ABSTRACT: This study aimed to investigate the occurrence of, and factors associated with, near misses related to the safety of patients undergoing inpatient treatment in the surgical clinic of a teaching hospital. It is a transversal study, undertaken with 750 episodes of inpatient treatment undertaken in 2010, using the medical records as the data source. Data collection occurred in January – May 2011. Univariate analysis and logistic regression were undertaken. The recording of near misses occurred in 1.7% of all the episodes of inpatient treatment. A total of 18 near misses was recorded, that related to the process of prescribing medications being the most frequent. Being male was associated as a protective factor. The need was ascertained to encourage health professionals to record near misses, so as to support the learning process at work, make it possible to study the causal factors, and promote improvements in the work process.

DESCRIPTORS: Patient safety; Medical errors; Management of quality.
INTRODUCTION

Medical responsibility and the increase of incidents with negative results are frequent topics in the health area, which has led to discussions regarding patient safety worldwide. Incidents are defined as any unexpected occurrence during the provision of care which can result in harm to the patient. The incident considered most serious is the adverse event, as this obligatorily results in some type of harm to the patient(1).

One transversal study undertaken in five countries of Latin America estimated the prevalence of adverse events at between 7% and 13%(2). In Rio de Janeiro, a cohort study undertaken in three hospitals indicated, as the main avoidable adverse events, healthcare associated infections, which represent 24.6% of the occurrences, followed by surgical and/or anesthetic complications with 20.0%; harm resulting from delays or shortcomings in diagnosis and/or treatment, 18.4%; and pressure ulcers, 18.4%. Other adverse events identified were associated with venipuncture, falls and the administration of medications. The study also indicated that these events were responsible for an additional 373 days spent in hospital.

In the surgical context, as a result of the 234 million operations undertaken each year, it is estimated that incidents occur with seven million patients, and that one million die(4). In Latin America, adverse surgical events vary from 3.5% to 16.4%(2), with 65.8% being considered avoidable, according to Brazilian research(5).

Following evidence that the care can entail unnecessary harm for the patient, health organizations’ interest in improving safety during care provision has grown. In this perspective, the study of the near miss, which is defined by the World Health Organization (WHO) as an incident which, by luck or judgment, was intercepted before it reached the patient(1), has been depicted as an indicator for evaluating an organizational system, as it indicates flawed points in the work process.

A prospective transversal analysis of nine endoscopy units evidenced the recording of 230 incidents, of which 29% were considered adverse events, and 71% considered near misses. Of the 164 near misses analyzed, 72% were used to assist in the adoption of interventions for correction and improvement of the work process, reducing the chances of an error reaching a patient(6).

As this represents a potential adverse event, the WHO encourages the recovery and active monitoring of near misses by health institutions(1); nevertheless, this initiative remains little observed and is incipient in the health institutions. With the aim of shedding light on the risks in healthcare, supporting the studying of the near miss so that corrective actions can be adopted, and stopping this potential adverse event from resulting in harm, this study aims to investigate the occurrence of, and factors associated with, the near misses related to the safety of patients receiving inpatient treatment in the surgical clinic of a teaching hospital.

METHOD

This is a retrospective cohort transversal study; its data source was the medical records of patients receiving inpatient treatment in the Surgical Clinic of a teaching hospital inserted in the Sentinel Hospitals Network of the Brazilian National Health Surveillance Agency.

The choice of the surgical clinic for undertaking the study was motivated by the researchers’ experience in the surgical context, by the professionals having received training regarding incidents and the importance of recording their occurrence, and by the hospital’s having participated in studies on safe surgery in conjunction with the Pan-American Health Organization.

The study population was made up of all the medical records for episodes of inpatient treatment in which the date of admission was between January and December 2010, totaling 2,610. In order to determine a sample which was representative of the total population, the OpenEpi calculation tool was used, considering the following parameters: hypothetical frequency of 50%, as there are no studies dealing with the prevalence of near misses in the context of the WHO classification; a margin of error of 5%; and a design effect of 2.0, so as to ensure a robust population to be studied. A further 80 medical records were added, due to possible losses related to the capturing of data, which totaled a sample of 750 medical records, which were selected at random in a probabilistic and systematic way.

