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Are adverse events related to the completeness of clinical records? Results from a retrospective records review using the Global Trigger Tool

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Abstract
Clinical record (CR) is a tool for recording details about the patient and the most commonly used source of information for detecting adverse events (AEs). Its completeness is an indicator of the quality of care provided and may provide clues for improving professional practice. The primary aim of this study was to estimate the prevalence of AEs. The secondary aims were to determine the completeness of CRs and to examine the relationship between the two variables. We retrospectively reviewed randomly selected CRs of patients discharged from the Academic Hospital of Udine (Italy) in the departments of general surgery, internal medicine, and obstetrics between July and September 2020. Evaluation was performed using the Global Trigger Tool and a checklist to evaluate the completeness of CRs. The relationship between the occurrence of AEs and the completeness of CRs was analyzed using nonparametric tests. A binomial logistic regression analysis was also performed. We reviewed 291 CRs and identified 368 triggers and 56 AEs. Among them, 16.2% of hospitalizations were affected by at least one AE, with a higher percentage in general surgery. The most common AEs were surgical injuries (42.6%; 24) and care related (26.8%; 15). A significant positive correlation was found between the length of hospital stay and the number of AEs. The average completeness of CRs was 72.9% and was lower in general surgery. The decrease in CR completeness correlated with the increase in the total number of AEs ($R = -0.14$; $P = .017$), although this was not confirmed by regression analysis by individual departments. Our results seem to suggest that completeness of CRs may benefit patient safety, so ongoing education and involvement of health professionals are needed to maintain professional adherence to CRs.

Keywords: clinical record; patient safety; adverse event; global trigger tool; quality; risk management

Introduction

Adverse events (AEs) may occur in 10–25% of hospital admissions, depending on the methods used to detect them and the local context [1–3]. They can not only lead to temporary or permanent disability but also increase mortality rates by up to 21.9% [4] and increase healthcare expenditures by 15–25% [5]. For these reasons, health-care organizations are constantly striving to reduce the occurrence of these events. Most of them continue to rely only on voluntary reporting systems as well as traditional clinical record (CR) review to detect and quantify AEs, although other cost-effective and time-saving complementary methods such as “trigger tools” have been available for many years [6]. The trigger tool method is based on a retrospective review of a random sample of CRs looking for triggers to identify potential AEs related to patient care. The Global Trigger Tool (GTT), developed by the Institute for Healthcare Improvement in 2003 [7], is the most widely used method. GTT has been shown to be a valid and reliable method to compensate for the large amount of time required for traditional reviews of CRs [8] and the underestimation of the frequency and severity of AEs by the voluntary reporting system [9, 10] and to allow for easier monitoring over time.

CRs are considered one of the most appropriate sources for AE detection. Indeed, the CR is the primary tool health professionals use to record clinical information about patients to support care delivery, clinical decision-making, effective communication among health professionals, and continuity of care. Several authors believe that completeness of the CR (i.e. the care with which information is recorded in it) can be a predictor of quality of care [11–14] and is an important indicator that health-care organizations must monitor. The governance of CR may nevertheless influence the identification [14, 15] and occurrence of AEs [11, 14, 16], although, to our knowledge, few studies have examined this association. Since our Quality and Accreditation Unit has been measuring the completeness of CRs at the Academic Hospital of Udine (Italy) for years, with the firm belief that better communication contributes to safer health care and better patient outcomes [17], we decided to investigate this association between the quality of CRs and the occurrence of AEs.

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The primary aim of this study was to determine the prevalence and type of AEs in hospitalized patients. The secondary aims were to determine the completeness of CRs and to investigate the correlation between the occurrence of AEs and the completeness of CRs.

Methods

Study design and setting

We performed a retrospective observational study to assess the prevalence of AEs and, second, the completeness of CRs and their correlation at the Academic Hospital of Udine (Italy). A random sample of CRs was evaluated that concerned patients discharged from the departments of internal medicine, general surgery, and obstetrics between July and September 2020. Only complete and finalized CRs from hospitalizations of adult patients with a duration of more than 24 hours who had signed an informed consent form to use the data for research purposes were included. CRs related to psychiatric and rehabilitation patients were excluded. Patients who were transferred during hospitalization were also excluded to obtain CRs' completeness data as much as possible related to a single department. In the departments analyzed in this study, the CRs are entirely paper based.

