

## Journal of Healthcare Quality Research



www.elsevier.es/jhgr

## **ORIGINAL ARTICLE**

# A hospital incident reporting system (2016–2019): Learning from notifier's perception on incidents' risk, severity and frequency of adverse events



L. de la Torre-Pérez<sup>a,\*</sup>, L. Granés<sup>b</sup>, A. Prat Marín<sup>b,c</sup>, M.J. Bertran<sup>b</sup>

- <sup>a</sup> Barcelona Institute for Global Health, Barcelona, Spain
- <sup>b</sup> Preventive Medicine and Epidemiology Department, Clinic Institute of Medicine and Dermatology (ICMiD), Hospital Clínic of Barcelona, Barcelona, Spain
- <sup>c</sup> Medicine Department, Faculty of Medicine and Health Sciences, University of Barcelona, Barcelona, Spain

Received 18 April 2022; accepted 14 August 2022 Available online 21 September 2022

## **KEYWORDS**

Patient safety; Incident reporting system Abstract Incident reporting systems (IRSs) are considered safety culture promoters. Nevertheless, they have not been contemplated to monitor professionals' perception about patient safety related risks. This study aims to describe the characteristics and evolution of incident notifications reported between 2016 and 2019 in a high complexity reference hospital in Barcelona and explores the association between notifications' characteristics and notifier's perception about incidents severity, probability of occurrence and risk. The main analysis unit was notifications reported. A descriptive analysis was performed and taxes by hospital activity were calculated. Odds ratios were obtained to study the association between the type of incident, the moment of incident, notifiers' professional category, reported incident's severity, probability and incidents' calculated risk. Through the study period, a total of 6379 notifications were reported, observing an annual increase of notifications until 2018. Falls (21.22%), Medical and procedures management (18.91%) and Medication incidents (15.49%) were the most frequently notified. Departments reporting the highest number of notifications were Emergency room and Obstetrics & Gynaecology. Incident type and notifiers' characteristics were consistently included in the models constructed to assess risk perception. Pharmaceutics were the most frequent notifiers when considering the proportion of staff members. Notification patterns can inform professionals' patient risk perception and increase awareness of professionals' misconceptions regarding patient safety.

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E-mail address: lr.delatorre.prz@gmail.com (L. de la Torre-Pérez).

<sup>\*</sup> Corresponding author.

#### PALABRAS CLAVE

Seguridad del paciente; Sistema de notificación de incidentes Un sistema de notificación de incidentes hospitalarios (2016-2019): aprendizaje de la percepción de los notificadores sobre el riesgo de los incidentes, la gravedad y la frecuencia de los eventos adversos

Resumen Los sistemas de notificación de incidentes promueven la cultura de la seguridad en los hospitales. Sin embargo, no se han considerado para conocer la percepción de los profesionales sobre los riesgos relacionados con la seguridad del paciente. Este estudio pretende describir las características y la evolución de las notificaciones de incidentes comunicadas entre 2016 y 2019 en un hospital de alta complejidad de Barcelona y explorar la asociación entre las características de las notificaciones y la percepción del notificador sobre la gravedad de los incidentes, la probabilidad de ocurrencia y el riesgo. La unidad de análisis principal fueron las notificaciones comunicadas. Se realizó un análisis descriptivo y se calcularon las tasas en relación con la actividad hospitalaria. Se obtuvieron las odds ratios para estudiar la asociación entre el tipo de incidente, el momento del incidente, la categoría profesional de los notificadores, la gravedad, probabilidad y riesgo calculado del incidente. A lo largo del periodo de estudio se registraron un total de 6.379 notificaciones, observándose un incremento anual de notificaciones hasta 2018. Las caídas (21,22%), los problemas en la gestión médica y de procedimientos (18,91%) y los incidentes de medicación (15,49%) fueron los más notificados. Los departamentos que reportaron el mayor número de notificaciones fueron urgencias y obstetricia y ginecología. El tipo de incidente y las características de los notificadores se incluyeron sistemáticamente en los modelos para evaluar la percepción del riesgo. Los farmacéuticos fueron la categoría profesional más notificadora considerando el número de profesionales en plantilla. Los patrones de notificación pueden informar sobre la percepción del riesgo de los pacientes por parte de los profesionales y ayudar a detectar creencias erróneas de los profesionales acerca de la seguridad de los pacientes.

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## Introduction

Incident reporting systems (IRSs) are key in patient safety developing.<sup>1</sup> The main goal of patient safety is considered to be the prevention of healthcare errors, reduce patient's safety risk and design measures to determine, report and correct the errors before they affect the patient.<sup>2</sup>

IRS aims to identify risks so actions can be implemented to minimize those risks. They allow continuous learning through the analysis of experiences that can compromise clinical safety. This gives the institutions the opportunity to design and implement preventive measures to ensure constant improvement of clinical practice. IRS are barely considered surveillance systems, as normally depend on surveillance awareness and honesty.<sup>2</sup> Moreover, concerns have been raised about the difficult interpretation and comparison of results and their usefulness.3 However, they are thought to be operatively useful in identifying local hazards, can be used to identify protocol deviances through the collection of uncommon events and repetitive incidents, and have been considered a key part of a safety culture construction. 1,4 Most groups claiming the IRS as safety culture promoter, relate to the fact that the more people notify, the more awareness there would be about patient safety and risks.<sup>5</sup> Nevertheless, considering that IRS functioning depends on notifiers' risk perception, to date, it has not been contemplated as a tool to monitor professionals' perception about patient safety.

Recent reports and studies published with IRS data, refer mostly to the analysis of incidents related to specific health departments<sup>6-10</sup> whereas some general country-level IRS analyses are available and based on hospital-level IRS data collection.<sup>11–13</sup> Moreover, some studies have shown certain repetitive patterns of notification (e.g. doctors notifying incidents considered more severe and nurses notifying more events) in IRS data analysis.<sup>12,14–16</sup>

This study aims to describe the characteristics and evolution of incident notifications reported between 2016 and 2019 in a high complexity reference hospital in Barcelona and explores the association between notifications' characteristics and notifier's perception about incidents severity, probability of occurrence and risk.

## Methodology

## Study setting

Hospital Clínic is a high complexity reference hospital in Barcelona with a reference population of 540,000 inhabitants.<sup>17</sup> It has 728 beds, and in 2019 reported 44,035 inpatient discharges, 142,823 Emergency room visits and 551,800 ambulatory visits. The hospital's activity is organized in divisions called institutes. Each institute is constituted by related departments – a description of these hospital sections has been described elsewhere.<sup>18</sup> On another note, hospital human resources management is different between professional categories. There are three

different shifts for nurses, auxiliary nurses, wardens and administrative staff – morning, noon and night, with 8 h per shift. While medical professionals can work shifts of 8, 10, 16 or 24h depending on their professional category.

Patient safety IRSwas piloted in Hospital Clínic de Barcelona (HCB) in 2014 and started its activity in October 2015. The implementation of the IRS led to the construction of multidisciplinary groups of delegates from each institute. These groups are called "Safety Nuclei" and they are responsible for analyzing and processing the notifications and for promoting and monitoring the implementation of improvement measures. Safety Nuclei are constituted by an interdisciplinary group of professionals and always include a pharmacist and a Preventive Medicine professional. This study includes notifications reported between 2016 and 2019, excluding the first months of implementation in 2015.

#### Data source and variables

The main analysis unit was notifications reported to the HCB patient safety IRS. Notification details were collected on The Patient Safety Company® (TPSC) platform. 19 TPSC platform is structured in different sections according to Hospital's institutes, 12 hereinafter referred to as departments. Some platform variables were calculated and recategorized for the analysis.

