveniences caused by reversing decisions made too early. Moreover, hospitals are keen on safeguarding the safety and well-being of the physicians involved in the incident. This includes monitoring their welfare and ensuring that decisions taken during the process do not put them at risk. By taking these measures, hospitals are striving to strike a balance between transparency, patient care, and the interests of their medical staff.

- Initiation of the first contact with the P/N

  Based on our observations, it is evident that several hospitals prioritize prompt communication of SAEs to P/N as soon as it becomes apparent that such an event has occurred. While the specific party responsible for initiating this initial contact varies among hospitals, this approach is handles with careful consideration. The treating physician, who maintains the highest level of interaction with the patient, the primary caregiver, the SAE committee, or a complaints officer could be involved in making the first contact.

  "We contact the patient or relative as soon as possible to explain the procedure and ask if they have any specific questions for the analysis. Their responses are included verbatim in the report, often revealing surprising and valuable insights."

Participant focus group 1

Considerations: Hospitals aim to establish a relationship of trust and transparency through open and honest communication. They prioritize keeping P/N informed, demonstrating accountability, and providing opportunities for clarification. The Dutch Association of Hospitals also explicitly mentions that restoring the trust of the P/N is the most important, as it forms the foundation of the doctor-patient relationship, and starts with a conversation.

- Identifying the needs and perspectives of the P/N

  Our study revealed that hospitals place a high priority on early identification of the needs of P/N during the SAE process, aiming to provide personalized support. Furthermore, we noticed that hospitals stress the importance of respecting the preferences of individuals who opt not to be involved, while making efforts to accommodate the preferences of those who choose to participate. Interestingly, certain hospitals go

a step further by integrating the information and inquiries from engaged P/N into the investigation and subsequent report.

"Every case is unique and asks for a tailored approach. We strive to respond to the needs of the patient or their next of kin in the hospital. If there is no desire for a conversation, we fully respect that, no matter how much we would like their input. What the patient wants is our priority."

Participant focus group 4

Considerations: Hospitals prioritize patient needs to demonstrate their commitment to taking patients seriously and providing patient-centered care. By valuing patient perspectives, they identify areas for improvement, enhance patient outcomes, and promote patient safety. This approach can foster a culture of continuous learning and ensure that hospitals are responsive to the needs and preferences of the individuals they serve.

"That is also often what the patient or next of kin are looking for - some recognition of their emotions and feelings. This was not the intention, and we would like to investigate it to understand and learn from it. We always receive a positive reaction from the patient or their next of kin when we do this".

Participant focus group 2

(2) Shaping patient involvement during the investigation

• P/N support services

Numerous hospitals recognize the importance of having a designated contact person to provide support to P/N. This role may encompass various titles such as disclosure coach, client contact person, or complaints officer. The crucial aspect is that this individual possesses undivided responsibilities and is accountable for guiding P/N throughout the process. In smaller hospitals, it was observed that this role tends to be frequently undertaken by a member of the SAE committee or the complaints officer.

"Because you see that the more open you are, there is actually much better collaboration, which ultimately helps us work more effectively with the patient or their next of kin."

Participant focus group 1

Considerations: Hospitals acknowledge the emotional impact that SAEs can have on P/N. They aim to provide compassionate care, offering support and assistance in navigating the healthcare system during challenging times. By being accessible and responsive, hospitals aim to ensure the well-being and comfort of P/N. Some hospitals see this as a separate process from the SAE investigation because they consider the investigation to be primarily for their internal purposes and the Inspectorate. Therefore, the conversations held with P/N serve the dual purpose of facilitating hospital learning and providing attention and space for the interests of the P/N.

(3) Shaping patient involvement after the investigation

• Decision to share or withhold the investigation report

We noticed a lot of variation concerning the decision to share the investigation report.

