BMJ Open Unit-based incident reporting and root cause analysis: variation at three hospital unit types

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ABSTRACT

Objectives: To minimise adverse events in healthcare, various large-scale incident reporting and learning systems have been developed worldwide. Nevertheless, learning from patient safety incidents is going slowly. Local, unit-based reporting systems can help to get faster and more detailed insight into unit-specific safety issues. The aim of our study was to gain insight into types and causes of patient safety incidents in hospital units and to explore differences between unit types.

Design: Prospective observational study.

Setting: 10 emergency medicine units, 10 internal medicine units and 10 general surgery units in 20 hospitals in the Netherlands participated. Patient safety incidents were reported by healthcare providers. Reports were analysed with root cause analysis. The results were compared between the 3 unit types.

Results: A total of 2028 incidents were reported in an average reporting period of 8 weeks per unit. More than half had some consequences for patients, such as a prolonged hospital stay or longer waiting time, and a small number resulted in patient harm. Significant differences in incident types and causes were found between unit types. Emergency units reported more incidents related to collaboration, whereas surgical and internal medicine units reported more incidents related to medication use. The distribution of root causes of surgical and emergency medicine units showed more mutual similarities than those of internal medicine units.

Conclusions: Comparable incidents and causes have been found in all units, but there were also differences between units and unit types. Unit-based incident reporting gives specific information and therefore makes improvements easier. We conclude that unit-based incident reporting has an added value besides hospital-wide or national reporting systems that already exist in various countries.

Strengths and limitations of this study

- This is a large multicentre study conducted in 30 hospital units of 20 hospitals across the Netherlands.
- Incident reporting and feedback was unit based.
- Incidents with and without harm for patients were reported and analysed, because other high-risk industries have shown that incidents without harm occur more frequently and seem to have the same root causes than incidents with harm (adverse events).
- Staff members were interviewed about the written incident report to gain insight into underlying causes.
- All incidents may not have been reported during the study period, as incident reporting depends on the willingness of the care professionals to report; almost all incidents were reported by nurses.

reporting systems in other high-risk industries such as aviation, nuclear power and the chemical process industry.[1] Incident reporting systems in healthcare are systematically filled with information on adverse events and near misses, with the aim of identifying basic risk factors and thus enabling healthcare providers to improve their quality of care. For this purpose, reporting should be non-punitive, confidential or anonymous, independent, timely, systems oriented and responsive, and it should enable a systematic root cause analysis.[2]

By now, various countries have established national incident reporting systems generating several thousands of reports each year. Well known is the National Reporting and Learning System (NRLS) for England and Wales.[3] It has spread out since 2003 and received over a million reports in a period of 5 years, mainly from acute care hospitals.[4] From 2010, it became mandatory for National Health Service (NHS) trusts in England to report all serious patient safety

INTRODUCTION

Considerable effort has been put into establishing incident reporting and learning systems in healthcare. The first reporting systems in healthcare were introduced more than a decade ago, following the examples of

incidents to the Care Quality Commission as part of the Care Quality Commission registration process.[5] Other systems are the US Veterans Administration,[6] the Medical Event Reporting System (MERS)[7] and the national system for incident reporting in Canada.[8] A recent overview of existing systems has been given by the Reporting and Learning subgroup of the European Commission.[9]

Less clear is whether the results of these national systems are applicable to hospital units, the very places where changes and improvements have to be implemented. The national figures on incident types and root causes do not necessarily reflect the risks of a specific hospital unit or unit type. Possible differences could be related to the type of care delivered, the urgency of the care or the dependency on other care units for the care process of the own care unit. Unspecific feedback might be a barrier for change and improvement, because incidents that are not relevant for their daily practice might not engage teams. The literature on implementation has shown that results from other organisations get less accepted and hinder the acceptance of necessary changes.[10 11]

For that reason, the government and healthcare providers in the Netherlands have opted for a local and decentralised unit-based approach[12 13] instead of a general national reporting system for hospitals. Dutch hospital units have, in general, 20–30 beds of one or more specialty, for example, cardiology, surgery, neurology, internal medicine. Healthcare providers can report incidents, defined as any unintended event that could have harmed or did harm a patient, to a small trained team of colleagues, who analyse the process and system failures.

