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Reported incidents in obstetric care of a public hospital and associated factors

Incidentes notificados no cuidado obstétrico de um hospital público e fatores associados

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ABSTRACT

Introduction: Patient safety seeks to reduce, to an acceptable minimum, the risk of unnecessary harm associated with health care. Regarding maternal and neonatal care, quality and safety have also occupied the agenda of Brazilian public policies intensively as a strategy for reducing perinatal morbidity and mortality. **Objective:** To analyze the incidents related to obstetric care reported in a public hospital according to the profile of the women involved and factors associated with serious adverse events. **Method:** A cross-sectional, retrospective study with incidents recorded in the Incident Reporting System of a public hospital in Federal District specialized in maternal and child care between 2015 and 2017. A logistic regression in one model, with subsequent adjustment of variables in a multiple model, was used to evaluate the factors associated with severe adverse events. **Results:** A total of 114 incidents were reported, of which 104 occurred in patients and resulted in mild (16.7%), moderate (32.5%) and severe (24.5%) injuries, with 4.8% of deaths related to the incident. The majority of the incidents occurred during the day (75.3%), in the Obstetric Center (51.7%), were notified by nurses (57.0%) and were related to health care procedures (48.3%). Serious adverse events were more likely to occur at the Obstetric Center (OR = 3.86, 95%CI 1.26–11.84) and at night (OR = 3.37, 95%CI 1.16–9.75). **Conclusions:** Most incidents caused moderate or severe damage to patients. Serious events were more likely to occur at the Obstetric Center and at night.

KEYWORDS: Patient Safety; Risk Management; Medical Errors; Women's Health; Quality of Health Care

RESUMO

Introdução: A segurança do paciente busca reduzir, a um mínimo aceitável, o risco de dano desnecessário associado ao cuidado de saúde. Em relação à assistência materna e neonatal, a qualidade e segurança também têm ocupado a agenda das políticas públicas brasileiras de forma intensa como estratégia para redução da morbimortalidade perinatal. **Objetivo:** Analisar os incidentes relacionados ao cuidado obstétrico notificados em um hospital público segundo o perfil das mulheres envolvidas e fatores associados aos eventos adversos graves. **Método:** Estudo transversal e retrospectivo, com incidentes registrados no sistema de notificação de incidentes de um hospital público do Distrito Federal especializado em atenção materna e infantil, entre 2015 e 2017. Para avaliar os fatores associados aos eventos adversos graves, foi utilizada a regressão logística em um modelo simples, com subsequente ajuste das variáveis em um modelo múltiplo. **Resultados:** Foram notificados 114 incidentes, sendo que 104 ocorreram com pacientes e resultaram em danos leves (16,7%), moderados (32,5%) e graves (24,5%), com 4,8% de óbitos relacionados ao incidente. A maioria dos incidentes ocorreu durante o dia (75,3%), no centro obstétrico (51,7%), por notificação de enfermeiros (57,0%) e foram relacionados aos procedimentos de assistência à saúde (48,3%). Os eventos adversos graves apresentaram maior chance de ocorrer no centro obstétrico (OR = 3,86; IC95% 1,26–11,84) e no período noturno (OR = 3,37; IC95% 1,16–9,75). **Conclusões:** A maioria dos incidentes causou dano moderado ou grave às pacientes. Os eventos graves apresentaram maior chance de ocorrer no centro obstétrico e no período noturno.

PALAVRAS-CHAVE: Segurança do Paciente; Gestão de Risco; Erros Médicos; Saúde da Mulher; Qualidade da Assistência à Saúde

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INTRODUCTION

The topic of patient safety has been increasingly discussed worldwide since the publication of a report by the Institute of Medicine (IOM) called *To Err is Human: Building a Safer Health System*, in 1999. Among several other consequences, the document addressed the impact of mortality rates and longer hospitalization times[1]. Patient safety is an important component of quality healthcare and is defined as the prevention, improvement and correction of adverse outcomes or injuries derived from the care process, with support to the patients and professionals involved[2,3].

