Effectiveness and limitations of an incident-reporting system analyzed by local clinical safety leaders in a tertiary hospital

Prospective evaluation through real-time observations of patient safety incidents

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Abstract

The effectiveness of a hospital incident-reporting system (IRS) on improve patient safety is unclear. This study objective was to assess which implemented improvement actions after the analysis of the incidents reported were effective in reduce near-misses or adverse events.

Patient safety incidents (PSIs), near misses and adverse events, notified to the IRS were analyzed by local clinical safety leaders (CSLs) who propose and implement improvement actions. The local CSLs received training workshops in patient safety and analysis tools. Following the notification of a PSI in the IRS, prospective real-time observations with external staff were planned to record and rated the frequency of that PSI. This methodology was repeated after the implementation of the improvement actions.

Ultimately, 1983 PSIs were identified. Surgery theaters, emergency departments, intensive care units, and general adult care units comprised 82% of all PSIs. The PSI rate increased from 0.39 to 3.4 per 1000 stays in 42 months. A significant correlation was found between the reporting rate per month and the number of workshop-trained local CSLs (Spearman coefficient = 0.874; P = .003). A total of 24,836 real-time observations showed a statistically significant reduction in PSIs observed in 63.15% (categories: medication P = .044; communication P = .037; technology P = .009) of the implemented improvements actions, but not in the organization category (P = .094). In the multivariate analyses, the following factors were associated with the reduction in near misses or adverse events after the implementation of the improvement actions: “adverse event” type of PSI (odds ratio [OR], 3.67; 95% confidence interval [CI], 1.93–5.74), “discussion group” type of analysis (OR, 2.45; 95% CI, 1.52–3.76), and root cause type of analysis (OR, 2.32; 95% CI: 1.17–3.90).

The implementation of a hospital IRS, together with the systematization of the method and analysis of PSIs by workshop-trained local CSLs led to an important reduction in the frequency of PSIs.

Abbreviations: CMHC = Community of Madrid Heath Council, CSLs = clinical safety leaders, FURM = Functional Unit of Risk Management, IRSs = incident-reporting systems, OR = odds ratio, PSIs = patient safety incidents.

Keywords: adverse event, effectiveness, incident, incident-reporting system, patient safety, patient safety incident
1. Introduction

Incident-reporting systems (IRSs) are methods of reporting near misses or adverse events to enable organizational improvement.1,2 Most developed countries have developed Clinical Safety Reporting Systems that are voluntary, anonymous, confidential electronic systems that allow the reporting of incidents and adverse events and analysis by a group of experts.3–5 Whether these systems improve the safety of patients, however, is unclear. Shojania6 spoke of the “frustrating case of incident reporting systems” and their many limitations: physician underreporting and bias; that IRSs cannot be used to measure safety or to compare organizations; the lack of a denominator in the metrics; that some reports provide little meaningful value about the usefulness of the safety system; and due to limited resources, error investigations and analysis in health care are often superficial. In addition, IRSs are associated with costs for training staff on their use, in addition to reporting, collecting, and analyzing data from these systems. On the contrary, IRSs could reduce patient injuries, which would lead to a subsequent reduction in costs. Some authors have tried to develop methods for assessing the impact of an improvement action to have a prompt and reproducible tool. Moccia et al7 developed methods for assessing the impact of an improvement action and now have a subsequent reduction in costs. Some authors have tried to develop methods for assessing the impact of an improvement action to have a prompt and reproducible tool. Moccia et al7 developed a methodology of risk management in surgery theaters based among others in the compliance to the single items of the surgical checklist used during real-time observations. Real-time observations had been used previously as the evaluation method of the impact of interventions to improve the hand hygiene.8,9

In this study, we analyzed the features of a hospital IRS analyzed by local clinical safety leaders (CSLs), its effectiveness and limitations. The endpoint was to assess which improvement actions were effective in reducing near-misses or adverse events. Following the notification of a patient safety incident (PSI) in the IRS, prospective real-time observations with external staff were planned to record and rate the frequency of that PSI. This methodology was repeated after the implementations of the improvement actions during the first 42 months of use of the IRS. We also aimed to establish which factors were related to the improvement measures and the recommendations that significantly reduced near misses or adverse events.