The assumption of the unit-based reporting system is that (1) incidents differ between units and unit types, and (2) incidents that are reported and analysed at the unit where the incident has happened will create a greater sense of urgency, and therefore more willingness to change practice. On the other hand, when incident types and root causes do not differ between unit types, then a national system is more efficient. Until now, no specific analyses have been conducted on existing unit-based incident reporting systems.

This article focuses on the first assumption and looks for variations in incident types and root causes reported in unit-based reporting systems in hospitals. The main research questions are: (1) What is the number of incidents reported in participating units? (2) What are the types of incidents, consequences for patients and root causes of reported incidents at unit level? (3) Are there differences in types and causes of incidents between types of units?

METHODS
Study design and setting
From October 2006 to February 2008, an observational study was performed to examine patient safety incidents at 30 hospital units of 20 hospitals in the Netherlands. The data of the study were gathered some time ago, but there has been no comparable study yet and the research questions are still valid and awaiting answers. The units of our study were of three different types (each type having 10 units), representing the core of hospital care: emergency medicine,[14] surgery[15] and internal medicine.[16] The data collection within the units took place in phases with a study period of 5–14 weeks per unit, depending on the reporting speed, to reach the advisable minimum of 50 incident reports per unit. When the number of reports is at least 50, the variety of possible patient safety incidents can be captured and a valid causal factor profile drawn up.[17] The study protocol was granted ethical approval by the VU University Medical Center review board in Amsterdam.

Healthcare providers (ie, nurses, resident physicians, medical consultants) at the unit were asked to report all patient safety incidents, directly after the incident had occurred or was discovered. Patient safety incidents were broadly defined as all events, no matter how seemingly trivial or commonplace, that were unintended and could have harmed or did harm a patient.[18]

Data collection
Reporting procedure
Before the start of the study, the staff received oral and written instructions about the aim and procedure of the study. They had two alternatives for the initial reporting of patient safety incidents: a pocketsize report card or a report form (either the report form developed for this study, or the report form that was already used by the hospital unit). On the report card, the name of the reporter, the moment in time and a short description of the incident were requested. The report form was more elaborate and additionally requested the involvement of the reporter in the incident, the phase of care, place, some patient characteristics and consequences for the patient. The reporters used the report card when they had no time to write down all details about the incident. A locked mailbox was placed in either the team or resident room, to drop the report cards and forms into. After each report, the researcher asked additional questions in a short interview. During these interviews, questions about the reported incidents and their context factors were asked. When the report was made on a report card, this interview took more time than when the detailed report form was filled out beforehand. No interviews were held with staff in hospital units other than the participating units.

Once or twice a week a researcher or trained nurse from outside the hospital visited the participating unit to collect the written reports and to interview the reporters. Occasionally, questions were asked by telephone.

Healthcare professionals were encouraged to report by means of bi-monthly newsletters giving information on types and numbers of incidents, and reminders during team meetings to direct staff's attention to reporting.

PRISMA analysis

All patient safety incidents were analysed by trained researchers using PRISMA-medical. PRISMA is a tool to analyse the root causes of a broad set of incidents.[19 20] The corresponding taxonomy with their categories and subcategories (see online supplementary appendix 1) to classify the root causes, the Eindhoven Classification Model (ECM), was used as a foundational component for the conceptual framework for the WHO World Alliance for Patient Safety's International Classification for Patient Safety.[21]

In general, PRISMA examines the relative contributions of latent factors (technical and organisational), active failures (human) and other factors (patient-related and other). Incidents are analysed in three main steps when using PRISMA. First, a causal tree is formulated. A short description of the incident is placed at the top of the tree, as the starting point for the analysis. Below the top event, all involved direct causes are mentioned. These direct causes often have their own causes. By continuing to ask 'why' for each event or action, beginning with the top event, the relevant causes can be revealed. In this way, a structure of causes arises, until the reporter cannot give any more factual information of underlying causes. The questioning also stops when the underlying cause lies outside the unit or hospital. Moreover, a lack of organisational or technical barriers is not labelled as an organisational or technical cause. An example: an electronic signal system for registration of medication can prevent an allergic reaction or double gift, but as long as such a system does not exist, this system can and will not be regarded as a cause. However, improvements of organisational procedures or techniques can arise from the identification of human errors. In the second phase, the identified root causes are classified with the ECM.