In Brazil, the National Patient Safety Program (PNSP) was instituted by Ministry of Health Ordinance n. 529, of April 1, 2013, and Resolution of the Collegiate Board (RDC) of the National Health Surveillance Agency (Anvisa) n. 36, of July 25, 2013, with the objective of improving the qualification of care in all healthcare institutions. These normative documents determined the establishment of Patient Safety Centers (NSP) in all hospital care institutions[4,5].

A relevant competence of the NSP is the surveillance of healthcare-related incidents and their reporting to the National Health Surveillance System (SNVS). This reporting must be done in the specific module of the Health Surveillance Notification System (Notivisa).

For this purpose, incident reporting forms or systems (SNI) are important NSP tools that should be available in all health services. This enables a culture in which patients, professionals and managers can understand the risk factors involved in healthcare, as well as devise strategies to prevent the recurrence of incidents[6,7].

The analyzed reports help identify opportunities for improvement and the development of a safety culture[8,9]. The data generated by these systems enable the production of information that supports corrective and preventive actions for safer healthcare[6].

Patient safety seeks to reduce, to an acceptable minimum standard, the risk of unnecessary harm associated with healthcare. Patient safety incident is the event or circumstance that may or may not have resulted in unnecessary patient harm. The incidents that cause care-related harm are referred to as adverse events (AEs) and may increase the patient's length of hospitalization or result in a disability at hospital discharge[4,7].

AEs are classified according to the presence of preventable harm and can be considered: Mild AE, when the patient has mild symptoms, short-lived minimal or intermediate harm without intervention or minimal intervention; moderate AE, when additional or complementary intervention is required, with prolonged hospitalization, loss of function, permanent or long-term harm; and severe AE, when major life-saving medical/surgical intervention is required or because there has been major permanent or long-term harm, fetal disturbance/risk or congenital anomaly; death caused or accelerated by the AE[10].

Regarding maternal and neonatal care, quality and safety have also played an important role in the agenda of Brazilian public policies as a strategy for reducing perinatal morbidity and mortality[3,5].

AEs in maternity care are often preventable, although the costs of care are increasing worldwide, as are legal disputes arising from healthcare-related harm[11,12].

Understanding the problem in different approaches is fundamental, since this would enable appropriate interventions to reduce deaths and unnecessary harm[13].

To increase knowledge about the occurrence of incidents in obstetrics, with or without harm, we must use information technology and analytical tools such as obstetric safety indicators, clinical sessions or reporting systems. Detecting the characteristics of an AE enables the creation of strategies to prevent or mitigate the impact of unpredictable events, and to build a sustainable model to improve patient care and safety[14,15].

In Brazil's Federal District, studies on the complications of the pregnancy-puerperal cycle are scarce[16]. Therefore, learning more about incidents related to obstetric care can contribute to improving interventions that can make care safer, which warrants the conduction of the present study.

This paper aimed to analyze the incidents related to obstetric care reported in a public hospital according to the profile of women involved and factors associated with severe AEs.

METHOD

The study is cross-sectional and retrospective. It was carried out in a public hospital in Brazil's Federal District, a reference for high-risk gestational care, specialized in maternal and child care.

The population consisted of all incident reports related to obstetric care in cases occurred during pregnancy, childbirth and up to 42 days after the end of pregnancy, filed from January 1, 2015 to June 30, 2017.

The reports were collected from the Patient Quality and Safety Center (NQSP) through the SNI, and additional information was surveyed from the electronic records of the patients involved. The NQSP was instituted in November 2013 and the SNI consists of an electronic form available since October 2014 to professionals, users and family members. After being filled in by the reporting party with basic information about the incident, the electronic reporting form is sent to the NQSP for analysis. When the information describes severe harm, it is the subject of a plan of action.

The variables of the reporting form that were surveyed and analyzed in this study were: date of the incident, date of reporting, place and shift of the incident, identification of the involved

patient (name, date of birth and medical record number), description of the incident and professional category of the reporting person. We also included the type, subtype and classification of the incident, as well as the occurrence or not of harm to the patient, which was confirmed in the medical records.

The percentages of women involved in AEs reported were calculated according to the number of women served per year. The incidents were categorized into types, according to the classification done in Notivisa.

