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Adverse event reporting and patient safety at a University Hospital: Mapping, correlating and associating events for a data-based patient risk management

Alessandra Buja[b,*], Anna Maria Saieva[a], Angela Vinelli[a], Rosaria Manola Cacco[a], Ketty Ottolitri[a], Elisa De Battisti[c], Claudio Dario[a] and Vincenzo Baldo[b]
[a]*Padua University Hospital, Padua, Italy*
[b]*Department of Molecular Medicine, Laboratory of Public Health and Population Studies, University of Padua, Padua, Italy*
[c]*School of Medicine, University of Padua, Padua, Italy*

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Abstract.
BACKGROUND: Reporting adverse events (AE) with a bearing on patient safety is fundamentally important to the identification and mitigation of potential clinical risks.
OBJECTIVE: The aim of this study was to analyze the AE reporting systems adopted at a university hospital for the purpose of enhancing the learning potential afforded by these systems.
RESEARCH DESIGN: Retrospective cohort study
METHODS: Data were collected from different information flows (reports of incidents and falls, patients' claims and complaints, and cases of hospital-acquired infection [HAI]) at an university hospital. A composite risk indicator was developed to combine the data from the different flows. Spearman's nonparametric test was applied to investigate the correlation between the AE rates and a Poisson regression analysis to verify the association among characteristics of the wards and AE rates.
SUBJECTS: Sixty-four wards at a University Hospital.
RESULTS: There was a marked variability among wards AE rates. Correlations emerged between patients' claims with complaints and the number of incidents reported. Falls were positively associated with average length of hospital stay, number of beds, patients' mean age, and type of ward, and they were negatively associated with the average Cost Weight of the Diagnosis-related group (DRG) of patients on a given ward. Claims and complaints were associated directly with the average DRG weight of a ward's patient admissions.
CONCLUSIONS: This study attempted to learn something useful from an analysis of the mandatory (but often little used) data flows generated on adverse events occurring at an university hospital with a view to managing the associated clinical risk to patients.

Keywords: Patient safety, adverse events, epidemiology and detection, safety culture, risk management, medical error, measurement/epidemiology

1. Introduction

A safety-oriented culture lies at the heart of a healthcare organization because of its importance in framing the organization's risk awareness, and nurturing and sustaining effective risk management strategies [1]. Risk management starts with a consistent, coordinated approach to the identification of

*Address for correspondence: Alessandra Buja, Department of Molecular Medicine, Laboratory of Public Health and Population Studies, Institute of Hygiene, University of Padova, Via Loredan 18, 35127 Padova, Italy. Tel.: +39 0498275387; Fax: +39 0498275392; E-mail: alessandra.buja@unipd.it.

risks and the analysis of incidents so that lessons can be learned and shared across the whole health system [2, 3].

The use of patient safety reporting systems (PSRS) based on voluntary or mandatory reporting systems with a view to identifying adverse events and mitigating risks to patients has become a priority [3]. Such reporting systems have proved extremely useful for error management in a number of industries, including aviation, nuclear power, and petrochemicals. To give an example, the Institute of Medicine in Washington cited the Federal Aviation Administration's voluntary Aviation Safety Reporting System and its associated mandatory accident reporting scheme as a model for safety improvement purposes [4]. With the increasing availability of safety data applications, the importance of patient safety data has increased commensurately.

Data relating to patient safety can be used for a number of purposes: for selecting improvement initiatives; for prioritizing the allocation of resources; for measuring the success of safety improvement efforts; for enhancing transparency through public reporting; for the accreditation of organizations [5]. The dominant frameworks are based on two safety metrics, one seeks to identify errors and the other seeks to identify injuries [5]. Several organizations have proposed indicators intended to identify adverse events (AEs) in terms of injuries, but injury-based patient safety measures are not without their shortcomings, primarily because not all harm to patients is preventable, and these measures are reactive (adopted after the event), and secondly because they are liable to a selective reporting bias [6]. The systematic investigation of AEs with a view to understanding and correcting the factors that triggered them has led to remarkable improvement in operator safety in high-risk industries. As reported by the WHO, however, the practice of learning from our mistakes–which could lead to effective changes in practice and behavior–is still not sufficiently advanced in the healthcare setting. Many institutions face inherent difficulties when it comes to analyzing effectively the growing body of often unstructured reports of AEs, and the opportunities afforded by reporting systems for organizations to share their experiences and understanding, and thus adopt more effective practical solutions are still less than optimal. In addition, reporting on patient safety and incidents should be disentangled from patients' and families' complaints about what they consider as AEs because the harm reported in their complaints may not be physical, but due to emotional stress, life disruption or loss of trust.