Statistical analyses

The incidents were classified into one of the eight types that were formulated after completion of the study, by looking at common themes in the reported incidents: Materials and equipment, Diagnosis and treatment, Medication, Protocols and regulations, Incorrect data and substitutions, Collaboration with resident physicians and consultants, Collaboration with other departments and Other.

The data of the reports were first summarised using descriptive statistics and frequency tables with 95% CIs. The 95% CIs were calculated using the simultaneous CI procedure for multinomial proportions.[22] Differences between the three unit types in the incidences of incident types and root causes were examined using multinomial logistic regression analyses. The analyses of incident types were performed with 2028 unique cases (N=2028 incidents); the analyses of root causes (main categories) were performed with 3015 cases (N=3015 root causes). Subcategories of root causes were only analysed for the two most frequently scored main categories:

human causes (N=2120) and organisational causes (N=521). SPSS V.20 and SAS V.9.2 were used to perform the statistical analyses.

RESULTS

Number of reports

A total of 2028 patient safety incidents were reported: 522 incidents in emergency medicine units, 881 incidents in surgical units and 625 incidents in units for internal medicine. The mean number of incident reports per unit was 52 (range 46–71) in emergency units, 88 (range 36–180) in surgical units and 63 (range 44–99) in internal medicine units. More than 80% of the reports were made by nurses, <10% by resident physicians or medical consultants and about 10% by other healthcare staff.

Types of incidents

All 2028 incident were classified into 1 of 8 incident categories (table 1). Nearly one-third of the incidents (29%) were related to medication. This includes medication preparation, administration and registration. In 15% of the incidents, there were problems with materials or equipment, such as defects of equipment or absence of necessary materials. In another 15% the incidents were related to problems with collaboration between departments.

The distribution of incidents per unit type differed. In general, most differences can be seen between emergency and internal medicine units. There were significant differences between all three unit types in the number of incidents in the categories Materials and equipment and Other. Incidents in units of emergency medicine were most often related to the collaboration between units, whereas surgical and internal medicine units most often reported medication-related incidents.

Consequences for patients

In more than half of the incidents (56% emergency, 62% surgery, 62% internal medicine), there were consequences for the patient. Between 3% and 10% (3% emergency, 6% surgery, 10% internal medicine) of the incidents involved physical injuries, for example, gastric bleeding when a protective drug was not administered or renal insufficiency because the patient had not received NaCl liquid for days. Mostly, consequences concerned suboptimal care (30% emergency, 41% surgery, 45% medicine) or inconvenience (45% emergency, 25% surgery, 11% medicine). An example of suboptimal care is a delay in starting the prescribed medication or administering less medication than prescribed, without observed consequences. Examples of inconvenience are: unnecessarily not being allowed to eat and drink before an operation, and long waiting times (eg, for medical consultant, physical examination, X-ray).

Table 1 Percentages and CIs of various types of incidents for all units and per unit type