Tools used for revision

To evaluate the prevalence of AEs and investigate the possible association between the completeness of CRs and the occurrence of AEs, we reviewed CRs using the Italian version of GTT [18] and then using a checklist to assess the completeness of CR. The GTT is a method to measure the occurrence of AEs through a retrospective review of a random sample of CRs. It consists of 53 triggers divided into six modules: Cares, Medication, Surgical, Intensive Care, Perinatal, and Emergency Department. This tool allows estimation and monitoring of AE rates over time, specifically: AEs per 1000 patient days, AEs per 100 admissions, and percentage of admissions with an AE. The review was conducted by a single physician and subsequently approved by a second physician; both investigators were experts in patient safety and in the use of GTT. All identified AEs were categorized by severity using the categorization of National Coordinating Council for Medication Error Reporting and Prevention (NCC MERP) [19] (only categories related to AEs were included: E—An error occurred that may have contributed to or resulted in temporary harm to the patient and required intervention; F—An error occurred that may have contributed to or resulted in temporary harm to the patient and required initial or prolonged hospitalization; G—An error occurred that may have contributed to or resulted in permanent patient harm; H—An error occurred that required intervention necessary to sustain life; I—An error occurred that may have contributed to or resulted in the patient's death) and by area, using the Swedish handbook classification used by Rutberg *et al.* in 2014 [20], which classifies AEs into 26 categories divided into four areas: care [allergic reaction; bleeding (not in connection with surgery); fall; thrombosis; pressure ulcers (grades 2–4); distended urinary bladder; and thrombophlebitis], hospital-acquired infections [central venous catheter infection; pneumonia (not ventilator-associated pneumonia); postoperative wound infection; sepsis; urinary tract infection; ventilator-associated pneumonia; and other hospital-acquired infection], surgical injury [wrong site surgery; injury of organ during operative procedure; postoperative bleeding/hematoma (not requiring reoperation); reoperation; and other surgical complication], and others (cardiac or pulmonary failure or arrest; anesthesia-related injury; medication-related injury; medical device–related injury; obstetric injury; neurological injury; and other injury).

The CR completeness assessment checklist is a validated tool developed by the Quality and Accreditation Unit of our hospital [17]. This checklist was selected because it has been shown to be reliable and easy to learn over more than a decade of routine use and development, as it was specifically designed to assess CRs at our hospital [17]. The version used in this study consists of 49 items grouped into 13 sections that examine specific areas of CR: discharge letter (4 items), initial medical assessment (4 items), care planning (4 items), clinical diary (2 items), initial nursing assessment (4 items), nursing planning (6 items), drug prescription (7 items), surgery (11 items), physiotherapy counseling (1 item), handover (1 item), interprofessional communication (2 items), infection risk management (2 items), and patient identification (1 item). The investigator assigns a score of 1 or 0 for each item if the corresponding field is completed or not; the "not applicable" option is also available. Based on the score assigned for each item, the percentage of completeness of each section and the entire CR is calculated.

Sample size and statistical analysis

Considering the primary aim of the study, a minimum sample size of 281 CRs was calculated to determine the prevalence of AEs, considering the data previously reported in the literature (24%) with a confidence interval of 95% $\pm$ 5.