#### Independent variables

The platform variables chosen as independent variables were the department where the incident took place, contributing factors related to patient or professionals, people involved in the incident (patient or professionals), way of knowing (Experienced, when the notifier has had a firsthand experience of the incident and has been involved in it, Observed, Heard from Other), professional category (Doctor, Nurse, Assistant Nurse, Medical Residents, Pharmacist, Administrative Staff, Other) and type of incident according to the WHO taxonomy.<sup>20</sup> The variable shift was calculated through the incident hour: 8.01-22.00 h for the first and second shift (day shift) and 22.00-8.00 for the third shift (night shift). Holiday period was defined as a qualitative variable with two categories; holiday period (including the periods from December 23rd to January 7th, Easter holidays in each year and from the 1st of July till 31st of August) and non-holiday period (the rest of the year). Variables including department groups were regrouped in 4 categories: surgical, medical, medical-surgical (otorhinolaryngology, ophthalmology and gynaecology) and Others (anatomopathology, biochemistry, genetics, analysis centre, pharmacy, radiology and nuclear medicine). Non-healthcare provider departments were excluded from the analysis.

### Dependent variable

Fig. 1 shows the characteristics of the platform variables included as dependent variables in this analysis. The risk assigned to each incident is calculated through the risk matrix presented on the platform (Fig. 2), which uses the variables "severity" and "probability of occurrence" for risk assignment (initially both reported by the notifier). The final risk assigned to each notification is the result of

a twofold evaluation, the initial evaluation performed by the notifier based on the risk matrix and the subsequent healthcare contextualisation of the incident by the Safety Nuclei. Severity with initially 5 categories (no harm, minor harm, moderate, severe and extreme) was recoded into 3 categories for the analysis: No harm/minor harm, Moderate and Severe. Notifications classified as Extreme risk by the notifier are considered sentinel events. The probability of occurrence was also recoded into 3 categories: Infrequent, Occasional/Probable and Frequent.

## Data analysis

A descriptive analysis of the selected variables was performed. Incidents rate per hospital activity was calculated for each department using both the department's total discharges and total days of hospitalization. Taxes were calculated only considering inpatient care. Distribution of the number of notifications per variable was reported in absolute and relative terms and statistical comparison was performed through Chi square test considering all forms of healthcare. In order to compare the number of notifications per professional category, adjusted rates were calculated considering the number of workers for each professional category in 2019. Variables with more than 30% of missing values are excluded. Sentinel events detection was summarized narratively through the identification and classification by cause rout analysis processes.

The odds ratios (OR) with 95% of confidence intervals (95% CI) were calculated to study the association between the type of incident, the moment of incident (shift and holiday season), notifiers characteristics (department and professional category), and reported incident's severity, probability and incidents' calculated risk. To calculate the OR, three ordinal logistic models were built following the Akaike Information Criterion<sup>21</sup> to study the association between notification factors and reported probability of occurrence, severity and risk (hereinafter, model A, B and C respectively). All analyses were made with Stata 15.

## **Results**

During the study period, a total of 6379 notifications were reported. Of these, 1170 (18.34%) were reported in 2016, 1637 (25.66%) in 2017, 1869 (29.30%) in 2018 and 1703 in 2019 (26.70%). Regarding the place where the notified incidents occurred, 3745 (58.71%) belonged to hospitalization episodes, 1212 (19.00%) to emergency episodes, 566 (8.87%) took place in the outpatient care, 492 (7.71%) in surgery, 361 (5.66%) belonged to non-assistance services and 3 (0.05%) were missing.

Considering the inpatient care activity, the Neuroscience and the Obstetrics & Gynaecology department had the highest rate of notifications per 1000 hospital discharges. This doubled other departments' rates such as Orthopaedic Surgery & Rheumatology and Nephrology & Urology. The Obstetrics & Gynaecology department presented the highest notification rate per 1000 days of hospitalization and Cardiology & Cardiac surgery department the lowest. Some departments increased the number of notifications adjusted

Institute	2016	2017	2018	2019	Total
Cardiology & cardiac surgery					
Number of notifications	75	61	62	63	261
Total discharges	4536	4325	4502	4608	17971
Notifications per 1000 hospital discharges	16.5	14.1	13.8	13.7	14.5
Total days of hospitalization	28808	28463	28056	27284	112611
Notifications per 1000 days of hospitalization	2.6	2.1	2.2	2.3	2.3
Orthopaedic Surgery & Rheumatology					
Number of notifications	46	78	54	49	227
Total discharges	5148	5236	5398	4970	20752
Notifications per 1000 hospital discharges	8.9	14.9	10.0	9.9	10.9
Total days of hospitalization	23812	23586	25413	23158	95969
Notifications per 1000 days of hospitalization	1.9	3.3	2.1	2.1	2.4
Obstetrics & Gynaecology					
Number of notifications	167	231	367	253	1018
Total discharges	6927	6727	6636	6527	26817
Notifications per 1000 hospital discharges	24.1	34.3	55.3	38.8	38.0
Total days of hospitalization	24004	23717	23945	20698	92364
Notifications per 1000 days of hospitalization	7.0	9.7	15.3	12.2	11.0
Gastroenterology & Metabolic Diseases					
Number of notifications	88	148	184	228	648
Total discharges	6189	6044	6049	6015	24297
Notifications per 1000 hospital discharges	14.2	24.5	30.4	37.9	26.7
Total days of hospitalization	39043	39343	37468	38113	153967
Notifications per 1000 days of hospitalization	2.3	3.8	4.9	6.0	4.2
Oncology & Haematology		•			•••
Number of notifications	52	91	66	82	291
Total discharges	2219	2172	2234	2413	9038
Notifications per 1000 hospital discharges	23.4	41.9	29.5	34.0	32.2
Total days of hospitalization	22753	23481	23901	26230	96365
Notifications per 1000 days of hospitalization	2.3	3.9	2.8	3.1	3.0
Internal Medicine & Infectious Diseases		44.4	40.4	402	200
Number of notifications	69	114	104	103	390
Total discharges	2981	3374	3283	3682	13320
Notifications per 1000 hospital discharges	23.1	33.8	31.7	28.0	29.3
Total days of hospitalization	2786	30092	29386	33169	95433
Notifications per 1000 days of hospitalization	24.8	3.8	3.5	3.1	4.1
Neurosciences Number of notifications	76	139	145	116	476
Total discharges	70 2912	2931	2916	2889	11648
Notifications per 1000 hospital discharges	26.1	47.4	49.7	40.2	40.9
Total days of hospitalization	30548	30884	31251	31611	124294
Notifications per 1000 days of hospitalization	2.5	4.5	4.6	3.7	3.8
Nephrology & Urology					
Number of notifications	73	63	50	76	262
Total discharges	3368	3404	3503	3816	14091
Notifications per 1000 hospital discharges	21.7	18.5	14.3	19.9	18.6
Total days of hospitalization	16838	16508	15760	16610	65716
Notifications per 1000 days of hospitalization	4.3	3.8	3.2	4.6	4.0
Respiratory Diseases					
Number of notifications	30	65	51	26	172
Total discharges	1586	1533	1701	1766	6586
Notifications per 1000 hospital discharges	18.9	42.4	30.0	14.7	26.1
Total days of hospitalization	11928	11904	12472	12850	49154
Notifications per 1000 days of hospitalization	2.5	5.5	4.1	2.0	3.5