Types of incidents	Emergency medicine N=522	Surgery N=881	Internal medicine N=625	Total N=2028
Collaboration between units*†	24.5 (20.5 to 28.9)	10.2 (7.0 to 13.5)	12.2 (8.3 to 16.0)	14.5 (12.4 to 16.7)
Eg, long waiting time for laboratory test results				
Eg, incomplete handover from other department				
Eg, difficulties finding a place for the patient in a nursing ward				
Collaboration with (resident) physicians†‡	17.0 (13.0 to 21.4)	10.1 (6.9 to 13.4)	5.0 (1.1 to 8.8)	10.3 (8.2 to 12.5)
Eg, long waiting time for resident or consultant to arrive				
Eg, insufficient supervision of resident physicians				
Eg, not able to reach resident or consultant				
Medication*†	7.3 (3.3 to 11.6)	33.0 (29.9 to 36.3)	41.9 (38.1 to 45.8)	29.1 (27.1 to 31.3)
Eg, prescription of medicine at incorrect dose				
Eg, medication expired				
Eg, medication instruction repeated twice				
Diagnosis and treatment‡	14.4 (10.3 to 18.7)	11.1 (8.0 to 14.4)	11.2 (7.4 to 15.1)	12.0 (9.9 to 14.1)
Eg, no assessment of amylase in drain fluid				
Eg, eyelid glued when gluing nose bridge				
Eg, no treatment for patient with wounds (pressure ulcers)				
Materials and equipment*†‡	20.3 (16.3 to 24.7)	15.6 (12.4 to 18.8)	8.5 (4.6 to 12.3)	14.6 (12.5 to 16.8)
Eg, materials out of stock				
Eg, error in electronic record system (unable to look up medical history of patient)				
Eg, examination cancelled because of defective radiology equipment				
Incorrect data and substitutions†‡	7.5 (3.5 to 11.8)	5.9 (2.7 to 9.2)	3.2 (0 to 7.1)	5.5 (3.4 to 7.6)
Eg, incorrect date on X-ray				
Eg, recovery nurse presents wrong patient to surgical department				
Eg, sticker with personal information of wrong patient pasted on laboratory request form				
Protocols and regulations*†	3.8 (0 to 8.2)	4.7 (1.5 to 7.9)	9.0 (5.1 to 12.8)	5.8 (3.7 to 7.9)
Eg, inconsistency in protocols				
Eg, protocol untraceable on the intranet				
Eg, staff not familiar with procedure in new protocol				
Other*†‡	5.2 (1.2 to 9.5)	9.4 (6.2 to 12.7)	9.1 (5.3 to 13.0)	8.2 (6.2 to 10.4)
Eg, fall				
Eg, loss of patient record				
Eg, patient leaves hospital without being discharged				
Total	100	100	100	100

*Significant difference between emergency medicine and surgery; $p < 0.05$.
†Significant difference between emergency medicine and internal medicine; $p < 0.05$.
‡Significant difference between surgery and internal medicine; $p < 0.05$.

Table 2 Percentages and CIs of main categories of root causes for all units and per unit type

Root cause type (main category)	Emergency medicine N=845	Surgery N=1250	Internal medicine N=920	Total N=3015
Human*†‡	60.2 (56.9 to 63.7)	72.1 (69.7 to 74.6)	76.7 (74.7 to 79.4)	70.2 (68.6 to 71.8)
Organisational†‡	25.0 (21.7 to 28.4)	16.1 (13.7 to 18.6)	11.8 (9.2 to 14.5)	17.3 (15.7 to 18.9)
Technical†‡	10.8 (7.5 to 14.2)	5.7 (3.3 to 8.2)	5.1 (2.5 to 7.7)	6.9 (5.3 to 8.6)
Patient related/other*†	4.0 (0.7 to 7.4)	6.2 (3.8 to 8.6)	6.3 (3.7 to 8.9)	5.6 (4.0 to 7.3)
Total	100	100	100	100

*Significant difference between emergency medicine and surgery; $p<0.05$.
†Significant difference between emergency medicine and internal medicine; $p<0.05$.
‡Significant difference between surgery and internal medicine; $p<0.05$.

Root causes of reported incidents

All 2028 incidents were analysed with PRISMA, resulting in 3015 root causes (ie, 845 in emergency medicine units, 1250 in surgery units, 920 in internal medicine units). Of all root causes, 70% were human, 17% were organisational, 7% were technical and 6% were categorised as patient-related or other (table 2). The three unit types had a different distribution of root causes. In general, more commonalities can be seen between surgical and emergency medicine units compared with in internal medicine units. The number of causes related to human factors significantly differed between all three unit types. Units of emergency medicine had the fewest patient-related causes, whereas units of internal medicine had the fewest organisational and technical causes.

The distributions of human and organisational root cause subcategories differed between unit types (tables 3 and 4). Several smaller and larger significant differences have been found between the three unit types. The most frequently occurring human root cause was related to faulty task planning and execution (intervention) (37%). Another frequent cause was a missing or faulty verification process (13%). Of the organisational root causes, 20% were related to safety culture and 19% to management priorities. The results show that emergency medicine units have a higher percentage of both human and organisational external root cause categories (causes outside the unit) than do surgery and internal

medicine units. In addition, in emergency units, an incorrect fit between the qualifications of hospital staff and the task to be performed is more often a cause of incidents than in internal medicine units. Internal medicine units have more causes related to the verification of the situation before starting an intervention, compared with the other two unit types. Surgical and internal medicine units had more intervention related causes than emergency medicine units. With regard to organisational causes, the results show that emergency medicine units have more causes related to transfer of knowledge and less causes related to culture than the other two unit types.