A descriptive analysis of the variables considered was performed. Absolute and relative frequency distributions were performed for the categorical variables, while the mean was calculated for the numerical variables. The normality of the distribution of the numerical variables was tested using the Kolmogorov–Smirnov test. For the comparison of continuous variables, the Student t-test or the Wilcoxon–Mann–Whitney test were; based on the results of the Kolmogorov–Smirnov normality test, and for the categorical variables, the X^2 analysis or the Fisher exact test, depending on the expected frequencies. If no more than 20% of cells had an expected frequency of less than five and no cell had an expected frequency of less than one, X^2 analysis was used; otherwise, Fisher's exact test was used. Spearman's rank correlation coefficients were calculated to examine the relationship between ordinal variables. The significance level was set at $P < .05$. Scatter plots and density plots were created to illustrate the results. We performed binomial logistic regression to examine the Adverse Event (AE) occurence with the independent variables AE occurrence, CR completeness, length of stay, department, sex, and age. Results were reported as crude and adjusted OR (95% CI) and statistical significance as P value. Given the nature of the tools used, it was not necessary to account for missing data: the missing items of the CRs were items of interest for the application of the CR completeness assessment checklist. All statistical analyses were performed using R software version 4.0.2 (R Core Team (2020). R: A language and environment for statistical computing. R Foundation for Statistical Computing, Vienna, Austria. URL https://www.R-project.org/.).

Ethics approval

This study has received the approval from the Regional Ethical Committee of Friuli Venezia Giulia (CEUR) (protocol no. CEUR-2021-OS-06).

Results

A total of 910 patients' CRs were extracted. Of these, 120 were excluded because they referred to patients who were transferred during hospitalization and 85 because they referred to patients who had not signed informed consent for research purposes. Of the remaining, a total of 291 randomly selected CRs were reviewed, evenly distributed among the three departments.

The mean age of the patients was 60.3 years, and women accounted for 68.3%. At GTT, 368 triggers were identified. The most common trigger category was *Cares* (165; 44.8%), followed by *Medication* (97; 26.4%), and *Emergency department* (48; 13.0%). The distribution of trigger categories is shown in Table 1. The most common triggers were *readmission within 30 days*, *time in Emergency Department (ED) greater than six hours*, *over-sedation/hypotension,* and *decrease in hemoglobin or hematocrit of 25% or greater.* In terms of *readmission within 30 days*, a total of 62 readmissions were observed: in 36 cases, the hospitalization studied was itself the readmission, while in 26 cases, the hospitalization studied was followed by a readmission. The mean time between discharge and readmission was 12.3 days.

Based on these triggers, a total of 56 AEs were identified. The rate of admissions with at least one AE was 16.2%; with 19.2 AEs per 100 admissions and 25.8 AEs per 1000 patient days. The department with the highest frequency of AEs was general surgery (28 AEs), followed by internal medicine (20 AEs) and obstetrics (eight AEs). Further details can be found in Table 2.

The identified AEs were then classified into the different categories: *surgical injuries* with 24 AEs (42.6%), care with 15 AEs (26.8%), hospital-acquired infections with eight AEs (16.1%), and others with eight AEs (14.3%). Further details are shown in Fig. 1. The most frequently identified AE were *other surgical complications* (13; 23.2%), followed by *medication-related injury* (5; 8.9%), and *other hospital-acquired infection* (4; 7.1%). The average time between hospitalization and the occurrence of AEs was 6.75 days. The observed AEs belonged exclusively to the NCC MERP categories E (37.5%) and F (62.5%). The occurrence of AEs is positively correlated with patient age (Fig. 2A) ($P = .01$) and, looking at the density plot (Fig. 3A), appears to have a bimodal distribution that becomes more evident from age 80 years. However, this correlation was not confirmed by logistic regression analysis by department (see supplementary material). The average length of stay was 7.6 days and was longer in patients with at least one AE (12 days) than in patients with no AEs during hospitalization (6.6 days), with a statistically significant correlation between the length of stay and the number of AEs ($P < .001$) (Fig. 2B). This

Table 1. Distribution of trigger modules in the three departments.

	Cares, *n* (%)	Medication, *n* (%)	Surgical, *n* (%)	Intensive care, *n* (%)	Perinatal, *n* (%)	Emergency department, *n* (%)	Total, *n* (%)
General surgery	59 (16.0)	43 (11.7)	12 (3.3)	0 (0.0)	0 (0.0)	14 (3.8)	128 (34.8)
Internal medicine	88 (23.9)	39 (10.6)	0 (0.0)	1 (0.3)	0 (0.0)	34 (9.2)	162 (44.0)
Obstetrics	18 (4.9)	15 (4.1)	1 (0.3)	0 (0.0)	44 (12.0)	0 (0.0)	78 (21.2)
Total	165 (44.8)	97 (26.4)	13 (3.5)	1 (0.3)	44 (12.0)	48 (13)	368 (100)

Table 2. Distribution of AEs in the studied departments.