Variable	Categories
Severity	No patient harm 1 An error is possible
	No patient harm 2 An error occurred but it did not arrive to the patient
	Minimum The error did not produce any lesion
	Minor The error led to patient monitoring, but not to patient lesions
	Moderate 1 The error led to patient lesion and/or treatment
	Moderate 2 The error led to a patient's temporal lesion or a longer hospital stay
	Critic 1 The error has produced a permanent lesion
	Critic 2 The error has produced a life-threatening situation
	Catastrophic Lethal
Probability of occurrence	Very infrequent Exceptional (one time in more than 5 years)
	Not frequent Could happen once between 2 and 5 years
	Possible Could happen 1 or two times a year
	Probable Could happen a few times a year
	Frequent Could happen in the next weeks or months
Incident's type	Medication
	Falls
	Blood products
	Assistive devices
	Healthcare associated infection
	Nutrition
	Patient's behavior
	Oxygen and other medicinal gasses
	Documentation
	Clinic and procedures management
	Clinico-administrative management and laboratory
	Infrastructures

Figure 1 IRS Platform variables: severity, probability of occurrence and incident's type.

for activity during the study period (Gastroenterology & Metabolic Diseases) whereas others showed a decreasing trend (Cardiology & Cardiac surgery). The overall rates of notifications per 1000 hospital discharges and 1000 days of hospitalization increased from 2016 to 2018 and slightly decreased in 2019. Detailed rates are reported in Table 1.

Departments reporting the highest number of notifications were Emergency room, with 1212, Obstetrics & Gynaecology, with 1130 notifications. While Emergency departments are prone to notify more frequent incidents, the Obstetrics & Gynaecology department has a

larger proportion of severe notifications when comparing to the distribution of severity in other departments. Regarding the type of incident, Falls were the most common; a total of 1352 Falls were reported during the study period, which represents a 21.19% of notifications. However, Falls were classified mostly as occasional or infrequent incidents by professionals (55.92 and 12.57%, respectively). Second most common type of incident was related to Medical and procedures management (18.91%). In third place were those related to Medication incidents (15.49%).

	Very infrequent	Not frequent	Possible	Frobable	Frequent
No patient harm 1	Very Iow Risk	Very low Hisk	Very low Risk	Low Risk	Low Risk
No patient harm 2	Very low Risk		Very low Risk	Low Risk	Law Risk
Minimum	Low Risk	Law Risk	Law Risk	Law Risk	Moderate risk
Minor	Low Risk	Low Risk	Moderate risk	Moderaterisk	Moderate risk
Moderate 1	Moderate risk	Moderate risk	High risk	High risk	High risk
Moderate 2	Moderate risk	Moderate risk	High risk		High risk
Critic 1	Moderate risk	High risk	High risk	Extreme risk	Extreme risk
Critic 2	Moderate risk		High risk	Extreme risk	Extreme risk
Catastrophic	Extreme risk	Extreme risk	Extreme risk	Extreme risk	Extreme risk

Figure 2 Calculation of incident's risk through the variables ''severity'' (transversal axis) and ''probability of occurrence'' (longitudinal axis).

Most frequent incidents are classified with low or moderate severity whereas less frequent notifications such as those related to blood products and oxygen are classified as high severity incidents. Nurses were the professionals who reported the highest number of notifications, in absolute value, reporting 60.44% of all notifications. Physicians were in second place, reporting 17.00% of incidents. However, considering the number of workers in each professional category, pharmacists were the professionals who notified more frequently, with 182.76 notifications per 100 workers in 2019, followed by nurses, with 52.42 notifications per 100 workers, assistant nurses with a rate of 51.63 and physicians, who reported 21.84 notifications per 100 workers in 2019. Administrative staff and other professionals had the lowest notification rates, with 3.08 and 2.78 notifications per 100 workers respectively. Administrative staff, doctors and medical residents notify a greater proportion of high severity incidents in comparison to other professionals. Pharmacists classified most of the reported incidents as frequent and minor severity. More than 75% of notifications referred to incidents occurred during the day shift. Notifications of night incidents were less frequent but more related to moderate and severe incidents. The most frequent way of knowing was the person's own experience (72.76%), followed by hearing from others (15.42%) and observed (11.82%). First-hand experienced incidents were more often classified as less severe and more frequent. Additionally, altogether, 28 sentinel events were notified (eight in 2016, five in 2017, twelve in 2018 and three in 2019).

Overall, contributor factors and people involved in the incident were more reported in those incidents classified as moderate or severe. The most frequent enabler factors reported as contributors to the incident were patients' (36.65%) and professionals' (35.49%). Incidents with a patient contributor were more often classified as moderate or severe in comparison to incidents with a professional enabler factor, classified mostly as no harm/minor harm. Patients were the most frequently involved in the incidents (69.69%) when the person involved was reported, further information in notification characteristics is shown in Tables 2 and 3.

In the models' construction, the inclusion of the moment of incident varied depending on the dependent variable assessed. On the one hand, none of the models included the holiday period as a significant variable through the Akaike Information Criterion. However, model B included the variable shift. Conversely, incident type and notifier characteristics (department and professional category) were consistently included in the three models.

In model A, Medical and procedures management incidents were consistently and significantly categorized as frequent (OR 2.21 [95% IC 1.30-3.76]) as well as Infrastructure incidents (OR 2.14 [95% IC 1.23-3.73]). In model B, where Analogic and digital documentation incidents was the reference category, all other incident types were significantly associated with higher reported severity notifications, However, Falls (OR 25.28 [95% IC 15.93-40.11]) and Oxygen & other gasses incidents (OR 12.19 [95% IC 3.62-41.07]) were the type of incidents more strongly associated with higher reported severity. Overall, in the adjusted model C, Falls (OR 13.79 [95% IC 7.47-25.46]), Patient Behaviour (OR 3.08 [95% IC 1.72-5.53]), Healthcare Associated Infection (OR 3.94 [95% IC 1.66-9.38]) and Medical and procedures management (OR 2.88 [95% IC 1.65-5.04]) were the incident types with more Risk OR.

Regarding notifiers characteristics, pharmacists and medical residents were the professional categories significantly associated with notifications categorized as frequent (OR 4.99 [95% IC 2.24-11.12] and 5.66 [95% IC 1.53-20.93] respectively). Whereas this tendency was maintained for severity in medical residents, pharmacists were the professionals that reported the mildest incidents (taken as a reference category in Model B). On the other hand, being a doctor or a nurse was significantly associated with the reporting of more severe incidents (OR 4.16 [95% IC 2.44-7.09] and 2.00 [95% 1.19-3.35]), respectively. When studying the association of areas of specialization, our data showed that medical and medical-surgical departments tend to report incidents that are considered more frequent in comparison to Surgery departments (non-statistically significant), whereas medical and surgical departments tend to report more severe notifications in comparison to

