ADVERSE EVENTS REPORTING SYSTEM AS EXPERIENCED BY CRITICAL-CARE NURSES IN KWAZULU-NATAL, SOUTH AFRICA

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ABSTRACT

Critically ill patients admitted to critical-care units (CCUs) might have life-threatening or potentially life-threatening problems. Adverse events (AEs) occur frequently in CCUs, resulting in compromised quality of patient care. This study explores the experiences of critical-care nurses (CCNs) in relation to how the reported AEs were analysed and handled in CCUs. The study was conducted in the CCUs of five purposively selected hospitals in KwaZulu-Natal, South Africa. A descriptive gualitative design was used to obtain data through in-depth interviews from a purposive sample of five unit managers working in the CCUs to provide a deeper meaning of their experiences. This study was a part of a bigger study using a mixed-methods approach. The recorded qualitative data were analysed using Tesch's content analysis. The main categories of information that emerged during the data analysis were (i) the existence of an AE reporting system, (ii) the occurrence of AEs, (iii) the promotion of and barriers to AE reporting, and (iv) the handling of AEs. The findings demonstrated that there were major gaps that affected the maximum utilisation of the reporting system. In addition, even though the system existed in other institutions, it was not utilised at all, hence affecting quality patient care. The following are recommended: (1) a non-punitive and non-confrontational system should be promoted, and (2) an organisational culture should be encouraged where support structures are formed within institutions, which consist of a legal framework, patient and family involvement, effective AE feedback, and education and training of staff.

Keywords: adverse events; harm; patient safety; quality patient care



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INTRODUCTION AND BACKGROUND

Adverse events (AEs) can be defined as injuries, large or small, as a result of incorrect medical treatment or management (Hooper and Tibballs 2014, 200). Critically ill patients remain vulnerable, and several circumstances predispose these patients to medical errors and AEs (Welters et al. 2011, 1)). It is not surprising that there may be a higher incidence of AEs in critical-care units (CCUs), compared to other healthcare settings (Welters et al. 2011, 1). The high occurrence of AEs and incidents leading to preventable deaths remains a global concern, meaning that AEs should be seen as a public health issue, not only because of the human cost (lives lost, bodily integrity harmed, suffering), but also because of the associated financial cost (Guillod 2013, 182). About 50 000 to 100 000 people die from AEs each year in the United States of America, moreover, AEs occur in about three per cent of hospitalisations and approximately 10 per cent lead to patient deaths which could have been prevented (Bauman and Hyzy 2014, 13; Guillod 2013, 182; Wu et al. 2013, 186).

The actual mortality rate for patients in intensive-care units (ICUs) in South Africa is 31.5 per cent, with the predicted mortality rate being 30 per cent (De Beer, Brysiewicz, and Bhengu 2011, 2). These incidences are as a result of invasive procedures, numerous medical devices, and risks associated with polypharmacy (Welters et al. 2011, 1). The most common contributing factors include a shortage of critical-care facilities, (shortage of ICU beds), a shortage of skilled, knowledgeable staff, increasing workloads, and faulty equipment (De Beer, Brysiewicz, and Bhengu 2011, 3; Welters et al. 2011, 2). In South Africa, CCUs are additionally faced with a crisis as they are inundated with a heavy disease burden, with the scourge of HIV and AIDs, as the main contributors. Of the world's 40 million HIV-infected people, five million are in South Africa representing 10 per cent of the country's population (De Beer, Brysiewicz, and Bhengu 2011, 2).

South Africa is witnessing a sharp rise in medical malpractice litigation as patients become more and more conscientised with regard to their rights in a setting of an overburdened health system with limited resources (Pepper and Slabbert 2011, 29). According to the Health Service Executive (HSE 2013), reporting is fundamental to detect patient safety problems which can be measured in terms of harm prevented and lives saved. There are important barriers that impede disclosure; blaming the individual and the threat of future litigation are dominant in healthcare (Mountzoglou 2010, 542; Pepper and Slabbert 2011, 29; Wu et al. 2013, 186).