Structure	AEs, *n* (%)	Admissions with AEs, %	AEs/100 admissions, *n*	Patient days, *n* (%)	AEs/1000 patient days, *n*
General surgery	28 (50)	21.6	28.9	787 (36.3)	35.6
Internal medicine	20 (35.7)	18.6	22.0	935 (43.1)	21.4
Obstetrics	8 (14.3)	8.2	8.2	447 (20.6)	17.9
Total	56 (100)	16.2	19.2	2169 (100)	25.8

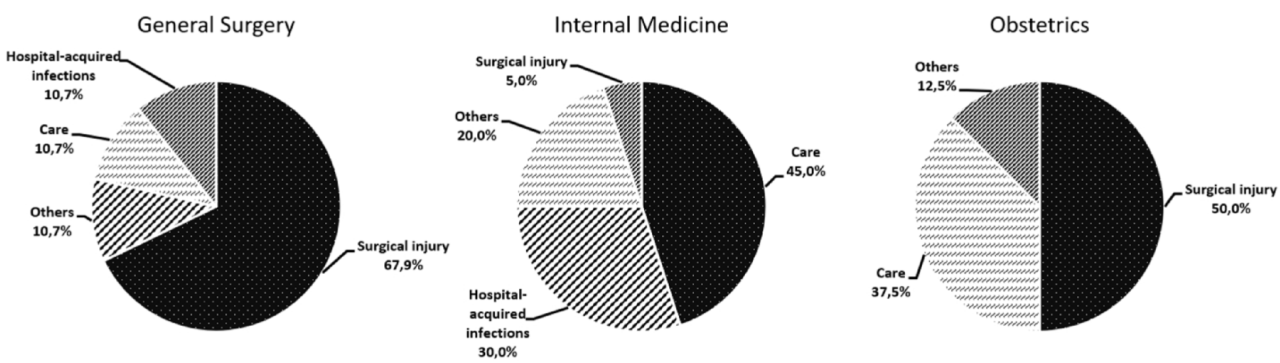

Figure 1 Distribution of AE categories among departments.