Incident type	55.92) 170 (12.5) 38.84) 523 (43.40) 48.63) 269 (27.2) 34.82) 279 (37.6) 36.59) 226 (39.3)		
Falls	38.84)       523 (43.40         48.63)       269 (27.25         34.82)       279 (37.65		
Medical & Procedures Management         1205         214 (17.76)         468           Medication         987         238 (24.11)         480           Medical Devices         741         202 (27.26)         258           Patient's Behaviour         574         135 (23.52)         210           Infrastructures         525         112 (21.33)         135           Analogic & Digital Documentation         413         104 (25.18)         190           Clinical & Lab Management         243         53 (21.81)         115           Nutrition         138         38 (27.54)         53           Health-Care Associated Infection         106         20 (18.87)         43           Blood Products         72         24 (33.33)         39           Oxygen & Other gasses         15         8 (53.33)         3           Non classified         8         2 (25.00)         1           Department         267         102 (38.20)         109           Obstetrics & Gynaecology         1130         237 (20.97)         464           Oncology & Haematology         439         116 (26.42)         206           Gastroenterology & Metabolic Diseases         695         213 (30.65)         306	38.84)       523 (43.40         48.63)       269 (27.25         34.82)       279 (37.65		<0.000
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Infrastructures	36.59) 226 (39.37)	5) 2 (0.27)	
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Clinical & Lab Management Nutrition Nutrition 138 38 (27.54) 53 Health-Care Associated Infection 106 20 (18.87) 43 Blood Products 72 24 (33.33) 39 Oxygen & Other gasses 15 8 (53.33) 3 Non classified 8 2 (25.00) 1  Department Cardiology & Cardiac Surgery 267 Obstetrics & Gynaecology 1130 237 (20.97) 464 Oncology & Haematology 439 Gastroenterology & Metabolic Diseases 498 105 (21.08) 1241 Nephrology & Urology 1140 Internal Medicine & Infectious Diseases 498 Internal Medicine & Infectious Diseases 458 In	25.71) 277 (52.76	, ,	
Nutrition         138         38 (27.54)         53           Health-Care Associated Infection         106         20 (18.87)         43           Blood Products         72         24 (33.33)         39           Oxygen & Other gasses         15         8 (53.33)         3           Non classified         8         2 (25.00)         1           Department         2         102 (38.20)         109           Obstetrics & Gynaecology         1130         237 (20.97)         464           Oncology & Haematology         439         116 (26.42)         206           Gastroenterology & Metabolic Diseases         695         213 (30.65)         306           Neurosciences         498         105 (21.08)         241           Nephrology & Urology         268         61 (22.85)         128           Internal Medicine & Infectious Diseases         458         146 (31.88)         234           General Surgery & Anaesthesiology         495         140 (28.28)         190           Orthopaedic Surgery & Rheumatology         247         64 (25.91)         108           Respiratory Diseases         178         65 (36.52)         63           Emergency department         1212         224 (18.48)			
Health-Care Associated Infection   106   20 (18.87)   43     Blood Products   72   24 (33.33)   39     Oxygen & Other gasses   15   8 (53.33)   3     Non classified   8   2 (25.00)   1     Department     Cardiology & Cardiac Surgery   267   102 (38.20)   109     Obstetrics & Gynaecology   1130   237 (20.97)   464     Oncology & Haematology   439   116 (26.42)   206     Gastroenterology & Metabolic Diseases   695   213 (30.65)   306     Neurosciences   498   105 (21.08)   241     Nephrology & Urology   268   61 (22.85)   128     Internal Medicine & Infectious Diseases   458   146 (31.88)   234     General Surgery & Anaesthesiology   495   140 (28.28)   190     Orthopaedic Surgery & Rheumatology   247   64 (25.91)   108     Respiratory Diseases   178   65 (36.52)   63     Emergency department   1212   224 (18.48)   447     Professional Category     Doctor   993   168 (16.92)   401     Nurse   3856   1029 (26.69)   1713     Assistant Nurse   454   130 (28.63)   167     Medical Resident   52   3 (5.77)   15     Pharmacist   175   15 (8.57)   118     Administrative Staff   64   17 (26.56)   33     Other   246   71 (28.86)   112     Non-registered   539   142 (26.35)   192     Shift     Night   1486   377 (25.37)   680     Day   4893   1198 (24.48)   2071     Contributing Factor Reported     Yes   4579   1104 (24.11)   2028     No   4701   1133 (24.10)   1922     No   4701   1133 (24.10)   1922     No   4701   1133 (24.10)   1922     Oxigent Resident   1678   442 (26.34)   829     No   4701   1133 (24.10)   1922     Oxigent Resident   1678   442 (26.34)   829     No   4701   1133 (24.10)   1922     No   4701   1133 (24.10)   1922     Catheral Resident   1678   442 (26.34)   829     No   4701   1133 (24.10)   1922     Oxigent Resident   172   172     Resident Resident   172   173     Resident Resident   172   173     Resident Resident   173   173     Resident Resident   173	47.33) 75 (30.86		
Blood Products	38.41) 47 (34.06		
Oxygen & Other gasses         15         8 (53.33)         3 Non classified         8 2 (25.00)         1           Department           Cardiology & Cardiac Surgery         267         102 (38.20)         109           Obstetrics & Gynaecology         1130         237 (20.97)         464           Oncology & Haematology         439         116 (26.42)         206           Gastroenterology & Metabolic Diseases         695         213 (30.65)         306           Neurosciences         498         105 (21.08)         241           Nephrology & Urology         268         61 (22.85)         128           Internal Medicine & Infectious Diseases         458         146 (31.88)         234           General Surgery & Anaesthesiology         495         140 (28.28)         190           Orthopaedic Surgery & Rheumatology         247         64 (25.91)         108           Respiratory Diseases         178         65 (36.52)         63           Emergency department         1212         224 (18.48)         447           Professional Category         20ctor         993         168 (16.92)         401           Nurse         3856         1029 (26.69)         1713           Assistant Nurse <td< td=""><td>40.57) 43 (40.57)</td><td>•</td><td></td></td<>	40.57) 43 (40.57)	•	
Non classified         8         2 (25.00)         1           Department         Cardiology & Cardiac Surgery         267         102 (38.20)         109           Obstetrics & Gynaecology         1130         237 (20.97)         464           Oncology & Haematology         439         116 (26.42)         206           Gastroenterology & Metabolic Diseases         695         213 (30.65)         306           Neurosciences         498         105 (21.08)         241           Nephrology & Urology         268         61 (22.85)         128           Internal Medicine & Infectious Diseases         458         146 (31.88)         234           General Surgery & Anaesthesiology          495         140 (28.28)         190           Orthopaedic Surgery & Rheumatology         247         64 (25.91)         108           Respiratory Diseases         178         65 (36.52)         63           Emergency department         1212         224 (18.48)         447           Professional Category         10ctor         993         168 (16.92)         401           Nurse         3856         1029 (26.69)         1713           Assistant Nurse         454         130 (28.63)         167           Medical Re	54.17) 9 (12.5)		
Department         Cardiology & Cardiac Surgery         267         102 (38.20)         109           Obstetrics & Gynaecology         1130         237 (20.97)         464           Oncology & Haematology         439         116 (26.42)         206           Gastroenterology & Metabolic Diseases         695         213 (30.65)         306           Neurosciences         498         105 (21.08)         241           Nephrology & Urology         268         61 (22.85)         128           Internal Medicine & Infectious Diseases         458         146 (31.88)         234           General Surgery & Anaesthesiology         495         140 (28.28)         190           Orthopaedic Surgery & Rheumatology         247         64 (25.91)         108           Respiratory Diseases         178         65 (36.52)         63           Emergency department         1212         224 (18.48)         447           Professional Category           Doctor         993         168 (16.92)         401           Nurse         3856         1029 (26.69)         1713           Assistant Nurse         454         130 (28.63)         167           Medical Resident         52         3 (5.77)         15 <td>20) 4 (26.67</td> <td></td> <td></td>	20) 4 (26.67		
Cardiology & Cardiac Surgery Obstetrics & Gynaecology Oncology & Haematology Aday Oncology & Haematology Gastroenterology & Metabolic Diseases Apphrology & Urology Internal Medicine & Infectious Diseases Apphrology & Haematology Apphrology & Haematology Apphrology & Urology Apphrology & Urology Apphrology & Urology Apphrology & Haematology Apphrology & Urology Apphrology & Haematology Apphrology & Urology Apphrology & Haematology Apphrology Apph	12.50) 5 (62.50	0)	
Obstetrics & Gynaecology       1130       237 (20.97)       464         Oncology & Haematology       439       116 (26.42)       206         Gastroenterology & Metabolic Diseases       695       213 (30.65)       306         Neurosciences       498       105 (21.08)       241         Nephrology & Urology       268       61 (22.85)       128         Internal Medicine & Infectious Diseases       458       146 (31.88)       234         General Surgery & Anaesthesiology       495       140 (28.28)       190         Orthopaedic Surgery & Rheumatology       247       64 (25.91)       108         Respiratory Diseases       178       65 (36.52)       63         Emergency department       1212       224 (18.48)       447         Professional Category       20ctor       993       168 (16.92)       401         Nurse       3856       1029 (26.69)       1713         Assistant Nurse       454       130 (28.63)       167         Medical Resident       52       3 (5.77)       15         Pharmacist       175       15 (8.57)       118         Administrative Staff       64       17 (26.56)       33         Other       246       71 (28.86) <td></td> <td></td> <td>&lt;0.000</td>			<0.000
Oncology & Haematology Gastroenterology & Metabolic Diseases Neurosciences Nephrology & Urology Internal Medicine & Infectious Diseases General Surgery & Anaesthesiology Orthopaedic Surgery & Rheumatology Professional Category Doctor Nurse Assistant Nurse Medical Resident Pharmacist Administrative Staff Other Non-registered  Shift Night Day  Patient Was a Contributing Factor Yes No  Neurosciences 498 105 (21.08) 213 (30.65) 306 498 105 (21.08) 241 105 (21.08) 241 105 (21.08) 241 105 (21.08) 241 105 (21.08) 241 106 (21.08) 241 107 (22.10) 248 105 (21.08) 241 106 (21.08) 241 106 (21.08) 241 107 (28.28) 1100 128.28 190 07thopaedic Surgery & Rheumatology 247 64 (25.91) 108 Respiratory Diseases 178 65 (36.52) 63 Emergency department 1212 224 (18.48) 447  Professional Category Doctor 993 168 (16.92) 401 Nurse 3856 1029 (26.69) 1713 Assistant Nurse 454 130 (28.63) 167 Medical Resident 52 3 (5.77) 15 15 (8.57) 118 Administrative Staff 64 17 (26.56) 33 Other 246 71 (28.86) 112 Non-registered 539 142 (26.35) 192  Shift Night 1486 377 (25.37) 680 Day 4893 1198 (24.48) 2071  Contributing Factor Reported Yes 4579 1104 (24.11) 2028 No 1800 471 (26.17) 723  Patient Was a Contributing Factor Yes 1678 442 (26.34) 829 No 1133 (24.10) 1922	40.82) 52 (19.48	3) 4 (1.50)	
Gastroenterology & Metabolic Diseases       695       213 (30.65)       306         Neurosciences       498       105 (21.08)       241         Nephrology & Urology       268       61 (22.85)       128         Internal Medicine & Infectious Diseases       458       146 (31.88)       234         General Surgery & Anaesthesiology       495       140 (28.28)       190         Orthopaedic Surgery & Rheumatology       247       64 (25.91)       108         Respiratory Diseases       178       65 (36.52)       63         Emergency department       1212       224 (18.48)       447         Professional Category       20ctor       993       168 (16.92)       401         Nurse       3856       1029 (26.69)       1713         Assistant Nurse       454       130 (28.63)       167         Medical Resident       52       3 (5.77)       15         Pharmacist       175       15 (8.57)       118         Administrative Staff       64       17 (26.56)       33         Other       246       71 (28.86)       112         Non-registered       539       142 (26.35)       192         Shift       No       1800       471 (26.17)	41.06) 429 (37.96	5)	
Neurosciences       498       105 (21.08)       241         Nephrology & Urology       268       61 (22.85)       128         Internal Medicine & Infectious Diseases       458       146 (31.88)       234         General Surgery & Anaesthesiology       495       140 (28.28)       190         Orthopaedic Surgery & Rheumatology       247       64 (25.91)       108         Respiratory Diseases       178       65 (36.52)       63         Emergency department       1212       224 (18.48)       447         Professional Category       Doctor       993       168 (16.92)       401         Nurse       3856       1029 (26.69)       1713         Assistant Nurse       454       130 (28.63)       167         Medical Resident       52       3 (5.77)       15         Pharmacist       175       15 (8.57)       118         Administrative Staff       64       17 (26.56)       33         Other       246       71 (28.86)       112         Non-registered       539       142 (26.35)       192         Shift       Night       1486       377 (25.37)       680         Day       4893       1198 (24.48)       2071      <	46.92) 117 (26.65	5)	