DISCUSSION
Principle findings

In general, the most frequently reported incidents were related to collaboration between units, medication, and materials and equipment. The most common root causes were human and organisational factors. About one-third of the human and organisational root causes originated outside the participating units. The most common human root cause was intervention-related, meaning that the right thing has been carried out by the caregiver, but not in the right way. Another frequent cause was a missing or faulty verification process. One-fifth of the organisational root causes were related

Table 3 Percentages of human root cause subcategories for all units and per unit type

Human root cause type (subcategory)	Emergency medicine N=510	Surgery N=904	Internal medicine N=706	Total N=2120
External*†	51.0 (46.9 to 55.5)	31.4 (28.0 to 34.9)	17.0 (13.3 to 20.9)	31.3 (29.1 to 33.6)
Knowledge-based behaviour	5.9 (1.8 to 10.4)	3.7 (0.2 to 7.1)	3.1 (0 to 7.0)	4.0 (1.8 to 6.3)
Qualifications*	3.1 (0 to 7.6)	1.2 (0 to 4.7)	0.6 (0 to 4.4)	1.5 (0 to 3.8)
Coordination‡	6.7 (2.6 to 11.1)	6.1 (2.7 to 9.5)	6.8 (3.1 to 10.7)	6.5 (4.3 to 8.8)
Verification*†‡	10.2 (6.1 to 14.7)	11.1 (7.6 to 14.5)	18.8 (15.2 to 22.7)	13.4 (11.2 to 15.7)
Intervention*‡	16.1 (12.0 to 20.6)	41.2 (37.7 to 44.6)	46.6 (42.9 to 50.5)	36.9 (34.7 to 39.2)
Monitoring‡	5.5 (1.4 to 10.0)	5.2 (1.8 to 8.6)	5.9 (2.3 to 9.8)	5.5 (3.3 to 7.8)
Other	1.6 (0 to 6.0)	0.2 (0 to 3.7)	1.1 (0 to 5.0)	0.8 (0 to 3.1)
Total	100	100	100	100

*Significant difference between emergency medicine and internal medicine; $p<0.05$.
†Significant difference between surgery and internal medicine; $p<0.05$.
‡Significant difference between emergency medicine and surgery; $p<0.05$.

Table 4 Percentages of organisational root cause subcategories for all units and per unit type

Organisational root cause type (subcategory)	Emergency medicine N=211	Surgery N=201	Internal medicine N=109	Total N=521
External*†‡	50.7 (44.1 to 57.5)	27.9 (20.9 to 35.2)	22.9 (13.8 to 32.6)	36.1 (31.7 to 40.5)
Protocols	8.5 (1.9 to 15.3)	12.4 (5.5 to 19.8)	20.2 (11.0 to 29.8)	12.5 (8.1 to 16.9)
Transfer of knowledge*†	16.6 (10.0 to 23.4)	8.0 (1.0 to 15.3)	12.8 (3.7 to 22.5)	12.5 (8.1 to 16.9)
Management priorities‡	15.2 (8.5 to 22.0)	21.4 (14.4 to 28.7)	22.9 (13.8 to 32.6)	19.2 (14.8 to 23.6)
Culture*‡	9.0 (2.4 to 15.8)	30.3 (23.4 to 37.7)	21.1 (11.9 to 30.7)	19.8 (15.4 to 24.2)
Total	100	100	100	100

*Significant difference between emergency medicine and surgery; $p < 0.05$.
†Significant difference between emergency medicine and internal medicine; $p < 0.05$.
‡Significant difference between surgery and internal medicine; $p < 0.05$.

to safety culture and management priorities. This general picture changes if we look more closely into the separate results of the three unit types. The results showed that there are differences in reported incident types that can be related to the unit type, for example, most incidents on collaboration with other units were reported in emergency units, whereas medication incidents were frequently reported in surgery and general medicine units. The three unit types also had different distributions of root causes, with most similarities between the surgical and emergency medicine units.