PROBLEM STATEMENT

The critical-care environment is fraught with medical errors that may harm patients (Wu et al. 2013, 186). AEs in hospitals contribute to patient harm and healthcare costs and yet remain under-reported (Hooper and Tibballs 2014, 199). It is perceived that irrespective of high percentages of occurrences of AEs, these incidences remain under-reported, and for those that are reported, little is done to prevent any recurrence as feedback may be

lacking (Moumtzoglou 2010, 546). There are gaps between patients and physicians in their attitude to the way errors should be handled, and between the disclosure policies and their implementation in practice (Wu et al. 2013, 186). It is clear that there has been a rising concern globally about the high occurrence of AEs and incidences leading to preventable deaths, ranging between 44 000 and 98 000, as a result of inadequate healthcare (Gonçalves et al. 2012, 72). Therefore, reducing the number of preventable AEs has become a public health issue (Guillod 2013, 182).

There is also an escalation in malpractice claims that may not encourage voluntary reporting, as there may be fear of punitive action. These punitive actions may have a negative impact on staff and patients, and that encourages under-reporting, decreased staff morale and it may even turn people away from the profession (Bhengu 2012, 59; Moumtzoglou 2010, 543; Wu et al. 2013, 188). The legitimate claims need to be compensated, and the state's ability to finance healthcare because of large payouts may be compromised (Pepper and Slabbert 2011, 29). South African nurses, including critical-care nurses (CCNs), are guided by the South African Nursing Council (SANC) and may face disciplinary actions due to professional misconduct (Bhengu 2012, 60). If the CCNs are found guilty owing to their acts or omissions, they may lose their jobs, and this may create a stigma.

The problem may be aggravated by the fact that there may be a lack of organisational support structures, both at professional and personal levels, and the absence of a legal framework to protect the disclosure of AEs (Wu et al. 2013, 190). Although the KwaZulu-Natal Department of Health has formulated AE reporting guidelines on the types, frequency and severity of AE, it is not clear if the existing strategies show evidence of implementation, monitoring and evaluation (KZNDOH 2013). It is still not clear if the culture of patient safety is diligently observed in most institutions and whether or not there exists the right attitude to and behaviour towards the effective utilisation of such a reporting system by staff. If this description is true, there should be evidence that a plan of action formulated to curb AEs, is implemented to ensure that the reported incidences are effectively dealt with and that the reporting system is effectively used to provide feedback and to reduce recurrences.

PURPOSE OF THE STUDY

To analyse the reported AEs and strategies employed to handle or deal with AEs in CCUs of the eThekwini District in KwaZulu-Natal, South Africa, in order to develop a framework of recommendations to remedy the situation.

The objectives of this study are to

- 1. examine the lived experiences of CCNs in relation to AE reporting in the selected hospitals in South Africa,
- 2. identify barriers to AE reporting in the selected hospitals in South Africa,

- 3. describe how AEs are handled or dealt with in the selected hospitals in South Africa, and
- 4. identify a gap in the handling of AEs with the aim of providing a solution.

DEFINITION OF KEYWORDS

Adverse events, in this study, refer to injuries that were directly caused by medical mismanagement or complications, instead of the underlying disease, that resulted in prolonged hospitalisation or disability at the time of discharge from medical care.

Harm, in this study, refers to an unintended physical injury, resulting from or contributed to by medical care that requires additional monitoring, treatment or hospitalisation, or resulting in death.

Patient safety means freedom from accidental injuries, and in this study, that an effort is made to ensure a safe environment for patients in CCUs resulting in the reduction of morbidity and mortality rates.

Quality patient care, in this study, means the standards of care that are rendered to ensure safe patient care and treatment, which lead to positive patient outcomes. It was reviewed as an important outcome in CCUs, as a result of the reduction of medical errors and other AEs.

RESEARCH METHODOLOGY

Research Design

A descriptive qualitative design was used to analyse the lived experiences of CCNs in relation to the AE reporting system.