The database was organized using Excel® version 15.26. For data analysis, we used the Statistical Package for the Social Sciences (SPSS®), version 25.0. In the descriptive analysis, the percentage distribution of qualitative variables and measures of central tendency and dispersion of quantitative variables were performed. To assess factors associated with severe AEs, this variable was considered as dependent and categorized as "yes" when the AE had severe harm and "no" when the AE had mild or moderate harm.

Independent variables were age (< or ≥ 35 years) in view of the association of severe maternal morbidity and women aged ≥ 35 years[17], days of hospitalization (≤ or > 4 days) due to the average length of stay of 4 days for high-risk cesarean sections[3] and AEs having caused more days of hospitalization in a previous study[18], place of occurrence of the incident (yes: obstetric center – OC; no: ward and intensive care unit) and occurrence shift (day and night), considering the variations in work processes, according to sector and time, and the possible relationship of this with the AEs.

To estimate the association between dependent and independent variables in a cross-sectional study, we decided to look for the odds ratio (OR) rather than the prevalence ratio, since a previous study did not find substantial differences between them and also because the dependent variable does not have high prevalence[19].

Initially a simple logistic regression model was performed to analyze the independent variables associated with the dependent variable with the chi-square test. Then, in a multiple logistic regression model (stepwise forward), the independent variables that presented $p < 0.25$ in the simple model[14] were adjusted. The variables with $p < 0.05$ remained in the multiple model. All association measures were estimated with their respective 95% confidence intervals.

The project was approved by the Research Ethics Committee of the Health Sciences Teaching and Research Foundation (FEPECS) under number 1.907.907.

RESULTS

During the study period, there were 9,323 births, of which 48.6% were cesarean sections and 51.3% were normal births, with an average of 310 births/month and 3,729 births/year. A total of 114 incidents were reported in the period, of which 104 involved patients, which means 1.1% of the women treated in the period. The other ten incidents were reported circumstances with potential risk of AEs, but that did not affect any patient, hence the discrepancy between the number of patients and the number of incidents in the study.

The women involved in the 20 AE reports in 2015 accounted for 0.4% of the total women; the 52 reports made in 2016 were equivalent to 1.3% of the total women; and the 42 reports made in the first half of 2017 corresponded to 2.8% of the number of women surveyed in the same period.

They had a mean age of 28.2 years (± 7.6 years), ranging from 16 to 44 years. The most frequent age group was from 20 to 34 years old (54.8%). The average length of hospitalization was 14 days (± 16.4 days), with a minimum of one and a maximum of 79 days of hospitalization. Most were nulliparous (53.5%), had a preterm pregnancy (<37 weeks) and were hospitalized to perform or because of cesarean section (49.0%) (Table 1).

Of the incidents reported and analyzed in this study, most had harm (73.7%), including 57.0% with moderate and severe harm. The most frequent site was the CO (51.7%). Nurses were the professionals responsible for most reports (57.0%). Most AEs occurred during the daytime (75.3%) (Table 2).

Most of them were related to healthcare procedures (48.3%) and healthcare-associated infections (HAI) (20.1%). Among the outcomes, 61.0% of the patients were discharged, 21.1% were transferred and 8.8% died. Of the ten deaths identified, five were related to the reported incidents.

In the simple logistic regression model, a statistically significant association was found between the occurrence of AEs with severe harm and the OC as the event site ($p = 0.002$) and the night shift ($p = 0.013$) (Table 3). These variables remained associated with AE with severe harm in the multiple logistic regression model, indicating three times more likelihood of this event occurring at night and in the OC (Table 4).

DISCUSSION

Most reported incidents in obstetric care caused harm to patients and more than half were classified as moderate or severe, including death in some cases. Events with severe harm were more likely to occur in the OC and at night.

Even though there was an increase in the number of reports over the studied period, the reports analyzed in this study certainly do not represent all the incidents that occurred in the period. This is because it is estimated that 421 million hospitalizations occur worldwide every year, with about 42.7 million incidents with harm[20].