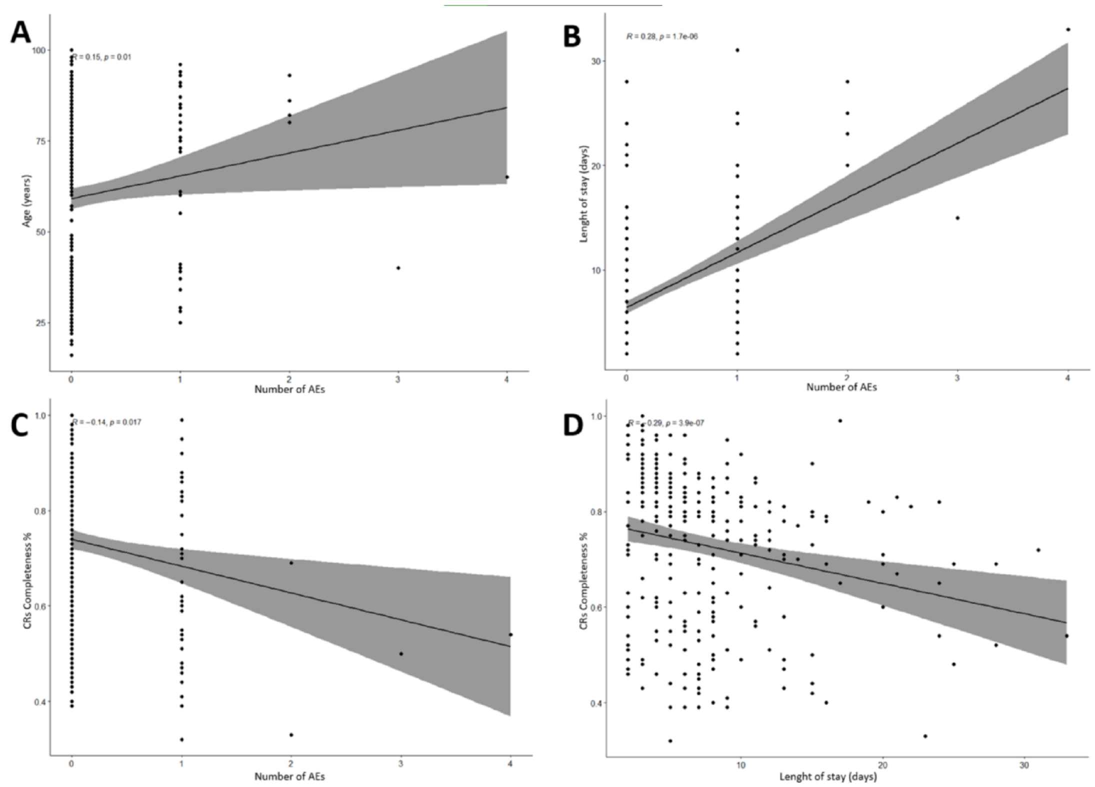

Figure 2 Correlation between the number of AEs and age (**A**), length of stay (**B**), and CR completeness (**C**); correlation between the length of stay and CR completeness (**D**).

particular aspect was confirmed by the density plot (Fig. 3B) and regression analysis (OR: 1.14, $P < .01$) (supplementary material).

The average completeness of CR was 72.9%, with a higher percentage in obstetrics (88.4%), followed by internal medicine (77.4%) and general surgery (52.9%). We observed a statistically significant inverse correlation between the completeness of CR and the number of AEs ($P = .017$) (Fig. 2C), although this was not confirmed by regression analysis (supplementary material). This relationship was also evident in the density plot analysis (Fig. 3C). Finally, a statistically significant inverse correlation between the completeness of CRs and the length of stay was also found ($P < .001$) (Fig. 2D).

Discussion

Statement of principal findings

We retrospectively reviewed 291 CRs using the GTT and the CR completeness evaluation checklist, to identify the prevalence and types of AEs in hospital inpatients and the completeness of CRs and to examine the correlation between these indicators. The most frequently identified triggers were only partially comparable to those previously reported by Mortaro *et al.* in Italy [3]. In particular, a hemoglobin or hematocrit decrease of ≥25% and time in ED >6 h were among the most frequently reported triggers in both studies, but we observed readmissions within 30 days and over-sedation/hypotension much more frequently. The observed frequency and distribution of AEs among the different departments is similar to that reported in other studies in the literature [1, 3]. The prevalence of AEs in internal medicine was similar to that reported in the Mortaro *et al.* study (20% vs. 18%), but lower in obstetrics (8% vs. 18%) and higher in general surgery (28% vs. 10%). Interestingly, our study also showed a distribution of AEs according to the NCC MERP severity scale, which is different from other studies [10, 21], as we observed that class F occurred most frequently, followed by category E. However, these results are similar to the reports of Rutberg *et al.* [20]. We did not observe more severe AEs, possibly due to the small sample size. The average completeness of the analyzed CRs was lower than that previously observed in our hospital, especially in general surgery [17]. This phenomenon could be partly due to a negative impact of the recent suspension of international accreditation, which was active in previous years and contributed to continuous improvement. The existence of an association between the length of stay and the occurrence of AEs, as already observed by colleagues [22, 23], seems to be confirmed by our study. This assumption is also supported by the fact that most AEs belonged to category F, which by definition resulted in a prolongation of hospital stay. We also observed some correlation between different variables, such as age and occurrence of AEs, completeness of CRs and occurrence of AEs, and finally completeness of CRs and length of stay. However, these correlations where not confirmed by departmental regression analysis, possibly due to the presence of a confounding interaction.