Nephrology & Urology       268       61 (22.85)       128         Internal Medicine & Infectious Diseases       458       146 (31.88)       234         General Surgery & Anaesthesiology       495       140 (28.28)       190         Orthopaedic Surgery & Rheumatology       247       64 (25.91)       108         Respiratory Diseases       178       65 (36.52)       63         Emergency department       1212       224 (18.48)       447         Professional Category       993       168 (16.92)       401         Nurse       3856       1029 (26.69)       1713         Assistant Nurse       454       130 (28.63)       167         Medical Resident       52       3 (5.77)       15         Pharmacist       175       15 (8.57)       118         Administrative Staff       64       17 (26.56)       33         Other       246       71 (28.86)       112         Non-registered       539       142 (26.35)       192         Shift       Night       1486       377 (25.37)       680         Day       4893       1198 (24.48)       2071         Contributing Factor Reported       Yes       4579       1104 (24.11)       2028	44.03) 174 (25.04		
Internal Medicine & Infectious Diseases   458   146 (31.88)   234	48.39) 152 (30.52	2)	
General Surgery & Anaesthesiology       495       140 (28.28)       190         Orthopaedic Surgery & Rheumatology       247       64 (25.91)       108         Respiratory Diseases       178       65 (36.52)       63         Emergency department       1212       224 (18.48)       447         Professional Category         Doctor       993       168 (16.92)       401         Nurse       3856       1029 (26.69)       1713         Assistant Nurse       454       130 (28.63)       167         Medical Resident       52       3 (5.77)       15         Pharmacist       175       15 (8.57)       118         Administrative Staff       64       17 (26.56)       33         Other       246       71 (28.86)       112         Non-registered       539       142 (26.35)       192         Shift       1486       377 (25.37)       680         Day       4893       1198 (24.48)       2071         Contributing Factor Reported         Yes       4579       1104 (24.11)       2028         No       1800       471 (26.17)       723         Patient Was a Contributing Factor	47.94) 78 (29.2		
Orthopaedic Surgery & Rheumatology       247       64 (25.91)       108         Respiratory Diseases       178       65 (36.52)       63         Emergency department       1212       224 (18.48)       447         Professional Category         Doctor       993       168 (16.92)       401         Nurse       3856       1029 (26.69)       1713         Assistant Nurse       454       130 (28.63)       167         Medical Resident       52       3 (5.77)       15         Pharmacist       175       15 (8.57)       118         Administrative Staff       64       17 (26.56)       33         Other       246       71 (28.86)       112         Non-registered       539       142 (26.35)       192         Shift         Night       1486       377 (25.37)       680         Day       4893       1198 (24.48)       2071         Contributing Factor Reported         Yes       4579       1104 (24.11)       2028         No       1800       471 (26.17)       723         Patient Was a Contributing Factor         Yes       1678       442 (26.34) <t< td=""><td>51.09) 78 (17.03</td><td>3)</td><td></td></t<>	51.09) 78 (17.03	3)	
Respiratory Diseases       178       65 (36.52)       63         Emergency department       1212       224 (18.48)       447         Professional Category       993       168 (16.92)       401         Nurse       3856       1029 (26.69)       1713         Assistant Nurse       454       130 (28.63)       167         Medical Resident       52       3 (5.77)       15         Pharmacist       175       15 (8.57)       118         Administrative Staff       64       17 (26.56)       33         Other       246       71 (28.86)       112         Non-registered       539       142 (26.35)       192         Shift       1486       377 (25.37)       680         Day       4893       1198 (24.48)       2071         Contributing Factor Reported       4579       1104 (24.11)       2028         No       1800       471 (26.17)       723         Patient Was a Contributing Factor       4579       1104 (26.34)       829         No       4701       1133 (24.10)       1922	38.38) 165 (33.33	3)	
Emergency department       1212       224 (18.48)       447         Professional Category       993       168 (16.92)       401         Nurse       3856       1029 (26.69)       1713         Assistant Nurse       454       130 (28.63)       167         Medical Resident       52       3 (5.77)       15         Pharmacist       175       15 (8.57)       118         Administrative Staff       64       17 (26.56)       33         Other       246       71 (28.86)       112         Non-registered       539       142 (26.35)       192         Shift       1486       377 (25.37)       680         Day       4893       1198 (24.48)       2071         Contributing Factor Reported       4579       1104 (24.11)       2028         No       1800       471 (26.17)       723         Patient Was a Contributing Factor       4579       1104 (24.11)       2028         No       1800       471 (26.34)       829         No       4701       1133 (24.10)       1922	43.72) 75 (30.36		
Doctor       993       168 (16.92)       401         Nurse       3856       1029 (26.69)       1713         Assistant Nurse       454       130 (28.63)       167         Medical Resident       52       3 (5.77)       15         Pharmacist       175       15 (8.57)       118         Administrative Staff       64       17 (26.56)       33         Other       246       71 (28.86)       112         Non-registered       539       142 (26.35)       192         Shift       Night       1486       377 (25.37)       680         Day       4893       1198 (24.48)       2071         Contributing Factor Reported       4579       1104 (24.11)       2028         No       1800       471 (26.17)       723         Patient Was a Contributing Factor       1678       442 (26.34)       829         No       4701       1133 (24.10)       1922	35.39) 49 (27.53 36.88) 541 (44.64		
Doctor       993       168 (16.92)       401         Nurse       3856       1029 (26.69)       1713         Assistant Nurse       454       130 (28.63)       167         Medical Resident       52       3 (5.77)       15         Pharmacist       175       15 (8.57)       118         Administrative Staff       64       17 (26.56)       33         Other       246       71 (28.86)       112         Non-registered       539       142 (26.35)       192         Shift       Night       1486       377 (25.37)       680         Day       4893       1198 (24.48)       2071         Contributing Factor Reported       4579       1104 (24.11)       2028         No       1800       471 (26.17)       723         Patient Was a Contributing Factor       1678       442 (26.34)       829         No       4701       1133 (24.10)       1922			<0.000
Nurse       3856       1029 (26.69)       1713         Assistant Nurse       454       130 (28.63)       167         Medical Resident       52       3 (5.77)       15         Pharmacist       175       15 (8.57)       118         Administrative Staff       64       17 (26.56)       33         Other       246       71 (28.86)       112         Non-registered       539       142 (26.35)       192         Shift       Night       1486       377 (25.37)       680         Day       4893       1198 (24.48)       2071         Contributing Factor Reported       Yes       4579       1104 (24.11)       2028         No       1800       471 (26.17)       723         Patient Was a Contributing Factor       Yes       1678       442 (26.34)       829         No       4701       1133 (24.10)       1922	40.38) 424 (42.7)		₹0.000
Assistant Nurse			
Medical Resident       52       3 (5.77)       15         Pharmacist       175       15 (8.57)       118         Administrative Staff       64       17 (26.56)       33         Other       246       71 (28.86)       112         Non-registered       539       142 (26.35)       192         Shift         Night       1486       377 (25.37)       680         Day       4893       1198 (24.48)       2071         Contributing Factor Reported         Yes       4579       1104 (24.11)       2028         No       1800       471 (26.17)       723         Patient Was a Contributing Factor         Yes       1678       442 (26.34)       829         No       4701       1133 (24.10)       1922	36.78) 157 (34.58		
Pharmacist       175       15 (8.57)       118         Administrative Staff       64       17 (26.56)       33         Other       246       71 (28.86)       112         Non-registered       539       142 (26.35)       192         Shift         Night       1486       377 (25.37)       680         Day       4893       1198 (24.48)       2071         Contributing Factor Reported         Yes       4579       1104 (24.11)       2028         No       1800       471 (26.17)       723         Patient Was a Contributing Factor         Yes       1678       442 (26.34)       829         No       4701       1133 (24.10)       1922	28.85) 34 (65.38	*	
Administrative Staff 64 17 (26.56) 33 Other 246 71 (28.86) 112 Non-registered 539 142 (26.35) 192 Shift Night 1486 377 (25.37) 680 Day 4893 1198 (24.48) 2071 Contributing Factor Reported Yes 4579 1104 (24.11) 2028 No 1800 471 (26.17) 723  Patient Was a Contributing Factor Yes 1678 442 (26.34) 829 No 4701 1133 (24.10) 1922	67.43) 42 (24.00		
Other       246       71 (28.86)       112         Non-registered       539       142 (26.35)       192         Shift         Night       1486       377 (25.37)       680         Day       4893       1198 (24.48)       2071         Contributing Factor Reported         Yes       4579       1104 (24.11)       2028         No       1800       471 (26.17)       723         Patient Was a Contributing Factor         Yes       1678       442 (26.34)       829         No       4701       1133 (24.10)       1922	51.56) 14 (21.88		
Non-registered       539       142 (26.35)       192         Shift       1486       377 (25.37)       680         Day       4893       1198 (24.48)       2071         Contributing Factor Reported       4579       1104 (24.11)       2028         No       1800       471 (26.17)       723         Patient Was a Contributing Factor       Yes       1678       442 (26.34)       829         No       4701       1133 (24.10)       1922	45.53) 63 (25.6°		
Shift       Night       1486       377 (25.37)       680         Day       4893       1198 (24.48)       2071         Contributing Factor Reported         Yes       4579       1104 (24.11)       2028         No       1800       471 (26.17)       723         Patient Was a Contributing Factor         Yes       1678       442 (26.34)       829         No       4701       1133 (24.10)       1922	,	5) 2 (0.37)	
Night       1486       377 (25.37)       680         Day       4893       1198 (24.48)       2071         Contributing Factor Reported         Yes       4579       1104 (24.11)       2028         No       1800       471 (26.17)       723         Patient Was a Contributing Factor         Yes       1678       442 (26.34)       829         No       4701       1133 (24.10)       1922	,	(3.7.3.)	0.000
Day       4893       1198 (24.48)       2071         Contributing Factor Reported       4579       1104 (24.11)       2028         No       1800       471 (26.17)       723         Patient Was a Contributing Factor       1678       442 (26.34)       829         No       4701       1133 (24.10)       1922	4E 74) 420 (28 8	7)	0.008
Contributing Factor Reported       4579       1104 (24.11)       2028         No       1800       471 (26.17)       723         Patient Was a Contributing Factor       1678       442 (26.34)       829         No       4701       1133 (24.10)       1922		5) 7 (0.14)	
Yes       4579       1104 (24.11)       2028         No       1800       471 (26.17)       723         Patient Was a Contributing Factor       1678       442 (26.34)       829         No       4701       1133 (24.10)       1922	42.33) 1617 (33.03	)) / (U.1 <del>4</del> )	
No       1800       471 (26.17)       723         Patient Was a Contributing Factor       1678       442 (26.34)       829         No       4701       1133 (24.10)       1922			0.029
Patient Was a Contributing Factor         Yes       1678       442 (26.34)       829         No       4701       1133 (24.10)       1922		9) 5 (0.11)	
Yes     1678     442 (26.34)     829       No     4701     1133 (24.10)     1922	40.17) 604 (33.56	5) 2 (0.11)	
Yes     1678     442 (26.34)     829       No     4701     1133 (24.10)     1922			<0.000
No 4701 1133 (24.10) 1922	49.4) 404 (24.08	3) 3 (0.18)	0.000
	,	3) 4 (0.09)	
	70.2 (51176	, (3.2.)	0.204
Professionals Was a Contributing Factor		1)	0.294
	14 40) 500 (00 10		
No 4754 1195 (25.17) 2028	44.49) 522 (32.12	7 (0.15)	
Patient Involved			<0.000
Yes 4445 1125 (25.31) 1971		6) 4 (0.09)	
	42.72) 1524 (32.1)		
Professional Involved	42.72) 1524 (32.1) 44.34) 1345 (30.26	5) 1 (0.16)	