A retrospective study conducted in Spain found an incidence of 3.6% of the occurrence of AEs related to obstetric care[12]. In Brazil, a study conducted in a general hospital found 3.3% of reported incidents among hospitalized patients[21]. In a retrospective cohort of 2017 through active search, we found the incidence of 7.2% of acquired conditions[22]. These two studies

Table 1. Characteristics of 104 patients involved in reported incidents related to obstetric care. Brasília-DF, 2017.

Variable	Category	N	(%)
Age range	≤ 19 years	19	18.3
	20 to 34 years old	57	54.8
	≥ 35 years	28	26.9
Number of pregnancies	First pregnancy	32	30.8
	Two or three pregnancies	41	39.4
	More than three pregnancies	25	24.0
	No records	6	5.8
Number of vaginal births	Nulliparous	53	51.0
	Primiparous	25	24.0
	Multiparous	21	20.2
	No records	5	4.8
Number of cesarean sections	No cesarean section	67	64.4
	One or more cesarean sections	30	28.8
	No records	7	6.7
Number of miscarriages	No miscarriage	67	64.4
	One or more miscarriages	31	29.8
	No records	6	5.8
Gestational age in weeks	< 22	10	9.6
	22 to 31	9	8.7
	32 to 36	29	27.9
	37 to 41	43	41.3
	No records	13	12.5
Reason for hospitalization	Vaginal birth	35	33.7
	Cesarean section	51	49.0
	Miscarriage	8	7.7
	Gestation	10	9.6
Patient outcome	High	70	67.3
	Transfer	24	23.1
	Death	10	9.6
Incident-related death	Yes	5	4.8
	No	99	95.1

Table 2. Characteristics of 114 reported incidents related to obstetric care. Brasília-DF, 2017.

Variable	Category	N	(%)
Incident classification	Incident without harm	30	26.3
	Adverse event with mild harm	19	16.7
	Adverse event with moderate harm	37	32.5
	Adverse event with severe harm	28	24.6
Incident location	Obstetric center	59	51.8
	Ward	20	17.5
	Intensive care unit	35	30.7
Incident reporter	Nurse	65	57.0
	Nursing technician	35	30.7
	Pharmacist	5	4.4
	Physician	7	6.1
	Patient	2	1.8
Incident occurrence shift	Day	73	64.0
	Night	24	21.1
	No records	17	14.9
Incident type	Related to healthcare procedure	55	48.2
	Related to surgical procedure	27	23.7
	Medication-related incident	21	18.4
	Related to medical-hospital device or equipment	11	9.6
Incident subtype	Healthcare-associated infection	23	20.2
	Technical complaint	21	18.4
	Avoidable injury during care	15	13.2
	Severe maternal morbidity	12	10.5
	Medication-related incident	12	10.5
	Non-recommended birth practice	6	5.3
	Related to the environment and processes	6	5.3
	Pressure injury and falls	6	5.3
	Identification failures	5	4.4
	Others	8	7.0

Table 3. Distribution of severe adverse event occurrences and association with patient characteristics and reported incidents. Brasília-DF, 2017.

		Adverse event with severe harm				
Variable	Category	No N (%)	Yes N (%)	p	OR	CI 95%
Age	< 35 years	57 (54.8)	19 (18.3)	-	1.00	-
	≥ 35 years	19 (18.3)	9 (8.7)	0.467	1.42	0.55-3.67
Days of hospitalization	≤ 4 days	25 (24.0)	8 (7.7)	-	1.00	-
	> 4 days	51 (49.0)	20 (19.2)	0.675	1.23	0.47-3.17
Obstetric center	No	49 (43.0)	6 (5.3)	-	1.00	-
	Yes	37 (32.5)	22 (19.3)	0.002	4.86	1.79-13.18
Shift of occurrence	Day	61 (62.9)	12 (12.4)	-	1.00	-
	Night	14 (14.4)	10 (10.3)	0.013	3.63	1.31-10.08

OR - odds ratio; CI - confidence interval; p - p value.

Table 4. Variables associated with the occurrence of an adverse event with severe harm in the multiple logistic regression model. Brasília-DF, 2017.