The aim of this paper was to analyze the AE reporting systems adopted at a university hospital with a view to enhancing the learning afforded by these systems and to generating valuable information to help healthcare providers implement more efficient risk management strategies and practices, and improve in-hospital risk prevention. First of all, we identify the AE rates in the various hospital wards to draw a map of the related injury indicators by single adverse event, and also to develop a composite AE indicator. Then we examine the correlations emerging from the AE metrics. Finally we investigate the associations between the AE rates and the organizational measures (average DRG weight, number of beds, average length of stay, mean age of patients).

2. Methods

2.1. Context

This survey was conducted at an University Hospital. This healthcare facility has 1,348 beds and 53 operating rooms, and in 2013 it managed 61,200 hospitalizations.

2.2. Materials

For this study, we analyzed the following data flows on in-hospital AEs:

- mandatory adverse event reports: 1) falls occurring from 1 January to 31 December 2014, reported by hospital staff to the hospital management's team at the Clinical Risk and Patient Safety Unit, using the hospital's standardized fall report form; 2) patients' claims refunded in 2014 (after a claim has been made, there is a latent period before any compensation is paid, but we assumed a constant latent period over time); and 3) cross-sectional data emerging from a survey on hospital-acquired infections (HAI) conducted from 27 May to 3 June 2013 by an expert panel on all university hospital wards, based on the ECDC Point Prevalence Survey protocol; and

- voluntary reports of injuries, analyzed as: 4) incident reports collected from 1 January to 31 December 2014 (submitted by hospital staff to the hospital management's team at the Clinical Risk and Patient Safety Unit using the hospital's standardized incident report form); and

- patients' complaints submitted to the Hospital Complaints Advocacy Service from 1 January to 31 December 2014.

Each hospital ward was considered as a single statistical unit. The hospital has 80 wards in all, but only 64 were included in the study, after excluding all units without beds for ordinary hospital admissions and the wards that had less than 100 ordinary admissions in the course of 2014.

2.3. Statistical methods

The cumulative annual incidence of AEs occurring on a given ward was calculated as the number of events divided by the number of admissions for that ward in the year considered. A ward's AE rate was calculated as the number of events divided by the number days of hospitalization in the year considered. A composite risk indicator was developed by combining the AE data flows (for falls, hospital-acquired infections and claims receiving compensation) using the SCIARE statistical software provided by AGENAS. The AE risk for each ward was converted into a score ranging from 1 to 100, where a score of 1 corresponded to a risk level of nil (no AEs had been reported) and a score of 100 was the highest level of risk registered at the hospital for a given type of AE-related phenomenon. The higher the total score, the higher number of AE-related phenomena on the ward.

Spearman's nonparametric test was applied to investigate the correlation between the AE rates identified. Poisson regression analysis to verify the association among characteristics of the wards (average DRG weight, number of beds, average length of stay, mean age of patients admitted in 2014) and AE rates. A logistic regression analysis was used to compare the characteristics of a given ward (average DRG weight, number of beds, average length of stay, mean age of patients admitted in 2014) with the prevalence of HAIs for each ward.

The level of statistical significance was set at $p < 0.05$. The statistical analyses were performed using Office 2003 Excel and STATA ver. 12.

2.4. Ethical issues

The study complies with the Declaration of Helsinki and with Italian Law n. 196/2003 on the protection of personal data. No identifiable human data were used for this study.

3. Results

Table 1 shows the cumulative in-hospital patient risk and the rates of each of the five AE-related phenomena analyzed.