Variables	Total		Probability		Missing values	p-Value <sup>a</sup>
	N	Infrequent	Occasional/Probable N (% of total)	Frequent		
Yes	1521	357 (23.47)	623 (40.96)	540 (35.50)	1 (0.07)	
No	4858	1218 (25.07)	2128 (43.80)	1506 (31.00)	6 (0.12)	
Way of Knowing						<0.000
Experienced	4186	956 (22.84)	1680 (40.13)	1545 (36.91)	5 (0.12)	
Observed	680	197 (28.97)	357 (52.5)	126 (18.53)		
Heard from Other	887	249 (28.07)	483 (54.45)	155 (17.47)		
Not informed	626	173 (27.64)	231 (36.90)	220 (35.14)	2 (0.32)	

Variables	Total	Se	everity		Missing values	p-Value
	N	No harm/Minor harm	Moderate N (% of total)	Severe		
Incident type						<0.000
Falls	1352	607 (44.90)	738 (54.59)	7 (0.52)		
Medical & Procedures Management	1205	892 (74.02)	287 (23.82)	26 (2.16)		
Medication	987	783 (79.33)	196 (19.86)	8 (0.81)		
Medical Devices	741	523 (70.68)	205 (27.67)	12 (1.62)	1 (0.13)	
Patient's Behaviour	574	386 (67.25)	177 (30.84)	8 (1.39)	3 (0.52)	
Infrastructures	525	409 (77.90)	98 (18.67)	17 (3.24)	1 (0.19)	
Analogic & Digital Documentation	413	385 (93.22)	26 (6.30)	2 (0.48)		
Clinical & Lab Management	243	210 (86.42)	30 (12.35)	3 (1.23)		
Nutrition	138	123 (89.13)	15 (10.87)	0 (0.00)		
Health-Care Associated Infection	106	73 (68.87)	30 (2.83)	3 (2.38)		
Blood Products	72	49 (68.06)	19 (26.39)	4 (5.56)		
Oxygen & Other gasses	15	10 (66.67)	4 (26.67)	1 (6.67)		
Non classified	8	7 (87.5)	1 (12.5)	0 (0.00)		
Department						<0.000
Cardiology & Cardiac Surgery	267	181 (67.79)	78 (29.21)	4 (1.50)	4 (1.50)	
Obstetrics & Gynaecology	1130	825 (73.01)	267 (23.63)	38 (3.36)	` ,	
Oncology & Haematology	439	305 (69.48)	129 (29.38)	5 (1.14)		
Gastroenterology & Metabolic Diseases	695	471 (67.77)	217 (31.22)	7 (1.01)		
Neurosciences	498	330 (66.27)	166 (33.33)	2 (0.40)		
Nephrology & Urology	267	190 (71.16)	76 (28.46)	1 (0.37)	1 (0.56)	
Internal Medicine & Infectious Diseases	458	297 (64.85)	160 (34.93)	1 (0.22)	` ,	
General Surgery & Anaesthesiology	495	365 (73.74)	122 (24.65)	1 (1.62)		
Orthopaedic Surgery & Rheumatology	247	148 (59.92)	95 (38.46)	4 (1.62)		
Respiratory Diseases	178	128 (71.91)	44 (24.72)	5 (2.81)	1 (0.56)	
Emergency department	1212	848 (69.97)	353 (29.13)	11 (0.91)	,	
Professional Category						<0.001
Doctor	993	653 (65.76)	307 (30.92)	33 (3.32)		
Nurse	3856	2622 (68.07)	1196 (31.05)	34 (0.88)	4 (0.10)	4 (0.10
Assistant Nurse	454	361 (79.52)	91 (2.04)	2 (0.44)	,	,
Medical Resident	52	27 (51.92)	23 (44.23)	2 (3.85)		
Pharmacists	175	157 (89.71)	17 (9.71)	1 (0.57)		
Administrative Staff	64	54 (84.38)	7 (10.94)	3 (4.69)		
Other	246	180 (73.17)	65 (26.42)	1 (0.41)		
Non-registered	539	403 (74.77)	120 (22.26)	15 (2.78)	1 (0.79)	