Study Setting

The study was conducted in the CCUs of five hospitals of the eThekwini district, in KwaZulu-Natal, South Africa. These sites were chosen because they were the largest, busiest hospitals in Durban, and they were referral hospitals, with diverse patient profiles, referred from the CCUs from rural, semi-urban areas and from different provinces.

Sampling Method and Sample Size

The researcher was directed by data saturation from a purposive sample of five participants working in CCUs in five purposefully selected sites, who had completed the surveys. The purposive sample included four operational managers and one quality control manager, a former CCU nurse who had recently been promoted to this position.

These participants were chosen because of their high level of experience in CCUs, they met the inclusion criteria and had detailed knowledge, hence an information-rich source with respect to the purpose of the study (Table 1).

Inclusion criteria	Exclusion criteria
Critical-care trained registered nurses	Non-registered nurses
Nurses with experience in critical care (more than 1 year of service in a CCU)	Nurses who are inexperienced, (less than 1 year)
Operational managers who worked in CCUs and quality control managers, who previously worked in these units	Operational managers not working in CCUs
Willingness to participate	Not willing to participate

Table 1:	Inclusion	and	exclusion	criteria

Instrument for Data Collection

An in-depth interview was conducted on a purposive sample of five operational managers that had already completed the questionnaire during the quantitative survey. The main aim was to elicit more in-depth data from these managers, to elaborate more on their experiences in relation to the AE reporting system in their units. All participants had critical-care speciality, with critical-care experience ranging from four to thirty-nine years. The participants were from the urban area; three were from major public hospitals and two from major private hospitals in KwaZulu-Natal.

The interview consisted of two parts; the first part focused on the participants' demographic information and the second part was the actual conversation, with probing questions in accordance with the interview guide.

Participants were invited to respond to one essential open-ended question and six probing open-ended questions. Subsequent questions depended on the participants' responses and were guided by the interview guide. All interviews were recorded and transcribed verbatim by the researcher.

Essential Question

Tell me about your experience of adverse events in your unit that you will never forget. It can be your most meaningful one or the one that stands out in your memory.

Probing Questions

- Why was it so important?
- How did you handle it?

- How can reporting of adverse events be promoted in your unit?
- Are there any barriers to adverse events reporting in your unit? And what are they?
- Have you identified any gaps in the handling of events, and what are they?
- Is there anything else you would like to tell me?

Method of Data Collection

Data were collected from December 2015 to February 2016 and the interviews lasted for 40 minutes. Appointments were made with the selected institutions and the selected participants. In-depth interviews were conducted in a quiet room, with the unit manager's permission. A sign was put outside the door, informing the staff not to disturb. Interviews were conducted according to the participants' availability, convenience and in a way that it did not disrupt the participants' daily activities within the unit. Permission was obtained from the participant to record the interview using a digital voice recorder.

Trustworthiness

Qualitative research is evaluated by using the concept of trustworthiness. Four criteria are used to determine trustworthiness, namely credibility, dependability, confirmability, and transferability (Polit and Beck 2008, 539). These concepts were applied during the research process. The researcher had a prolonged engagement during the data collection process and interpretation which helped to gain an in-depth understanding of the phenomena under study. Persistent observations were made during the interview process. A detailed account of the research process, findings and recommendations was provided for the prospective researchers to make a judgement if the data apply to their context, and for transfer to their contexts.

Ethical Consideration

The research proposal received ethical approval from the Human Science Research Ethics Committee of the University of KwaZulu-Natal (reference HSS/1554/015D). Written permission to conduct the research was obtained from the KwaZulu-Natal Department of Health. Permission was also obtained from the heads of department and operational managers including the participants. Information sheets were given to the five participants, and the study and the purpose were presented to the participants. A written informed consent document was completed by every participant and signed, if they were willing to participate. Participants' and their institutions' names were not mentioned, codes were used, and recordings were kept by the researcher, under lock and key thereby ensuring confidentiality and anonymity. Participants were informed that they were not forced to participate and that they could withdraw from the study

even if they had already signed the consent form, without any negative consequences. Therefore voluntary participation was assured.