Generally, hospitals share the report or a modified version, such as a summary or governance reflection. Most hospitals do note that sharing should be accompanied by a conversation providing explanations. Some also include a disclaimer highlighting that the report focuses on learning and improving quality rather than assigning liability. They prioritize systemic issues over individual responsibility.

Hospitals often highlight that the report is intended for internal learning purposes, sanctioned by the Inspectorate, rather than for patients. This viewpoint is also supported by the Dutch Association of Hospitals.

Considerations: Hospitals value transparency and openness by sharing the report or key findings to demonstrate their commitment to learning and improvement. However, concerns about legal implications and negative media exposure may cause hesitation in some hospitals, as they aim to protect their reputation.

"In the beginning, we sometimes created a summary, but the reports have become so concise that a summary is no longer necessary. We have nothing to hide; on the contrary, we want to share everything openly, and this is very well received. (…) It is, however, important to provide a clear explanation alongside the report."

Participant focus group 5

"Ultimately, that report ended up in some Facebook group as soon as she had it. So, it raises the question of how safe it is to share the report. The report is anonymous, of course, but she can still attach names to it. These are difficult issues, in my opinion."

Participant focus group 7

• Final conversation or meeting

In accordance with the available data, hospitals invite P/N to participate in a concluding discussion. Some hospitals consider this discussion mandatory for receiving the report, seeing it as essential for providing comprehensive explanations. The composition of attendees at these discussions varies among hospitals and may include healthcare professionals directly involved in the case, a representative from the complaints department, a designated contact person, and, in some instances, a member of the Board of Directors.

Considerations: Through these final discussions, hospitals aim to ensure a comprehensive understanding of the incident, address any unresolved issues, and offer an opportunity for P/N to express their thoughts and concerns. This approach promotes transparency, supports patient-centered care, and fosters a sense of trust and accountability.

"We also keep our group small, so we do not sit there with four or 5 people facing one or 2 vulnerable individuals. Besides the report, we always have legal information with us, because some people, not always, still ask questions like 'What now?' or 'Can I get something?' We are very open about what the possibilities are in that regard."

Participant focus group 2

• Follow-up care and support

Most hospitals state that the responsibility of the SAE committee ends with report delivery. However, some hospitals extend postcare through dedicated patient contact persons, continuing support until the P/N expresses satisfaction or no longer requires further clarification.

Considerations: Hospitals recognize the importance of repairing and recovering the relationship with the P/N after a SAE. By providing ongoing support and addressing any remaining concerns or questions, they demonstrate their commitment to taking patients' feelings seriously and ensuring their satisfaction. This approach aims to rebuild trust, foster a positive patient experience, and strengthen the patient-provider relationship.

"We continue until the patient is satisfied. We try to prevent discrepancies by discussing the factual part with the patient before it goes to the Inspectorate. (...) We also want the patient to be satisfied with the content of the report, without compromising the accuracy of what actually happened."

Participant focus group 5

After collecting data, we conducted an interactive reflection seminar to discuss our findings. It was evident that while the consensus on the benefits of P/N involvement was strong, there were diverse approaches to its application. Postseminar feedback indicated that all participants viewed the reflection seminar positively, gaining new insights and practical tips applicable to their hospitals. Some saw it as validation of their current practices, while others identified areas for substantial improvement in how they involve P/N throughout the phases of SAE investigations. Participants appreciated the opportunity to exchange experiences and found it very useful to receive research results translated into concrete tips and recommendations for practical implementation.

DISCUSSION

This study highlights a notable shift where hospitals increasingly acknowledge the importance of SAE investigations for P/N. Previously, Dutch hospitals showed reluctance, such as hesitancy in sharing investigation reports.[24] This study shows that while there is now greater openness, hospitals vary in how they implement this approach. Hospitals' decisions in this regard are primarily driven by 2 motives: viewing P/N as valuable sources of information for learning and recognizing them as stakeholders with their own interests.