2. Materials and methods

2.1. Setting

The study was conducted at University Hospital La Paz-Cantoblanco-Carlos III (1254 beds, 1153 functional beds, 2016), which offers services in all fields of specialized medical care.

2.2. Characteristics and conditions of hospital IRS

The hospital’s IRS is voluntary, anonymous, nonpunitive, and confidential. The IRS aims to promote improvements within the organization, independent of an external authority, while analyzing the time to response and providing feedback to the reporting individual. A “patient safety incident” was defined as an event during an episode of patient care that had the potential to (near miss) or actually caused injury or harm (adverse events) to the patient. Only hospital staff (health care staffs, non-health care staffs) can report PSIs to the IRS. The patients cannot report PSIs, but the Patient Liaison Service and Social Work Unit is notified of the claim if it is related to patient safety. Research permission for the IRS was obtained from the hospital board as a database holder; according to organization policy, ethics committee approval was not needed. The IRS was conducted in accordance with the Spanish Personal Data Protection Law.10

2.3. Local clinical safety leaders

The Community of Madrid Heath Council (CMHC) in its Patient Safety Strategy, agrees with the hospitals so that each service or unit names a clinical safety leader. At our institution, 175 local CSLs are physicians and nurses designated by the medical and nursing chief officers. After the designation, the local CSL attended training workshops in patient safety and analysis tools taught by Functional Unit of Risk Management (FURM) members or by the CMHC.

2.4. Data collection

Each report requires the following: reporter status (physician, medical resident, nurse, nursing assistant, other professionals), age and sex of patient, date of incident, date of the report, phase, type, and evolution (degree of harm). Drop-down menus facilitate location of the PSI. These are categorical variables, mainly captured in drop-down menus. There is also a free text section in which the reporter is asked to describe in detail what occurred and what action was taken as a result. Another section asks who was informed of the PSI (multiresponsive possible): patients, relatives, hospital staff, or unknown. The reporter is retrospectively asked whether the PSI could have been prevented (yes, no, or unknown) and prospectively, in a free text box, how it could have been prevented. The PSIs reported from Patient Liaison Service and Social Work Unit were loaded into the IRS. In addition, the PSIs of the primary care report system (CISEM-AP) or from the Emergency Medical Service of Madrid (SUMMA-112) associated with the hospital were introduced into the system and vice versa.

2.5. PSI analysis

When a report is entered into the system, a report manager reviews the incident report and assigns it a priority. The IRS uses the Australian classification system to assign a priority.11 The report managers send the reports for analysis to the local CSLs of the nursing unit and the medical service involved in the report. If the report is a severe adverse event, it is also assigned a member of the FURM to offer assistance with the analysis. The reports were studied using the analytical tools. The analysis and the method were registered in the IRS. The report managers could change the phase of the PSI and determine the latent or contributing factors. The managers chose the improvement measures, and the local CSLs implemented the improvements. Corrective proposals are system oriented. The IRS provided feedback to the reporter on the improvement actions implemented. The improvement measures were divided into 4 categories: Communication, Medication, Organization, and Technology. The types of barriers to implementation, from more to less important, were as follows: physical natural, human action, and administrative. Three working groups within primary care analyzed and coordinated the improvement measures derived from these reports.

2.6. Software description

The SINIORES (MC13080056; July 14, 2014) was developed as a project of JAVA, programming a Struts framework as a database using Microsoft SQL Server.
2.7. Effectiveness of improvement actions

Real-time observations were planned with external staff (n = 17) to record and rate the effectiveness of the improvement measures before each PSIs analysis and after the implementation of the improvement actions. Events observed in the location of each PSI were measured in 2 different times: the number of real-time observations per PSI planned was 8 to 10 in 2 consecutive months before PSI analysis; the real-time observations after the improvement implemented were carried out during the second half of 2017, 8 to 12 per each PSI in 2 consecutive months.