METHOD OF DATA ANALYSIS

The findings of the study, and the thoughts and feelings expressed by the participants during the individual in-depth interviews were outlined. Content was analysed using the Tesch method of analysis process which consists of eight steps (Creswell 2009, 207). Transcribed interviews were read a number of times and descriptive words were identified for the formulation of thematic statements. Concepts that created meaning were noted and notes were made of any ideas that came to mind. Each institution and participant was coded. Excerpts from the data supporting the identified categories and themes were coded and recorded. The data were categorised according to the perceived experiences of the reporting system and how the CCNs handled the AEs.

RESULTS

The participants were purposively chosen according their job level and experience in CCUs and management.

Table 2 shows the participants' demographic data. The type of CCU, the level of the participants' experience, whether they were ICU trained or not, and their job levels are shown. The names given to the participants are pseudo names to protect their identity.

Chosen name	Type of ICU	Age	Female/Male	Academic status: ICU trained	Level of experience in ICU	Job level
Carol	General ICU	52	Female	Yes	20 years	Quality manager
Stacey	Cardiothoracic surgical ICU	54	Female	Yes	39 years	Unit manager
Nomusa	Multidisciplinary ICU	45	Female	Yes	20 years	Unit manager
Monica	Surgical ICU	38	Female	Yes	10 years	Unit manager
Ranuka	Surgical ICU and paediatrics	40	Female	Yes	4 years	Unit manager

Table 2:	Participants'	demographics

Categories of information that emerged during data analysis included (i) the existence of an AE reporting system, (ii) the occurrence of AEs, (iii) the promotion of and barriers to AE reporting, and (iv) the handling of AEs.

Examination of the Lived Experiences of Critical-Care Nurses in Relation to Adverse Event Reporting in the Selected Hospitals

Findings demonstrated that CCUs are more prone to AEs and there were major gaps that affected the maximum utilisation of the reporting system. All participants verbalised that a reporting system existed in their institutions and that the structures and procedures for reporting were in place, but that in some institutions it was not effectively utilised or not utilised at all, hence affecting quality patient care.

An example was given by the quality manager, Carol, who was a unit manager before her promotion, of her experience in her institution:

I think reporting of adverse events should start outside the unit, with the management from the top, to create awareness in the units. Although we have an adverse event reporting management policy which is in line with WHO guidelines, we are not implementing that policy in terms of management. The reporting is there, we just don't have functional systems to manage them effectively.

Carol further expressed the following when she related her experience of AEs:

In the past years the adverse event reporting system did not exist. I used to think nobody has died, and therefore I don't see the importance of reporting.

It was clear that there were concerns about certain experiences by the CCNs when reporting AEs. Nomusa verbalised her concerns about the safety of patients in her unit:

We tend to focus on the prevention of adverse events, rather than reporting these incidences to monitor them closely, to identify the causes, the trends and report to prevent future occurrence and thus ensuring a safe environment for our patients.

Nomusa, who has 15 years of ICU experience and five years' experience as an operational manager outlined her experience as follows:

The ICU environment is prone to adverse events. Being in the management position, adverse events make your work hard as you have to be on the lookout of everything, to prevent the occurrence of adverse events, but they still do happen and you become accountable. It becomes scary, very scary ...

Renuka verbalised the following:

Adverse events do happen even if you have put preventable measures in place, and must be used as a learning curve.

Identification of Barriers to Adverse Event Reporting in the Selected Hospitals

Barriers that resulted in under-reporting were identified and were verbalised by almost all participants. These ranged from fear of litigation, victimisation, disciplinary action, punitive measures and ridicule by peers.

Renuka expressed her concerns:

Sometimes, especially on medication errors, the staff becomes afraid to report as it leads to disciplinary action, by the management or the South African Nursing Council.

This was echoed by experienced CCN, Stacey:

The system should not victimise people who come forward. People are scared, scared of litigation, ridicule from peers, as an adverse event is linked to a person, and you are professionally undermined by peers. We are also not supported by the management, if you report an adverse event it is perceived as you have done something very big or something very wrong. It becomes very discouraging ...