Figure 1a shows the composite indicator for mapping AE-related phenomena by ward at the university hospital. Eleven of the 64 wards (17.2%) were apparently "risk-free" in 2014 for the combination of

Table 1
Adverse event flows by number (No.), cumulative incidence %, rate*100,000 days

	No.	Cumulative incidence %	Rate *100,000 days	Prevalence %
Voluntary incident reporting	426	0.66 (95% CI 0.60–0.73)	109.56 (95% CI 99.41–120.48)	
Mandatory reporting of Falls	367	0.57 (95% CI 0.52–0.63)	94.39 (95% CI 84.98–104.56)	
Claims	104	0.16 (95% CI 0.13–0.20)	26.75 (95% CI 21.86–32.41)	
Hospital-acquired infection (HAI)	80			9 (95% CI 7.13–10.89)
Complaints	382	0.59 (95% CI 0.54–0.66)	98.25 (95% CI 88.64–108.61)	

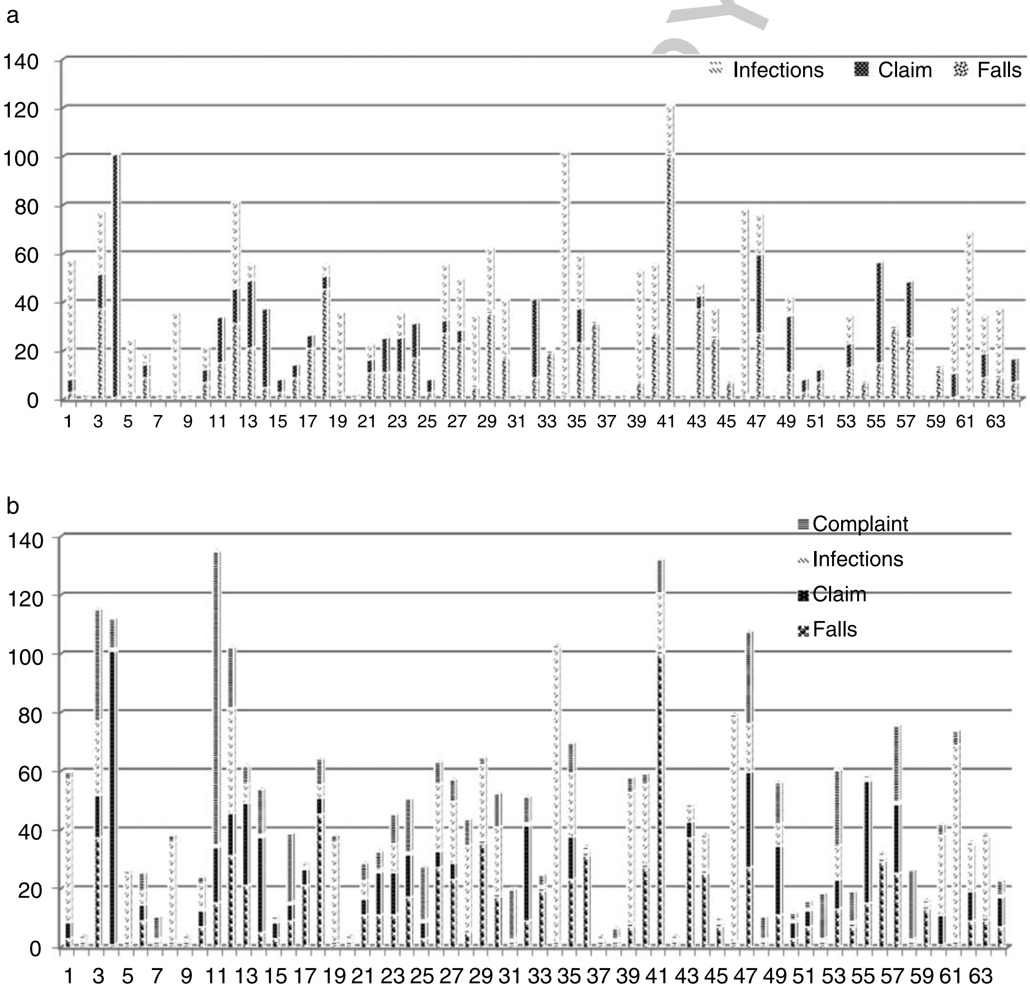

Fig. 1. (a) Mapping of adverse event scores among hospital units. (b) Mapping of adverse event scores among hospital units, including complaints.

the three AE-related phenomena. Three different wards had the highest scores (the worst level of risk) for three different AE-related phenomena. Figure 1b includes patients' complaints in the scores.