Variable	Category	adjusted OR	CI 95%	p
Obstetric center	No	1.00	-	-
	Yes	3.86	1.26-11.84	0.018
Shift of occurrence	Day	1.00	-	-
	Night	3.37	1.16-9.75	0.025

OR - odds ratio; CI - confidence interval; p - p value.

took place in accredited services with quality management systems. The variation of AE estimates can be explained by different incident identification methods, form of data collection, and the rationale for incident detection, definition and confirmation[23]. Nevertheless, we believe there is underreporting of incidents in the present study, which demonstrates the need to put more effort into strengthening the safety culture of the researched institution.

The patients involved in the reports remained hospitalized for a longer period than the average length of stay for high-risk pregnant women who gave birth vaginally (3.2 days) or through cesarean section (4.2 days) in the Brazilian Unified Health System (SUS)[3]. In a retrospective study conducted in Rio de Janeiro, preventable AEs were responsible for an additional 373 days of hospitalization in the study population, which consisted of adult patients admitted to general hospitals, public hospitals and teaching hospitals in 2003[18]. A retrospective analysis with active search of incidents done in Spain has shown that 36.7% of AE occurrences prolonged women's hospitalization time[11].

However, no association was found between longer hospital stays and the occurrence of severe AEs, which may be explained by the limitation of the study, which included only data from patients who were involved in incidents.

Most reported incidents were related to healthcare procedures. Healthcare-associated infections were the most prevalent subtype of incident. Similar results were achieved in Spain, where the most frequent obstetric care-associated AEs were those involving surgical interventions or health procedures[14].

The procedures performed in obstetric care, especially the most complex and consequently the most risky ones, are performed in the OC and this may be the reason for the association between this site and the occurrence of AEs with severe harm. However, it is not possible to rule out the possibility that shortcomings in the workflow of this sector have favored AEs with severe harm. Further studies involving these variables are indicated to evaluate this hypothesis.

Regarding the shift where the incidents occurred, in this study, we found the predominance of the day shift, and so did other studies, probably due to the higher frequency of procedures that take place during daytime[8,21,24]. However, we observed that severe harm was three times more likely to happen on the night shift. This suggests that managers should pay more attention to workers on this shift to assess whether lack of training or any particularities may be related to the occurrence of AEs on this shift.

Regarding incidents reported with death outcome, the present study found a higher percentage than that found in a Brazil-wide study with data from Notivisa (0.6%)[25]. Notivisa data refer to reports about the population in general, unlike this study, which is limited to women in obstetric care. The records of investigations of cases that resulted in death in Notivisa are scarce, which hinders the association of the death with the AE[25].

The professionals who filed reports most often were the nurses, a result similar to other studies on incident reporting[9,24,26]. Although in this study only two reports were made by patients, it is worth noting the importance of incident reporting by patients, since it helps develop a safety culture[27], which has already been verified in a Norwegian study[28]. Patient and family engagement is a promising path for better quality, more efficient care and better health for the population[29].

Since this is a retrospective study with data from reported incidents only, there are limitations in the generalization of the results, as well as in the association between the variables, once the cross-sectional design limits the understanding of the cause and effect relationship. Nevertheless, the analysis of data from voluntary incident reports enables the improvement of the instruments, as well as contributes to institutional decisions to improve the quality and safety of maternal and child care.

CONCLUSIONS

In the analysis of the incidents reported in the period, we observed that most were characterized as AEs because they caused harm to women and, of these, more than half were classified as moderate or severe, with death in some cases. We also observed that severe AEs are more likely to occur in the OC and at night. This shows the importance of implementing improvement strategies in this sector, with tools like care protocols, setup of workflows and continuing education, analyzing the reason for the occurrence of more severe harm on this shift and how to prevent it from happening. Furthermore, the results indicated the relevance of reporting, which, associated with the understanding, analysis and investigation of these cases, increases awareness of the contributing factors of the incidents and enables action plans and effective interventions.

Other studies are suggested to enable the estimation of obstetric incidents through active search and use of systematic methodologies. This can increase our understanding of the occurrence of AEs and related factors and enable continuous improvement of obstetric care.

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Conflict of Interest

Authors have no potential conflict of interest to declare, related to this study's political or financial peers and institutions.