Variables	Total	Se	Missing values	p-Value <sup>a</sup>		
	N	No harm/Minor harm	Moderate N (% of total)	Severe		
Shift						<0.000
Night	1486	913 (61.44)	544 (36.61)	29 (1.95)		
Day	4893	3544 (72.43)	1282 (26.20)	62 (1.27)	5 (0.10)	
Contributing Factor Reported						<0.000
Yes	4579	3019 (65.93)	1490 (32.54)	67 (1.46)	3 (0.07)	
No	1800	1438 (79.89)	336 (18.67)	24 (1.33)	2 (0.11)	
Patient Was a Contributing Factor						<0.000
Yes	1678	868 (51.73)	786 (46.84)	22 (1.31)	2 (0.12)	
No	4701	3589 (76.35)	1040 (22.12)	69 (1.47)	3 (0.06)	
Professionals Was a Contributing Factor						0.029
Yes	1625	1160 (71.38)	434 (26.71)	31 (1.91)		
No	4754	3297 (69.35)	1392 (29.28)	60 (1.26)	5 (0.10)	
Patient Involved						<0.000
Yes	4445	2870 (64.57)	1516 (34.11)	57 (1.28)	2 (0.04)	
No	1934	1587 (82.06)	310 (16.03)	34 (1.76)	3 (0.16)	
Professional Involved						<0.000
Yes	1521	1249 (82.12)	242 (15.91)	29 (1.91)	1 (0.07)	
No	4858	3208 (66.04)	1584 (32.61)	62 (1.28)	4 (0.08)	
Way of Knowing						<0.000
Experienced	4186	3040 (72.62)	1093 (26.11)	49 (1.17)	4 (0.10)	
Observed	680	387 (56.91)	283 (41.62)	10 (1.47)		
Heard from Other	887	561 (63.25)	309 (34.84)	17 (1.92)		
Not informed	626	469 (74.92)	141 (22.52)	15 (2.40)	1 (0.16)	

medical-surgical departments. Further OR and 95% CI of the three models can be observed in Table 4