National and international literature support these findings, illustrating various global approaches that hospitals adopt to integrate P/N perspectives into SAE processes.[5,9,12] Involving P/N in adverse event investigations has been shown to provide valuable information and contribute to the investigation quality, although it can also be emotionally challenging and increase the workload for investigators.[9] To address these challenges, it is important to structure the involvement in a patient-centered way.[25] This can be achieved by providing support and preparation for the P/N, using easily accessible language, and offering different methods of involvement.[5] Overall, the involvement of P/N in SAE investigations can lead to a more comprehensive understanding of events and contribute to the learning potential.[9]

A significant contribution of our study is the identification of a third motive for involving P/N in SAE investigations: the restoration of the patient-provider relationship. This goes beyond viewing - P/N as valuable sources of information for learning and recognizing them as stakeholders with their own interests. It emphasizes the need to continue care and move forward together following a SAE. This relational intervention does not have to compromise the research quality but rather enhances it by fostering trust between patients and providers, as emphasized by the Dutch Association of Hospitals and corroborated by our interviews with P/N.[18]

We learned that most hospitals in our study, along with the umbrella hospital organization, stress the importance of restoring the patient-provider relationship by involving P/N throughout all stages of the SAE process. We identified three stages in which hospitals can take action to rebuild this relationship. The later this action is taken, the more challenging it seems to be.

Dutch hospitals are actively exploring strategies to balance the increased central role of P/N with other important interests, such as physician safety and institutional reputation. The diverse approaches highlight the nuanced decision-making hospitals face in maintaining credibility and operational integrity during SAE investigations. This complexity presents challenges. For example, as SAE investigations progress and conclusions are drawn, hospitals vary in how they share the investigation report with P/N, balancing organizational learning with concerns about institutional reputation.

The way we conducted our study contributed to learning at various levels. Hospitals shared insights and practices, such as sharing investigation reports with P/N, informed by discussions in our focus groups and reflection seminar. Our findings also inform regulatory bodies like the Inspectorate on adapting supervision to these evolving practices. Additionally, we hope our study promotes international knowledge exchange.

Strengths and Limitations

The study engaged a substantial number of hospitals (N = 37), exceeding initial expectations. An extensive reflection seminar with over 60 participants was also organized, along with discussions with the Dutch Association of Hospitals. This comprehensive approach provided a reliable overview of the situation in the Netherlands, forming a strong foundation for insights in other countries. It addresses universal challenges faced by healthcare systems globally. Many countries are grappling with how to effectively involve P/N in the aftermath of SAEs, aiming to improve transparency, accountability, and trust within the healthcare system. By examining the approaches and motives for P/N involvement in the Netherlands, our study provides insights that can be applied in various international settings. The emphasis on restoring the patient-provider relationship and balancing interests such as physician safety and institutional reputation resonates with global healthcare priorities. As healthcare systems worldwide strive to improve patient safety, our findings offer actionable insights that can help shape international best practices and policies.

However, this research primarily focuses on P/N involvement during the SAE process, leaving aspects like post-SAE care less examined. It captures hospital staff perspectives, offering insight into their viewpoints but does not detail how these align with healthcare providers' daily experiences or P/N perspectives. Additionally, while hospitals believe that P/N participation leads to deeper insights, it remains unclear whether this actually contributes to more effective learning from SAEs.

CONCLUSIONS

Involving P/N in all stages of the SAE process—initiation, investigation, and postinvestigation—ensures transparency and fosters trust. Hospitals involve P/N in SAE investigations not only to promote learning and recognize their interests but also to restore the patient-provider relationship. By emphasizing this third motive, our findings extend beyond the existing literature, illustrating a holistic approach to post-SAE care that prioritizes ongoing patient support and trust-building. The insights gained offer practical guidelines for involving P/N in SAE processes, addressing universal concerns about transparency, safeguarding institutional and physician interests, accountability, and trust within the healthcare system. By sharing these findings, hospitals worldwide can learn from our well-developed experiences, fostering global improvements in patient safety and care quality.

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