2.8. Data analysis

2.8.1. Sample size calculations. The required sample size for population proportion confidence interval (CI; margin of error ± 2.5%, 95% CI, assuming a variability of 50%, being the population the total patient stays during the period of the study) was 1400 PSIs. Accepting an alpha risk of 0.05 and a beta risk of 0.2 in a 2-sided test, 1344 real-observations was necessary to recognize as statistically significant an odds ratio (OR) ≥ 2. A proportion of exposed subjects in the control group (previous improvement actions) has been estimated to be 0.035.

2.8.2. Statistical analyses. The categorical variables were expressed in absolute terms and percentages. Age was categorized in groups of age ranges: 0 to 1 year, 2 to 5 years, 6 to 11 years, 12 to 17 years, young adults (ages 18–45 years), middle-aged adults (ages 46–64 years), older adults (aged >65 years).

Uncertainty of estimation was assessed by a calculation of the 2-sided Wald 95% CI. To calculate the reporting rate for a 1000-day stay, the total of all the reports during the study period was used as the numerator, and the total patient stays in that period was the denominator. Pearson or Spearman correlation coefficient was used, when appropriate, to assess a possible link between the number of reports and the training workshops. To evaluate possible differences in the percentage of groups of age ranges with respect to the expected distribution and in the events real-time observations before and after the improvement measure, we used the Chi-squared test. Fisher exact test was used to assess the differences between types of PSI (near-miss or adverse event) notified by physicians versus nurses. OR and 95% CI values were obtained. The level of significance <.05 was considered statistically significant. Next, we developed logistic regression model to determine the factors associated with the improvement actions statistically significant in reducing the frequency of near-misses or adverse events, (dichotomous dependent variable), ORs and 95% CIs, based on univariate analysis. Single factors used were the characteristics of PSIs, the types of PSIs categorized to near-miss or
adverse event, and the methods of analysis. In multivariate analysis, we introduced the factors considered significant in univariate analysis \((P < .10)\). To control the type I error rate of multiple testing, logistic regression analysis was adjusted by a bootstrap resampling analysis with 10,000 samples. For each sample, logistic regression was performed entering the factors with \(P < .01\) on univariate analysis. The data analyses were performed using IBM SPSS Statistics version 20.0 (IBM Corporation, Armonk, NY).

### 3. Results

#### 3.1. Characteristics of the reports

A total of 2096 reports were identified from January 2014 to June 2017; of these, 113 were excluded because they were not PSIs. Of the 1983 PSIs, 91 were related to primary care or SUMMA-112 and 58 were reported from the department of Patient Liaison Service and Social Work Unit. The median of reports per department or nursing unit was 1 (range from 0 to 331). The PSI

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#### Table 1

Characteristics of PSIs \((n = 1983)\): phase, type, evolution, who was informed, and if the PSI could have been prevented.

| Phase                              | Number | Percentage | 95% CI |
|------------------------------------|--------|------------|--------|
| Surgical procedure                 | 455    | 22.94      | 21.15–24.85 |
| Medication or vaccine              | 286    | 14.42      | 12.94–16.04 |
| Care and monitoring of the patient | 234    | 11.80      | 10.45–13.30 |
| Diagnostic test                    | 139    | 7.01       | 5.96–8.22  |
| Therapeutic procedure              | 133    | 6.72       | 5.68–7.90  |
| Continuity of care                 | 116    | 5.84       | 4.90–6.97  |
| Other                              | 101    | 5.11       | 4.21–6.15  |
| Infrastructure                     | 93     | 4.67       | 3.84–5.72  |
| Medical device, equipment or furniture | 78   | 3.94       | 3.26–4.89  |
| Organizational management/citations | 78    | 3.94       | 3.26–4.89  |
| Patient identification             | 75     | 3.80       | 3.02–4.72  |
| Clinical documentation/information/informed consent | 70 | 3.51 | 2.80–4.44 |
| Clinical evaluation/diagnosis      | 43     | 2.19       | 1.61–2.91  |
| Patient accident                   | 26     | 1.31       | 0.89–1.92  |
| Infection related to health care    | 23     | 1.17       | 0.76–1.74  |
| Preventive activities              | 20     | 1.02       | 0.64–1.56  |
| Blood and blood products           | 12     | 0.58       | 0.27–1.27  |