Some participants indicated that ignorance played a major role as a barrier to AE reporting. There was no difference in education, whether the staff had been trained in critical care or not. This was confirmed by Renuka:

My observation with some staff members is that there is lack of understanding of a formation of an adverse event and understanding of what an adverse event is or to realise that an adverse event has occurred. Therefore they see no reason for reporting ...

A shortage of staff was the main complaint from most participants. The CCNs see this as time-consuming and unimportant in relation to the critically ill patients' lives they are currently dealing with.

Nomusa commented:

It just becomes too much work, especially when you are busy, there is just no time. It is worse when you are short-staffed, the nurse:patient ratio increases, and you find yourself looking after two or even three patients. It's just too hectic! You really go home exhausted and you do not look forward to come to work the next day. I think this has contributed to high absenteeism rate and it defeats the whole purpose of trying to improve quality patient care.

Effective communication becomes essential when it comes to the reporting of AEs. Carol acknowledged the importance of communication within her units and expressed her feelings as follows:

There should be effective procedures that need to be clearly communicated to the staff. Sometimes we face challenges, especially when you try to involve family. You can try and explain an adverse event to them, and they may misunderstand and use the information given as a complaint.

Carol further expressed her frustration:

How much information do you give the family becomes challenging as you must be careful not to implicate yourself, as they may see it as negligence, if they don't understand what you are explaining. The hospital policy should be clearly communicated to the staff, on how reporting should be done and the feedback mechanism should be communicated and well understood by all involved individuals.

All participants unanimously suggested that the reporting of AEs should be used as a learning opportunity. Staff should be encouraged to report, and the information gained should be used for learning and sharing with colleagues, different units and institutions. This exercise can hugely improve patient outcomes.

Description of How Adverse Events are Handled or Dealt with and Identification of a Gap in the Selected Hospitals

Effective feedback becomes important as future occurrences of the same events are to be prevented. It was clear that the participants were not satisfied with the process of handling the reported AEs.

Stacey explained that some staff perceived the writing up of AEs as something complicated:

The nurses do not write what actually happened, most of the time the writing is disjointed, not flowing, and not reflecting a clear picture. The reports must be meaningful to the quality manager, so that they can be adequately captured.

Stacey echoed these comments:

There is no feedback from quality manager, unless there is an enquiry or a report needs to be rewritten or is not worded properly. This happens most of the time if the patient wants to sue the hospital. There is usually no response on the reported incidences, just to acknowledge that we have received the report and read it ... I feel that there must be some kind of feedback.

Most participants commented that when it comes to feedback of what has happened, most of the time the patients and their families are not involved. Carol stated:

According to the WHO guidelines family involvement should play an integral part of the reporting system. This is another gap, because we don't involve families, unless there is an investigation that needs to be done when the hospital is sued.

DISCUSSION

Examination of the Lived Experiences of Critical-Care Nurses in Relation to Adverse Event Reporting in the Selected Hospitals

Participants confirmed that, although the reporting system was in place, for some hospitals, reporting was not done. Anonymity of those staff members reporting was ensured to encourage reporting and staff members were encouraged to report in order to learn from AEs. The system was easily accessible, simple, quick and easily captured by the quality manager. As supported by the literature, simple anonymous incident reporting systems may improve reporting rates over complex non-anonymous computer-based systems (Welters et al. 2011, 7). Therefore, high incident reporting was evident in these hospitals, and it did not reflect poor quality, but revealed that the employees were actively reporting the AEs. According to West and Eng (2014, 1), more work and research are needed to develop a national reporting system template that has standard definitions, methodology, and reporting procedures.