Table 2 shows the correlations between the rates for falls, incident reports, patients' claims and complaints, and the prevalence of HAI phenomena by ward. The data show a correlation between

Table 2
Spearman's nonparametric correlations between the rates of incident reports, falls, patients' claims, and the prevalence of HAI and the rates of patients' complaints (Spearman's rho = Sρ)

	Incident reports Sρ (*p*)	Falls Sρ (*p*)	Claims Sρ (*p*)	Complaints Sρ (*p*)	HAI Sρ (*p*)
Incident reports	1				
Falls	0.12	1			
	(0.348)				
Claims	0.29	0.37	1		
	(0.020)*	(0.002)*			
Complaints	0.25	0.20	0.48	1	
	(0.046)*	(0.120)	(<0.001)*		
HAI	–0.04	0.09	–0.15	–0.03	1
	(0.770)	(0.488)	(0.252)	(0.80)	

claims phenomena and incident reports, falls, and the number of patients' complaints. The analysis also revealed a correlation between the number of patients' complaints and incident reporting.

Table 3 shows the results of the Poisson regression. Our analyses revealed that falls were positively associated with average length of stay, number of beds, and mean age of patients on a given ward, but inversely associated with the average DRG weight of admissions to the ward. Unlike patients' claims, their complaints were directly associated with the average DRG weight of admissions to the ward. Age was also associated with the prevalence of HAI. Finally, average length of stay is inversely associated with both claims and complaints.

4. Discussion

Using a composite indicator, this study revealed the overall distribution of AE-related phenomena on different hospital wards. We identified a correlation between the AE-related phenomena, and also between the AE-related phenomena and patients' complaints. Our analysis also revealed that the different wards' structural characteristics and productivity were associated with the rates of AE-related phenomena, and also with the number of patients' complaints.

A previous study had found little overlap among different AE reporting systems, although each of them identified important and complementary safety issues. The authors concluded that, to obtain a comprehensive picture of their patient safety problems, hospitals should use a broad portfolio of approaches and then pool the information gleaned from all the different inputs into a collated and cohesive whole [7]. Hence our decision to produce a composite indicator that could integrate a large amount of information in a format that could be easily understood and therefore serve as a useful tool for conveying a summary assessment of performance. Our aim was not to weight the AE-related phenomena differently, but to arrive at a composite indicator to map the extent of each type of AE (scoring each measure from 0 to 100) to pinpoint the areas of poor performance where remedial action needed to be focused. Our composite indicator enabled us to obtain a global impression of the hospital's handling of AE-related phenomena by ward, with a view to prioritizing the resources dedicated to risk prevention where these phenomena were more frequent. Mapping the clinical risk represents a first step towards enhancing a patient safety culture: it is important to monitor the safety measures adopted in each clinical setting, to ascertain what kinds of AE are more likely to occur, what aspects of patient care warrant particular attention, and how safety-related information can be integrated and exploited [8].

Table 3
Results of Poisson regressions–dependent variables: incident reports, falls, claims, complaints awarded compensation; covariates: structural and organizational characteristics of the wards. Logistic regression–dependent variables: HAI; covariates: structural and organizational characteristics of the wards

	IRR	$P > \|z\|$	[95% CI]	
Incident reports				
Average DRG weight	1.02	0.699	0.91	1.14
Mean age of patients	1.01	0.020	1.00	1.01
Average hospital stay	0.98	0.201	0.96	1.01
Number of beds	1.00	0.353	1.00	1.01
Pseudo R2	0.013			
Falls	IRR			
Average DRG weight	0.83	0.006	0.72	0.95
Mean age of patients	1.03	0.000	1.02	1.032
Average hospital stay	1.03	0.021	1.002	1.052
Number of beds	1.01	0.036	1.002	1.02
Pseudo R2	*0.260*			
Claims	IRR			
Average DRG weight	1.41	0.010	1.08	1.83
Mean age of patients	1.00	0.395	0.99	1.01
Average hospital stay	0.84	0.000	0.78	0.92
Number of beds	1.00	0.540	0.98	1.01
Pseudo R2	*0.103*			
Complaints	IRR			
Average DRG weight	1.31	0.000	1.16	1.49
Mean age of patients	1.00	0.198	0.99	1.00
Average hospital stay	0.91	0.000	0.88	0.95
Number of beds	1.01	0.000	1.01	1.02
Pseudo R2	*0.095*			
HAI	OR			
Average DRG weight	1.68	0.152	0.83	3.43
Mean age of patients	1.03	0.039	1.00	1.06
Average hospital stay	0.99	0.82	0.87	1.11
Number of beds	1.03	0.202	0.99	1.07
Pseudo R2	*0.135*			