Interpretation within the context of wider literature

The partial discrepancies in trigger rate and AE severity compared with other studies may be due in part to the fact that GTT was not designed as an instrument to compare different healthcare facilities/departments [7]—and to other possible biases in data collection, such as differences in reviewer

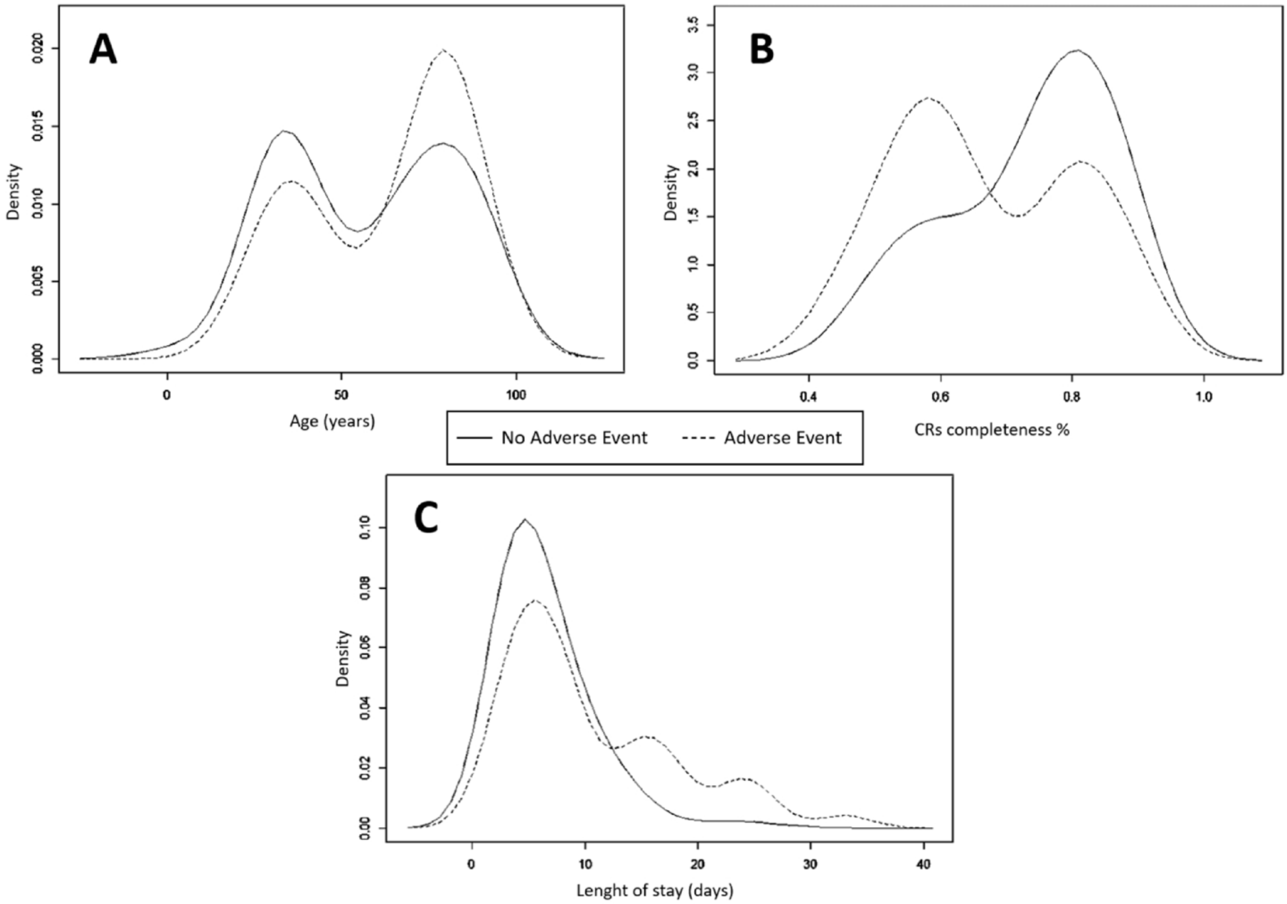

Figure 3 The density plot by age (**A**), CR completeness (**B**), and length of stay (**C**).

experience and interpretation [1] and differences in study population and data reporting [24].

This study confirmed the positive correlation between patient age and the occurrence of AEs, even if only when not accounting for possible interactions between the variables. However, this correlation is well known in the literature and is probably due to the greater frailty of these patients, as well as the greater number of medications (polypharmacy) [25], longer length of stay [22, 23], and probably lower patient engagement [26].