| Type                               | Number | Percentage | 95% CI |
|------------------------------------|--------|------------|--------|
| Incident that reached the patient  | 1143   | 57.64      | 55.81–59.45 |
| Situation with the ability to cause a PSI | 585 | 29.50 | 27.53–31.55 |
| Incident that did not reach the patient | 255 | 12.86 | 11.04–14.92 |

| Evolution                          | Number | Percentage | 95% CI |
|------------------------------------|--------|------------|--------|
| Near-miss PSIs                     | 1785   | 90.02      | 88.85–91.07 |
| Circumstances or events with the capacity to cause error | 585 | 29.51 | 27.53–31.55 |
| An error reached the patient, but caused no harm | 495 | 24.96 | 23.11–26.91 |
| An error occurred, but it has been impossible to know the damage | 290 | 14.61 | 13.14–16.25 |
| An error that could have caused harm, but did not reach the patient | 255 | 12.86 | 11.46–14.41 |
| An error occurred that reached the patient and required monitoring to confirm that it resulted in no harm | 160 | 8.07 | 6.95–9.29 |
| Adverse event PSIs                 | 198    | 9.98       | 8.74–11.39 |
| The patient presented temporary injury that required medical intervention | 120 | 6.05 | 5.08–7.19 |
| Intervention has been required to maintain patient’s life | 23 | 1.17 | 0.76–1.74 |
| The patient has specified or prolonged hospitalization | 23 | 1.17 | 0.76–1.74 |
| The incident could have been related to the death of the patient | 20 | 1.02 | 0.64–1.56 |
| The patient presented permanent damage | 12 | 0.58 | 0.33–1.07 |

| Who was informed                   | Number | Percentage | 95% CI |
|------------------------------------|--------|------------|--------|
| Hospital staff                     | 1115   | 56.24      | 54.03–58.40 |
| Unknown                            | 258    | 13.00      | 11.60–14.56 |
| Patient, relatives, and hospital staff | 170 | 8.57 | 7.42–9.89 |
| Relatives and hospital staff       | 101    | 5.11       | 4.21–6.15  |
| Patient                           | 87     | 4.38       | 3.57–5.38  |
| Patient and hospital staff         | 49     | 2.49       | 1.67–3.26  |
| Patient and relatives             | 32     | 1.61       | 1.14–2.28  |
| Relatives only                    | 32     | 1.61       | 1.14–2.28  |
| The hospital staff, rest it is unknown | 14 | 0.73 | 0.41–1.19 |
| Not registered                     | 125    | 6.28       | 5.31–7.87  |

| Prevented                          | Number | Percentage | 95% CI |
|------------------------------------|--------|------------|--------|
| Yes                                | 1681   | 84.77      | 83.12–86.29 |
| Unknown                            | 201    | 10.14      | 8.88–11.54 |
| Not registered                     | 51     | 2.57       | 1.96–3.37  |
| No                                 | 50     | 2.54       | 1.91–3.31  |

CI = confidence interval, PSI = patient safety incident.

*According to the reporter.
rate increased from 0.39 (2014) to 3.4 (2017) per 1000 stays. The reporting ratio ranges from 8.2 per 1000 stays in intensive care units to 0.02 per 1000 stays in outpatient units. Surgery theaters, emergency departments, intensive care units, and general adult care units comprised 82% of all PSIs (Fig. 1A). During the period of analysis, the FURM performed 10 training workshops on patient safety. There was a significant correlation between reporting rate and the number of workshop-trained local CSLs (Spearman coefficient = 0.874; P = .003) (Fig. 1B). The top 3 types of PSIs were due to surgical procedures (22.94%; 95% CI, 21.15–24.85), medications or vaccines (14.42%; 95% CI, 12.94–16.04), and care or monitoring of the patients (11.80%; 95% CI, 10.45–13.30) (Table 1). The groups of patients under 2 years of age and over 65 years were the most likely to have reported a PSI (Chi-squared test, P < .015 and P = .048, respectively) (Fig. 2A); male patients were more likely to have reported a PSI than female patients (Chi-squared test, P = .041) (Fig. 2B); and nurses were more likely to report PSIs than physicians (Fig. 2C). The ratio between near misses and adverse events was 9.02. Nurses were more likely to report near misses (1144/1247, 91.74%), than physicians (459/555, 82.70%) (OR, 2.31; 95% CI, 1.89–2.79; P < .001).