#### Discussion

Since the implementation of the IRS system in the Hospital Clinic de Barcelona, the overall notification rate increased during the first years of implementation, stabilizing during the last year analyzed. Nurses were the professional category that notified the most, followed by doctors. Falls were the most frequent incident notified, followed by Medical and procedures management and Medication notifications. While the decrease in the number of notifications in 2019 can be interpreted as a regression towards the mean (or stabilization of the tendency), the great number of Falls notifications may be related to the previous existence of a Falls notification system in our hospital. Moreover, it might be associated with how easier it could be for professionals to notify incidents they attribute to be related to a patient's action or environmental conditions. This system was led by nurses and implemented before the IRS and might have contributed to the hospital's safety culture. The same reasoning applies to the great number of notifications in the Obstetrics & Gynaecology department and the Emergency room, two departments that were pioneers in safety culture in the Hospital Clinic of Barcelona.

As in previous evidence, <sup>12</sup> Falls were the incident most frequently reported, it was one of the incidents perceived as less frequent. The opposite notification pattern can be observed in Health-care Associated Infections. These are perceived as being frequent and minor, however, they were the third least frequently notified and a recognized cause of healthcare associated deaths. <sup>22</sup> As such, the notifier's perception did not reflect neither the healthcare professionals' notification behaviour nor patient safety risks. Nevertheless, this provides us an overview of what the professional perception about patient risk is and this could be used as a tool to improve notification behaviours and safety culture.

Globally, incidents perceived as less severe (no harm or minor harm) were more notified, and in line with previous research, incidents were more frequently reported when they rely on the professional's direct experience. 14 Over the four years of the period study, most notifications of incidents considered as mild are notified by nurses, whereas notifications of the severe ones are done both by nurses and doctors. This is consistent with previous literature. 12,14–16 However, physicians have been identified as the most notifying professionals in some specific IRS<sup>7</sup> and when adjusting by the total number of hours worked. 3

Conversely, pharmacists consistently tend to notify incidents perceived as minor and more frequent. These differences in notification patterns could depend on context,

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	Model A: Reported Probability			Model B: Reported Severity			Model C: Calculated Risk		
	Odds Ratio	[OR 9	5% Conf. Interval]	Odds Ratio	[OR 9	5% Conf. Interval]	Odds Ratio	[OR	95% Conf. Interval
Shift									
Night				1.00					
Day				0.76	0.66	0.87			
Type of Incident									
Blood products	1			7.81	3.93	15.50	1.00		
Falls	1.189	0.707	1.999	25.28	15.93	40.11	13.79	7.47	25.46
Patient behaviour	1.668	0.968	2.872	9.63	5.95	15.60	3.08	1.72	5.53
Medical devices	1.340	0.786	2.284	7.72	4.80	12.43	2.23	1.27	3.93
Analogic & digital documentation	1.375	0.788	2.399	1.00			1.03	0.58	1.82
Clinical & Lab Management	1.628	0.896	2.959	2.49	1.39	4.44	1.95	1.03	3.68
Medical & procedures management	2.211	1.301	3.757	5.14	3.23	8.17	2.88	1.65	5.04
Health-care associated infection	1.913	0.943	3.881	9.06	4.87	16.88	3.94	1.66	9.38
Infrastructures	2.138	1.226	3.730	4.66	2.83	7.66	2.42	1.35	4.34
Medication	1.352	0.796	2.296	5.28	3.28	8.50	1.48	0.85	2.57
Nutrition	1.292	0.674	2.475	2.69	1.29	5.62	2.30	1.12	4.70
Oxygen & other gasses	0.454	0.136	1.513	12.19	3.62	41.07	2.43	0.49	12.03
Medical or Surgical Departments									
Surgery	1.00			1.99	1.26	3.14	1.91	1.13	3.24
Medical	1.171	1.000	1.372	1.71	1.11	2.66	1.59	0.97	2.61
Medical-Surgical Departments	0.778	0.520	1.166	1.00			1.00		
Others	1.247	0.984	1.580	2.07	1.29	3.31	1.97	1.14	3.40
Professional category									
Administrative stuff	1			1.78	0.73	4.32	1.00		
Doctors	1.827	0.996	3.353	4.16	2.44	7.09	3.09	1.65	5.79
Nurses	1.219	0.676	2.198	2.00	1.19	3.35	2.03	1.11	3.70
Pharmacists	4.991	2.240	11.120	1.00	,		1.51	0.75	3.03
Assistant Nurse	1.129	0.602	2.119	1.24	0.69	2.22	1.42	0.74	2.74
Medical Residents	5.659	1.530	20.931	6.82	3.19	14.57	9.65	2.07	45.05
Others	0.981	0.521	1.843	1.76	0.99	3.13	2.16	1.10	4.25

time spent with the patient,<sup>23</sup> patient safety awareness, safety cultural background and type of healthcare activity. Although different patterns between pharmacists, doctors and nurses are probably related to job characteristics (relationship with the patient, level of responsibility), it has been shown that professionals tend to notify incidents that potentially have more direct and quick solutions, such as Falls or Medication.<sup>14</sup> Considering these dimensions in further analysis could help characterize patient risk misconceptions among different professional groups and design interventions that could be adapted to the group safety culture.

IRSs have been recently overlooked as a surveillance tool and as a proxy of patient safety due to the dependence on notifiers' perspective. Nevertheless, recognizing the different notification patterns and professional risk perceptions, IRS information can be analyzed in conjunction with mortality, morbidity and work-related data to build interventions in order to improve safety culture. A Moreover, personalized feedback on IRS information reporting, could be used as a patient safety learning platform. The identification of notification gaps (such as the lack of notifications of severe healthcare related infections) and notification reporting patterns (qualify Falls as not as frequent) in professional groups or departments can be used as a tool to work over patient risks, safety and developed safety culture in a more contextualized way.

This study shows notification department's activity and offers the possibility of analyzing departments and professional's notifying patterns, allowing contextualized comparison of safety culture. We also provide a more in-depth analysis about notifiers perception by using a calculated risk variable. Nevertheless, some departments, such as Surgery, notify by department-specific IRS which has led to an underrepresentation of this group of notifiers. As this study does not aim to analyze incidents, but notifications, no proxy patient safety indicator was calculated, and no direct measure of patient safety can be obtained through this study, however, this data provides a framework for future analysis and provides indirect quantitative data on notifiers risk perception. Even though we considered the potential relevance of shifts or holidays in our models, more detailed analysis considering professional hours worked or time should be performed in order to evaluate how this can evaluate the notification rate. As Tricarico et al. referred, changes in the notification rate overtime or per working hour could help contextualize safety risk perceptions or notification patterns<sup>3</sup> which might imply continuous improvement of IRS reporting.<sup>26</sup>

In conclusion, IRS data analysis can provide sectorize information about notification patterns that show notifiers' patient risk perception. Our results show how incidents perceived as minor and frequent are less frequently notified while incidents perceived as less frequent are the most frequently notified. Moreover, the professional category and department play a role in notification culture.

## Conflicts of interests

The authors declare no conflict of interest in this article.

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