Relation with previous research

Various articles have described incidents of specific specialities or departments,[23–27] but no comparison of incidents and root causes between different hospital unit types has been made before. Pronovost, for example, described the results of voluntary and anonymous web-based incident reporting in the US Intensive Care Unit Safety Reporting System (Patient Safety Reporting System, PSRS). The 23 participating intensive care units (ICUs) reported 2075 incidents in 2 years. Common event types were medication, incorrect care delivery and line/tube/drain incidents. Contributing factors were deficiencies in training and teamwork issues. In contrast to our study, no specific unit-based feedback was given because the reporter could elect on whether to identify his/her ICU.[24] Another study of critical incidents in two UK emergency departments (EDs) revealed 443 critical incidents over a 12-month period. Common root causes were related to organisational issues outside the EDs, internal management issues and human errors (knowledge or task verification and execution). The authors also found significant differences between the EDs.[25] Compared with both studies, we found in our study a larger willingness of healthcare professionals to report incidents (on average 50 incidents in 2 months), but the results regarding root causes are similar.

In contrast to our study, research based on national reporting systems often describes large numbers and types of incidents, but lacks an analysis of underlying root causes, which is easier to set up in unit-based reporting systems.[28–30]

Strengths and limitations

In this large multicentre study, we analysed incidents with and without harm to patients, because other high-risk industries have shown that incidents without harm are also worth analysing and occur more frequently than incidents with harm (adverse events).[31] They seem to have the same root causes and contributing factors as adverse events. Therefore, learning can take place before patients are harmed.[32]

To gain insight into the quality of care, it is necessary to know more about the types of incidents, their root causes and the possibility of changing the context in which incidents occur.[33] But, besides the report of an incident, a discussion with those involved at a local level can lead to a deeper understanding. To facilitate this discussion, we gave participating units in our study more insight into their quality of care because of our knowledge of their specific root causes and context.

Our study has some limitations. First, it is possible that not all incidents were reported during the study period, as incident reporting depends on the willingness of care professionals to carry out. We do not know whether knowing that researchers would ask questions about the causes of an incident would inhibit care professionals from reporting. This may have biased our results, but we cannot be sure towards which direction. Second, most unintended events were reported by nurses. Consequently, the study mainly gives an idea about incidents related to nursing care and to a lesser extent to care processes by residents and consultants in the units.

Another limitation is related to the identification of root causes. Different researchers have interviewed the reporters. This may have introduced variation in the information gathered by the researchers. To minimise this effect, we trained the researchers extensively. A reliability study on the inter-rater reliability showed positive results. The inter-rater reliability for the number of root causes used in the causal tree was moderate (κ 0.45). The inter-rater reliability of classifying root causes with the ECM taxonomy was moderate to substantial at main category level (κ 0.70) and subcategory level (complete taxonomy) (κ 0.63).[17] Another study found similar results for the main category level (κ 0.70–0.81) and less positive results for the subcategories (0.40–0.47).[34]

Finally, the interviews about the events depend on the recall of the reporter. However, we strived for a small time lag between the occurrence of the incident and the interview.

Conclusion and implications

A decentralised incident reporting system is valuable if hospital units differ in the incidents that occur and in the underlying root causes. We found significant differences in incident types and especially root causes between emergency, surgery and internal medicine units. This means that it is important for hospital units to get insight into their own local pattern of root causes and prioritise improvement activities based on weak spots in their specific system. This can be achieved more easily in a unit-based incident reporting and feedback system than by a hospital-wide or even national reporting system providing aggregated general information back to all units. Furthermore, the opportunity to obtain elaborated information concerning the circumstances of the incident is important for improvement and more easily achieved in local reporting systems.

The next step, after reporting and analysing incidents, is actual learning and change in daily practice to prevent incidents from happening again. Future research should focus on effective strategies to change behaviour and learn from the incidents that have occurred. This change should be based on thorough insight into the incident types and their root causes at unit level. Direct and immediate feedback to healthcare professionals is extremely important, to keep them continuously engaged. A database with information on types of incidents and types of root causes may help to identify trends, record contributory factors and allow units to monitor changes over time.

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