3.2. PSI analysis
At the time of the analysis, 1546 (77.96%) reports had been analyzed. The number of local CSLs assigned to an analysis was 2 or 3 in 96% of reports (Fig. 2D). The time from reporting to analysis varied from within 24 hours, for high priority PSIs, to within 3 months, median 26 days. The most frequently used method of PSI analysis was the discussion of cases (52.56%), followed by discussion groups (33.51%) (Table 2). The median of time from analysis to the implementation of the improvements was 30 days (range from 1 to 98 days). Contributing or latent factors were reported for 1427 PSIs, not having a contributing factor listed in 7.70% of PSIs. Contributing factors were multifactorial for some PSIs; the mean of contributing factors was 1.63 per PSI (Table 2).

3.3. Improvement measures
At the time of the data analysis, 207 (of 1427, 14.50%) improvement measures were pending implementation. Finally, 1635 improvement measures were implemented. The mean of the improvement measures was 1.34 per PSI, with 1774 related contributing or latent factors (Table 3).

3.4. Effectiveness of the improvements implemented
A total of 24,836 real-time observations were made over 1220 PSIs, before analysis (n = 12371; median of 10, range 8–20, observations per PSI) and after implementation of the improvement (n = 12,465, median of 10, range 8–25, observations per PSI). A summary of the improvement measures (n = 1774 factors) per category and type of barrier before and after improvement actions and the statistical significance in the reduction of PSIs are recorded in Table 3: 13 recommendations in organization (n = 635 factors), 10 to prevent medication errors (n = 422 factors), 8 to enhance communication (n = 391 factors), and 7 in the category of technology (n = 326 factors). The analysis showed a statistically significant reduction in near misses or adverse events, observed in 63.15% (medication, P = .044; communication, P = .037; and technology, P = .009) of the improvements implemented, but not in organization category (P = .094).
Events, the incidence density of adverse events is 14 per 1000 reporting; according to the Spanish National Study of Adverse fact, the main drawback of the IRS is the high level of under-reporting. A logistic regression model is shown in Table 4. The logistic analysis (n = 1893). Discussion of the cases by local clinical safety leaders. Medical chart review has been considered the “gold-standard” for identifying adverse events in many patient safety studies. Compared with medical chart reviews, the IRS identified a larger number of preventable incidents and required significantly fewer resources than did the retrospective medical chart review. For example, the IRS identified adverse events related to the organization or to technology (35% of all PSIs); possibly, the staff believed that the patients’ medical records were not the correct place for reporting these types of safety problems. Medical chart review cited incidents such as iatrogenic infections and unrelieved pain, which were identified less often by the IRS. However, the hospital has other data collections, such as the hospital-acquired infections program (Spanish Prevalence Study of Nosocomial Infections), the Bacteraemia Zero project, the Pneumonia Zero project, and the hospital pain program, which identified and performed actions to reduce their incidence. Both the IRS and the medical chart review are likely able to identify problems of patient safety that are responsive to actions to improve the quality of care, but they must provide evidence of changes in process or outcomes. In this sense, this study examined the effectiveness of the improvement measures over 1774 contributing or latent factors on the reduction or the occurrence of near-miss or adverse events. In agreement with the data in the literature, improvement actions that included physical or natural barriers proved to be more effective than human and administrative barriers. In addition, the improvement measures achieved a reduction in litigation claims in the hospital following the implementation of the IRS, moving from the second-highest number of claims among Spanish hospitals in 2015 to the 4th highest in 2016.

4. Discussion

Voluntary IRSs are not intended to be an accurate picture of the occurrence of adverse events. A positive correlation between reports and the workshops are accepted as a sign of a better safety culture of the organization.