The decision whether or not to include the flow of complaints in our composite indicator could depend on how complaints are interpreted: they might or might not be considered as an adverse event measure. Few healthcare institutions interpret patients' complaints as adverse events, [9] though the thoughtful paper by Spittal et al reminds us that, like any adverse event, patients' complaints have an epidemiology that can yield important lessons for prevention [10]. Patients are the direct recipients of our medical intervention and should be the center of clinical processes, so they have the potential to provide feedback on their care [11]. That is why, in a patient-centered view of healthcare, some composite indicators could capture reports from people who have experienced unexpected medical problems during their hospital stay (i.e. reports of complaints). The link between patients' complaints and AE-related phenomena in our study was confirmed by the significant correlation between the rate of complaints and the incident reporting measure and claims rate. Many authors have emphasized the importance of patients as "smoke detectors" for patient safety [12]. Complaints are usually only the tip of the iceberg: for every complaint received, unknown numbers of patients have probably had similar experiences and suffered similar harm or conflict without lodging a complaint. In addition, whenever a patient makes a complaint, it means there has been a breakdown in the relationship between the healthcare personnel and their patient that might pave the way to a variety of patient safety problems.

We opted not to include voluntary incident reports in our composite indicator because, not being mandatory, this information flow is not a reliable measure of AEs and therefore cannot shed light on the epidemiology of patient safety problems. One way to see this issue is to note that some institutions celebrate an increase in the number of events being reported as a reflection of a "reporting culture", while others celebrate a reduction in the number of events reported based on the assumption that it means a reduction in the actual number of AEs taking place [13]. Our study shows, however, that voluntary incident reporting is a phenomenon that correlates with patients' complaints and claims, giving the impression that a high rate of voluntary safety issue reporting is an indication of an unsafe environment accustomed to glitches, routine foul-ups, with a culture that tends to avoid doing anything much about them, preferring to focus on other, overriding goals – and this would lead to more AEs prompting the payment of compensation and to higher levels of patient dissatisfaction.

Our regression analysis showed that a higher mean age of patients admitted to a ward increased the risk of falls and of hospital-acquired infections. The same situation has already been amply described in many other studies. For example, an English and Welsh national observational study based on the retrospective analysis of 12 months of patient safety incident reports concluded that "older people are proportionately the most vulnerable group for falls" [14]. The Point Prevalence Survey of healthcare-associated infections and antimicrobial use in European acute care hospitals in 2011-2012 identified a higher prevalence of HAI in older people too [15].

The average DRG weight of a given ward was associated positively with patients' claims, and complaints and negatively with falls. The average DRG weight could be seen as a proxy for the complexity of the cases admitted to a ward and adverse events are more likely to occur where patients have more complex conditions, because they require more complex care too, and this may exacerbate the risk of claims and complaints. On the other hand, more complex patients are more likely to be bedridden, so they are less liable to falls. Nurses may also take more care when looking after more complex patients. Previous research supports these latter data, with many studies reporting lower falls rates in surgical wards, which have high average DRG weights [16, 17].

The present study has several limitations. First of all, we could not include drug-related adverse events in our composite indicator because this mandatory data flow at the hospital in Padua was only developed recently, and the data it generates are still unreliable. Second, HAIs are not monitored routinely inside the hospital, making it possible to calculate the HAI rates only by means of a cross-sectional study conducted every two years.

In conclusion, this study aimed to learn something useful for the organization and management of clinical risks by analyzing the data on the mandatory (but often little used) reporting of adverse events affecting patient safety at a university hospital. This type of data analysis could help to promote a safety culture within the organization, whereas the hospital staff's perception that this type of feedback is irrelevant to their daily work may have a detrimental impact on their efforts to improve patient safety.

Conflict of interest

None declared.

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