It was also apparent that some participants lacked the knowledge on how to detect and analyse AEs, and what type of AE to report. According to Walshe (2008, 51), AEs are clearly important to healthcare organisations, not only because of their impact on patients but also because they can provide an insight into the quality of healthcare and an opportunity for improvement. There was a lack of awareness of the existing AE reporting system, and some participants indicated that they were not even aware that it existed in their institutions, hence there was no reporting. The literature suggests that an analysis of AE types and frequencies is crucial to raise awareness, identify common incidents, and implement preventive strategies (Welters et al. 2011, 1).

Identification of Barriers to Adverse Event Reporting in the Selected Hospitals

Findings revealed that AEs were not reported as expected to be reported. It was apparent that there were factors that led to under-reporting. The participants verbalised that although some actively reported the AEs, some did not report them owing to barriers that prevented them from reporting. There was a lack of support structures for healthcare professionals; they did not know where to go to seek support after an AE had occurred. Many hospitals still react to AEs as anomalies and attach blame to the healthcare professionals involved (Moumtzoglou 2011, 542). The main barrier was fear of litigation, disciplinary action by the SANC, victimisation and ridicule by peers, hence the under-reporting. Although some participants were encouraged to report, as an exercise to improve quality patient care, some CCNs felt that they were not adequately provided with a safe environment, for instance ensuring anonymity of the person reporting (Wu et al. 2013, 186). To some participants there was no clear definition of

what an AE is and they did not know what AEs to report on, therefore this led to the under-reporting of AEs.

Description of How Adverse Events are Handled or Dealt with and Identification of a Gap in the Selected Hospitals

The participants indicated that there was a huge gap in information on how the AEs should be handled or dealt with. This study also revealed that the AEs were not adequately dealt with in some of the institutions. It is important to communicate how AEs are handled, that is, effective communication between the healthcare provider, patients and their families becomes crucial, especially in the aftermath of an AE (Gauntlett and Laws 2008, 122). However, some participants verbalised that there was a lack of communication, especially the feedback on the reported AEs. According to Gauntlett and Laws (2008, 123), a lack of communication is experienced in CCUs; the ability to communicate well with professional colleagues, patients and their relatives is a fundamental clinical skill in intensive care medicine and central to good medical practice. The majority of the participants confirmed that there was a lack of communication among them, with the management, patients and their families. Participants also verbalised that communication with patients and staff does not occur most of the time as patients are critically ill, and on life support.

RECOMMENDATIONS

It is clear that there are still challenges experienced by CCNs from most institutions concerning the AE reporting system. Reporting of AEs must be perceived as an opportunity to learn and prevent recurrences to ensure quality patient care and patient safety. The following recommendations are based on the findings of this study:

- A simple, quick, web-based reporting system should be implemented in most institutions to eliminate time-consuming paperwork.
- A non-punitive and non-confrontational system should be promoted, where CCNs cannot divulge their identity and therefore "speak up" but remain anonymous. An organisational culture should be encouraged, where support structures are formed within institutions, and which consist of a legal framework.
- Patients and their families should be an integral component of the multidisciplinary team and must be involved in making informed decisions. There must be clear communication by a skilled health professional of what happened and how an AE occurred, how it was managed, and what improvement plans are put in place to prevent recurrences.

• CCNs should be taught how to detect and analyse AEs and what type and categories of AEs they need to report on. Awareness within the institution should be created, where policies and guidelines on what and how to report are clearly communicated. The process of writing up an incident report should be taught, and in-service training programmes on the need for and use of the reporting system should be conducted.

LIMITATIONS OF THE STUDY

The data collection was done over three months, therefore, other important information might have been missed. The sample might have been small, as the study was limited to only one district, not covering all districts in KwaZulu-Natal, therefore a multi-centred study might need to be conducted at a later stage. The eThekwini district has more hospitals with CCUs compared to other districts, therefore there might be no statistical difference in the findings. However, most of the participating hospitals are referral hospitals within the province and some parts of the neighbouring provinces.

CONCLUSION

The participants revealed that it is crucial to detect and analyse the AEs, for quality improvement and plans to be implemented to prevent recurrences. However, there were barriers that impeded the reporting of these AEs, hence the under-reporting owing to different contributing factors.

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