Episodes of inpatient treatment lasting over
24 hours were included, and which had pages on the actions undertaken and on the patients’ progression. All the medical records selected were subjected to evaluation so as to estimate the occurrence of near misses in the surgical environment. The search for incidents was guided by operational definition, based in the scientific literature and elaborated by the researchers themselves. The investigation took place through the thorough reading of all the conducts of the multi-professional team recorded in the pages relating to actions undertaken with the patient’s prescription and to the patient’s progression, from admission through to discharge from hospital.

The data were collected between January and May 2011. A structured questionnaire divided in two parts, pre-validated in a pilot study, was used. The first part contained questions for the investigation of the patients’ characteristics and aspects of the inpatient treatment. The second part investigated the characteristics of the incident, and contained space for transcribing the record identified, for later analysis and classification of the incident.

The transcriptions of the records of the incidents formed the corpus of analysis, being identified by the letter R, followed by a cardinal number, in accordance with the order of the episodes of inpatient treatment. Following this stage, the study proceeded to the analysis of the incidents identified for the classification of the near misses, which was undertaken by three researchers, lecturers and specialists in the issue of patient safety, with training in nursing. The specialists’ work was to analyze and compare the records collected with the definition of near miss proposed by the WHO, in the International Classification for Patient Safety.

The data were inserted in the Statistical Package for the Social Sciences software, version 20.0, for Windows. Descriptive analysis of the data was undertaken, and, in order to estimate the factors associated with the near miss in univariate analysis, the Chi-squared test was used and, when necessary, Fisher's exact test, with the OR (Odds Ratio) as the measurement of association. Multivariate logistic regression analysis was undertaken with the following variables: sex, age, and those which obtained $p<0.10$ in univariate analysis. Confidence intervals of 95% were calculated, and those associations which obtained a value of $p<0.05$ were considered statistically significant.

The work was approved by the Ethics Committee, under protocol N. 064/2008. All the Brazilian and international standards for ethics in research involving human beings were respected.

RESULTS

A near miss was recorded, at least once, in 1.7% (13) of the 750 episodes of inpatient treatment. A total of 18 near misses was recorded, corresponding to 1.4 occurrences per episode of inpatient treatment affected by a near miss, with 17 (94.4%) cases being related to medication, and one (5.6%) related to the surgical intervention.

The prescription of medication for an allergic patient corresponded to 16 (88.9%) near misses, and, in all the situations, the administration was intercepted by the patient him-or herself, who mentioned the allergic condition on questioning the health professional regarding the name of the medication:

10hrs. Patient mentions allergy to dipyrone. (R12)

22hrs. Prior to initiating the administration of Dipyrone, in accordance with the prescription, I was informed by the patient that she was allergic. (R351)

The main professional conduct was to stress, in the page relating to actions undertaken with the patient, the patient’s allergic condition, followed by a request to suspend the use of, and substitute, the medication. The professional category responsible for recording all the near misses relating to the administration of medications to allergic patients was the nursing technician.

One (5.6%) recorded of a near miss related to overdose of radiocontrast medium was verified. The near miss was intercepted by the professionals from another department, in the same institution, as they prepared the patient for a test which required the use of contrast. The test was cancelled after they ascertained that, on the same day, the patient had already received an intravenous dose of contrast:

15hrs. Patient prepared and sent for test, but this was cancelled due to the patient already having...
undertaken a test today, in the morning, involving the use of contrast. Test re-scheduled for next Wednesday. (R122)

The conduct taken in relation to the near miss was the rescheduling of the test, which extended the patient’s period of inpatient treatment. It is noteworthy that the patient was prepared for the test, was moved from the inpatient unit and occupied the place of patients who might have needed the same test, interrupting the unit’s work plan.

In relation to the clinical process, the occurrence was ascertained of one (5.6%) case of mistaken diagnosis which resulted in a near miss related to the surgical intervention:

08:30hrs. Operation cancelled. Disregard trophic wound and start clinical treatment. (R75)

Although the operation was intercepted, the patient underwent preoperative tests, as well as being subjected to unnecessary inpatient treatment and to preparation for surgery.

Table 1 presents the univariate analysis related to the occurrence of near misses recorded in the patients’ medical records.

In the univariate analysis, the values of p< 0.05 indicated a statistical difference for the following variables: male sex, time of inpatient treatment equal or superior to four days, prescription of three or more medications per day, use of a urinary catheter and transfusion of blood products, evidencing patients with characteristics of greater probability for being exposed to a near miss.

In order to ascertain the behavior of these variables as independent factors for the occurrence of near misses, the same were subjected to logistic regression analysis, as shown in Table 2.