Finally, our results also suggest the possibility that a high level of completeness of CRs might reduce the likelihood of AE occurrence, although the results are not confirmed by regression analysis by individual departments. However, this hypothesis was supported by Zekers *et al.* in 2011 [14] who observed that poor quality of CRs correlated with a higher incidence of AEs [14]. Nevertheless, probably due to lower detectability, a lack of completeness correlates with a lower rate of AEs [14, 15]. Thus, our study seems to confirm that the quality of recorded information is an indicator of the quality of care delivered, and this may be related to the mechanisms identified by Mann *et al.* 2003, namely, lack of clarity regarding policy decisions and changes, reasons for admission, and inadequate or incomplete CRs [16].

Strengths and limitations

Our study has several limitations that must be considered when interpreting our results. First, the lack of statistically significant correlations when looking at individual departments may be due to the presence of confounding factors such as differences in the length of hospital stay and the small sample size. Another limitation of our study was the use of the GTT by a single reviewer, although this choice was made to address the need to identify a single expert to use both the GTT and the CR completeness evaluation checklist and to minimize interviewer variability, as suggested by Zegers *et al.* [14]. Nevertheless, it has been reported that a record review process with two physicians is not more reliable than a record review process with one physician [14]. Another weakness could be related to the retrospective nature of the review process, which may lead to confirmation bias, as the already-known presence of an AE may influence the judgment of the quality of CRs [14, 27]. Nevertheless, we attempted to control for this potential bias by using an objective checklist and verifying the completeness of CRs before using GTT. In addition, the monocentric study design and limited sample size may have affected the sensitivity in detecting AEs, which also affects the completeness of CRs between departments. Despite some limitations, our study also has some strengths:

by analyzing admissions from three clinically distinct departments (medicine, surgery, and obstetrics) and including both planned and emergency hospitalizations, we achieved good representativeness across departments. In addition, to the best of our knowledge, this study is the first in which the correlation between the completeness of CRs and the occurrence of AEs was analyzed using validated instruments. Finally, the use of graphical analyses, such as density plots, allowed a clearer representation of the relationship between the completeness of medical records and the occurrence of AEs.

Implications for policy, practice, and research

Our results confirm that AEs account for a substantial proportion of hospitalizations and correlate with increased length of hospital stay. In addition, our results may suggest that improving the thoroughness of recording patient information in CRs is desirable to improve the quality of care, although further observations with a larger sample size are needed to confirm this observation. Higher completeness could be achieved by implementing educational interventions [13] in conjunction with the introduction of electronic health records, which have shown encouraging results in terms of AE occurrence [28, 29]. Such systems could indeed help to increase standardization; facilitate recording, completeness, and accessibility; and facilitate the exchange of clinical patient data [14].

Conclusion

This study has shown that the frequency and distribution of AEs in our sample are similar to those previously reported in the literature, although the completeness of CRs leaves much room for improvement. The correlation between the length of hospital stay and the occurrence of AEs seems to be confirmed. Finally, the results partially suggest that there is an inverse relationship between the completeness of CR and the occurrence of AEs, but further studies with larger samples are needed to confirm this hypothesis. Hopefully, these findings will help consolidate and deepen knowledge about the safety of care and provide further consideration of clinical risk assessment and risk management to continuously improve the quality of health care. Finally, these considerations should draw attention to the importance of staff education and awareness activities, including document completeness, as part of continuous quality improvement.

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None.

Author contributions

E.S., L.B., F.F., and C.L. conceptualize and designed the research; P.C. and F.M. collected data; P.C., E.S., F.M., and L.B. discussed investigation methodology and contributed to the result interpretation; A.T. performed the formal data analysis; L.B. and R.C. supervised the study conduction; P.C. and F.M. wrote the original draft; E.S. and L.B. revised and editing contents; and all authors revised the paper and agreed with the final version of the manuscript.

Supplementary data

Supplementary data is available at *IJQHC* online.

Conflict of interest

None declared.

Funding

None declared.

Data availability

The data are available on reasonable request from the corresponding author (E.S.).

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