The logistical regression evidenced that the only independent variable associated with the occurrence of the near miss was male sex, which behaved as a protective factor, indicating a lower probability of the occurrence of a near miss in comparison with the female sex.

Table 1 – Univariate association between the variables of exposure and the occurrence of near misses, during inpatient treatment in the Surgical Clinic of a teaching hospital. Goiânia-GO, 2011.

<table>
<thead>
<tr>
<th>Variables</th>
<th>n exposed/total</th>
<th>%</th>
<th>p</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age in years</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Up to 45</td>
<td>7/351</td>
<td>2,0</td>
<td>0,781</td>
</tr>
<tr>
<td>46 or over</td>
<td>6/399</td>
<td>1,5</td>
<td></td>
</tr>
<tr>
<td>Sex</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Male</td>
<td>1/301</td>
<td>0,3</td>
<td>0,016*</td>
</tr>
<tr>
<td>Female</td>
<td>12/449</td>
<td>2,7</td>
<td></td>
</tr>
<tr>
<td>Comorbidity</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Yes</td>
<td>8/312</td>
<td>2,6</td>
<td>0,141</td>
</tr>
<tr>
<td>No</td>
<td>5/438</td>
<td>1,1</td>
<td></td>
</tr>
<tr>
<td>Type of admission</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Emergency</td>
<td>4/134</td>
<td>3,0</td>
<td>0,264</td>
</tr>
<tr>
<td>Elective</td>
<td>9/616</td>
<td>1,5</td>
<td></td>
</tr>
<tr>
<td>Time of inpatient treatment in days</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Four or more</td>
<td>10/329</td>
<td>3,0</td>
<td>0,015*</td>
</tr>
<tr>
<td>One to three</td>
<td>3/421</td>
<td>0,7</td>
<td></td>
</tr>
<tr>
<td>Number of medications prescribed per day</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Three or more</td>
<td>10/325</td>
<td>3,1</td>
<td>0,014*</td>
</tr>
<tr>
<td>Up to two</td>
<td>3/425</td>
<td>0,7</td>
<td></td>
</tr>
<tr>
<td>Surgical intervention</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Yes</td>
<td>9/644</td>
<td>1,4</td>
<td>0,098</td>
</tr>
<tr>
<td>No</td>
<td>4/106</td>
<td>3,8</td>
<td></td>
</tr>
<tr>
<td>Antibiotic prophylaxis</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>No</td>
<td>6/277</td>
<td>2,2</td>
<td>0,565</td>
</tr>
<tr>
<td>Yes</td>
<td>7/473</td>
<td>1,5</td>
<td></td>
</tr>
<tr>
<td>Use of urinary catheter</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Yes</td>
<td>8/235</td>
<td>3,4</td>
<td>0,030*</td>
</tr>
<tr>
<td>No</td>
<td>5/515</td>
<td>1,0</td>
<td></td>
</tr>
<tr>
<td>Use of penrose drain</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Yes</td>
<td>2/107</td>
<td>1,9</td>
<td>1,000</td>
</tr>
<tr>
<td>No</td>
<td>11/643</td>
<td>1,7</td>
<td></td>
</tr>
<tr>
<td>Use of intravenous catheter</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Yes</td>
<td>12/680</td>
<td>1,8</td>
<td>1,000</td>
</tr>
<tr>
<td>No</td>
<td>1/70</td>
<td>1,4</td>
<td></td>
</tr>
<tr>
<td>Transfusion of blood products</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Yes</td>
<td>4/62</td>
<td>6,5</td>
<td>0,017*</td>
</tr>
<tr>
<td>No</td>
<td>9/688</td>
<td>1,3</td>
<td></td>
</tr>
</tbody>
</table>

*Statistical significance, as p<0.05. Obtained using the x2 test.
Table 2 – Logistic regression and measurement of association (Odds Ratio) of the variables for exposure to a near miss, with p<0.05 obtained in univariate analysis, which occurred during inpatient treatment in the Surgical Clinic of a teaching hospital, Goiânia-GO, 2011.

<table>
<thead>
<tr>
<th>Risk factors for near miss</th>
<th>Odds ratio (ic 95%)</th>
<th>P</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age &gt; 45 years old</td>
<td>1.8 (0.6 – 5.8)</td>
<td>0.311</td>
</tr>
<tr>
<td>Male sex</td>
<td>0.1 (0.0 – 0.9)</td>
<td>0.039*</td>
</tr>
<tr>
<td>Time of inpatient treatment &gt; 4 days</td>
<td>1.5 (0.3 – 7.2)</td>
<td>0.638</td>
</tr>
<tr>
<td>Medications prescribed &gt; 3/day</td>
<td>2.3 (0.5 – 10.6)</td>
<td>0.290</td>
</tr>
<tr>
<td>Undertake surgical intervention</td>
<td>0.3 (0.1 – 1.1)</td>
<td>0.065</td>
</tr>
<tr>
<td>Use catheter</td>
<td>3.1 (0.8 – 12.4)</td>
<td>0.115</td>
</tr>
<tr>
<td>Transfuse blood products</td>
<td>2.6 (0.6 – 10.6)</td>
<td>0.199</td>
</tr>
</tbody>
</table>

*Statistical significance, as p<0.05. Obtained based on the x2 test.

DISCUSSION

Near misses occurred at a rate of 1.7%. The development of the culture of recording these indicators must be encouraged, taking into account the WHO recommendations for the detection of latent failures, with the allocation of resources being directed towards preventive actions.

James Reason\(^{(7)}\) argues that the health system may be compared to a Swiss cheese. The holes represent the latent failures of the work process which, if not controlled and/or resolved, can result in an active failure, that is, an incident which reaches the patient. Therefore, studying near misses can contribute to the identification of gaps, and be reflected in an increase of the health institutions’ chances of success in dealing with unsafe acts and allowing the continuous improvement of the work process.

Two types of near misses were identified, which evidence the multifactorial characteristic and the systematic dimension in which they are inserted. Those related to medication indicated the need to alter the process for prescribing medications, particularly, in the factor of patient involvement during the prescription, as this must be preceded by investigation relating to the medications in continuous use and to a history of allergic manifestations.

Prescribing errors can vary from 24.0% to 29.3%, depending on the actions adopted by the health institution. However, reducing their occurrence does not influence the seriousness of the consequences for the patient\(^{(8)}\). One transversal study undertaken in a teaching hospital ascertained that of the total number of incidents related to medication, 4.1% related to prescribing errors, which were classified as near misses, as they were intercepted by the nursing team in the administration phase\(^{(9)}\).

The nursing team’s knowledge regarding medications is essential for constructing a safety barrier for the patient, which can be more effective when allied with electronic prescribing and the clinical pharmacist\(^{(10)}\).

A study which analyzed the process of administration of medications in a teaching hospital evidenced that 43.9% of the system’s failures are related to the management of organizational processes, with work overload and absence of routines and continuous education; 41.4% are related to the human resources, with knowledge and skills deficits and lack of attention, and 12.6% evidenced needs related to the physical and material structure\(^{(11)}\).

Among the factors associated with the occurrence of incidents with medications, one finds the time of inpatient treatment of over four days, the prescription of four or more medications per day, and the undertaking of a surgical intervention\(^{(12)}\), indicating the need to focus greater attention on these patients. The use of risk analysis tools, such as the Failure Mode and Effect Analysis (FMEA), has been shown to be effective for managing failures in the medication process, assisting in the directing of actions for improvement and safety\(^{(11)}\).

Another tool for reducing incidents, evidenced in the majority of the near misses reported in the education process identified in this study, is the participation of the patient him- or herself in the care actions. Care centered on the patient and her family is one of the main dimensions
to be emphasized in the health system if it is to achieve quality\(^{[13]}\). The patient, therefore, is seen as an active subject in the health-illness process, contributing to a more effective, adequate and safe treatment\(^{[14-15]}\).

The importance of maintaining adequate communication between the different departments of a hospital organization was evidenced in the intercepting of a near miss related to the administration of contrast. One study which analyzed the near misses experienced by nurses, in a perioperative environment in the United States, ascertained that communication failures within the health team constitute the main cause of near misses\(^{[16]}\). Transmitting information about the patient in a calm environment without interruptions, recording the patient’s conditions, the necessary medications, the results of tests, the planned treatment, the recommendations relating to care, the significant changes and the procedures undertaken are some examples of advice in order to establish effective and safe communication – in particular, between the departments between which the patient moves during the inpatient treatment\(^{[17-18]}\).

Lack of training of health professionals is recognized as one of the main factors influencing the quality of communication, which has motivated change in the curricula of courses in the health area. The development of communication skills must be included in the training, as happens with other technical and clinical skills, and these need to be systematically updated\(^{[19]}\).

The near miss related to the surgical intervention resulted from a diagnostic error. The analysis of the processes recorded in the Regional Council of Medicine of the State of Goiás evidenced that 10.3% of the cases denounced for medical incompetence relate to diagnostic errors\(^{[20]}\). It is important for the professional to pay attention to the meaning of the doctor-patient relationship, in particular when this relates to communication and to the establishment of a more humanistic model of medicine, with a view to respect and to patient dignity, providing possibilities for better investigation of cases and, therefore, avoiding a series of discomforts and nuisances\(^{[19-20]}\).

The appropriate investigation of the patient’s health situation, and scientific knowledge, make it possible to reduce unnecessary preparation for surgery and, mainly, mistaken diagnoses. Strengthening the integration of actions between the various professional categories can minimize the potential risks of inpatient treatment and increase the possibilities of detecting near misses such that serious incidents do not occur.

One transversal study held with 427 professionals, including doctors, nurses and anesthetists, evidenced other problems in the operating theater. Among these professionals, 38% mentioned having experienced near misses related to patient identification, 60% to preparation of the patient for the procedure, and 81% to the site or side of the operation\(^{[21]}\).

Male sex was a protective factor for the occurrence of a near miss, which differs from other studies, which indicated a greater probability of the occurrence of incidents in male patients\(^{[22]}\).

The use of a urinary catheter and the transfusion of blood products did not indicate association for the occurrence of near misses. The use of these devices is commonly associated with the patient’s clinical condition and the seriousness of the patient’s condition, and relates to the increase in clinical risks, and the number of interventions during the inpatient treatment, and the time expended by the professionals\(^{[23]}\). Moreover, various studies have indicated the use of tubular devices as increasing the risk of occurrence of incidents, and advise specific care for the prevention of these\(^{[24]}\).

Blood transfusions, when undertaken unsafely, can be associated with transfusion reaction, the transmission of infection, increase in postoperative morbidity and mortality, and the risk of immunosuppression\(^{[25-26]}\), which requires greater attention from the professional.

In the light of the current scenario, therefore, the need is evidenced to study the near misses so as to avoid potential adverse events occurring and thus further compromising the care for, and the safety of, the patient.

In the United States of America, the National Fire Fighter Near Miss Reporting System is an initiative coordinated by the International Association of Fire Chiefs and by the Drexel University School of Public Health, which uses the Internet for building a database for studies of near misses, and aims to alert firefighters regarding dangers at work. Notification is voluntary and confidential, and follows a non-punitive and
secure information system; the near misses are used as learning tools(27).

In the health context, one can observe a scarcity of literature describing experiences reporting near misses, in particular, for studying failures and taking preventive actions. Studies focusing on more serious incidents requiring immediate corrective interventions and which, in the majority of situations, caused harm to the patient, still predominate.

Ordinance N. 529 of 1st April 2013, of the Ministry of Health, which instituted the National Safety Program(28), might encourage the interest of managers and health professionals to extending their knowledge regarding the incidents, as well as developing a culture of patient safety in institutions which provide training and health care.

It is believed, however, that for significant learning at work, it is firstly necessary to systematize the process of monitoring incidents and near misses resulting from healthcare. The challenge for health managers, therefore, is to strengthen the risk management commissions, involve the health professionals in the active search for latent failures, and to sensitize them to changing attitudes, with emphasis on the adoption of good practices in the promotion of a system with systematic resilience, continuously contributing to care with quality and excellence.

CONCLUSION

The occurrence of 1.7% of near misses was observed, which indicated failures in the process of administering medications, in interdepartmental communication, and in the clinical evaluation of the patient for assessment in medical diagnosis, which are configured as potential adverse events, if not monitored and discussed by the health service.

The study presents limitations relating to the method used, and may not reflect the real number of near misses which took place, as the recording of the incidents depends on the attitude of the health professional and on the institution’s organizational culture.

One can observe, therefore, the need to encourage the health professionals to record near misses, so as to allow the study of the causal factors and the promotion of changes in the organization of the health work. Education at work is suggested so as to awaken the professional to, and cause the professional to develop in, the culture of safety, as is also the adoption of specific instruments for recording near misses, so as to facilitate their tracking and to create a database of indicators for analysis and directing of the work processes, making it possible to reduce the chances of an accident resulting in harm to the patient.

REFERENCES