Other studies have evaluated the effectiveness of IRSs. Hutchinson et al analysis patterns in reporting of PSI as trend over time, the relationship between reporting rates and other safety and quality data sets. There was no apparent association between reporting rates and the following data: standardized mortality ratios, data from other safety-related reporting systems, hospital size, average patient age, or length of stay. They found a correlation between higher reporting rate and a more positive safety culture. Anderson et al examined the perceived effectiveness of IRSs through a documentary analysis and semi-structured interviews. They found that using incident reports to improve care is challenging and the study highlighted the complexities involved and the difficulties faced by staff in learning from incident data. These studies were not designed to assess the effectiveness of the different types of improvement actions or barriers. The methodology of this study has been revealed which improvement actions have been most effective, and which those improvement actions should be prioritized by the organization.

Medical chart review has been considered the “gold-standard” for identifying adverse events in many patient safety studies. Compared with medical chart reviews, the IRS identified a larger number of preventable incidents and required significantly fewer resources than did the retrospective medical chart review. For example, the IRS identified adverse events related to the organization or to technology (35% of all PSIs); possibly, the staff believed that the patients’ medical records were not the correct place for reporting these types of safety problems. Medical chart review cited incidents such as iatrogenic infections and unrelieved pain, which were identified less often by the IRS. However, the hospital has other data collections, such as the hospital-acquired infections program (Spanish Prevalence Study of Nosocomial Infections), the Bacteraemia Zero project, the Pneumonia Zero project, and the hospital pain program, which identified and performed actions to reduce their incidence. Both the IRS and the medical chart review are likely able to identify problems of patient safety that are responsive to actions to improve the quality of care, but they must provide evidence of changes in process or outcomes. In this sense, this study examined the effectiveness of the improvement measures over 1774 contributing or latent factors on the reduction or the occurrence of near-miss or adverse events.

4.1. Lessons and limitations

To use real-time observations as a measure to assess the reduction of near misses or adverse events is a good proxy for the effectiveness of an IRS. A systematic review of health care workers compliance with hand hygiene guidelines in hospital suggested that comparing with self-reported behaviors, observed practice showed very poor rate of adherence to guidelines. That is in part because, previous studies have generally linked predictors of hand hygiene with health care workers intended or self-

**Table 2**

| Method analysis | Number | Percentage | 95% CI |
|-----------------|--------|------------|--------|
| Discussion of cases | 995    | 52.56      | 50.31–54.80 |
| Discussion groups | 634    | 33.51      | 31.40–35.65 |
| RCA             | 86     | 4.54       | 3.69–5.58  |
| Review of medical records | 78     | 4.12       | 3.31–5.12  |
| Not registered  | 36     | 1.90       | 1.37–2.63  |
| FMEA            | 18     | 0.95       | 0.59–1.51  |
| Interviews      | 15     | 0.78       | 0.47–1.32  |
| Briefing        | 14     | 0.74       | 0.43–1.25  |
| Focus groups    | 9      | 0.47       | 0.24–0.92  |
| London protocol (casual model of accidents) | 5 | 0.26 | 0.09–0.64 |
| Significant events audits | 3 | 0.16 | 0.03–0.49 |

Factors linked to training and learning: 738 (37.22% vs 36.81%), Organizational and strategic factors: 566 (28.55% vs 27.88%), Factors linked to task (protocols): 290 (14.65% vs 13.77%), Factors linked to equipment and devices: 246 (12.41% vs 11.55%), Factors of communication between professionals: 219 (11.06% vs 10.20%), Factors related to patients: 9 (0.45% vs 0.24%), Factors of individual professionals: 6 (0.30% vs 0.13%), Factors related to environment: 80 (4.12% vs 3.31%), Factors of teamwork: 172 (9.04% vs 8.67%), No factor was found: 119 (6.20% vs 5.98%), FMEA: 18 (0.92% vs 0.95%), Not registered: 36 (1.90% vs 1.32%), Review of medical records: 78 (4.12% vs 3.31%), Focus groups: 9 (0.47% vs 0.24%), Interdisciplinary team: 14 (0.74% vs 0.43%), FMEA: 18 (0.92% vs 0.95%), Not registered: 36 (1.90% vs 1.37%), Review of medical records: 78 (4.12% vs 3.31%), Focus groups: 9 (0.47% vs 0.24%), Interdisciplinary team: 14 (0.74% vs 0.43%).

CI = confidence interval, FMEA = failure mode and effects analysis, PSI = patient safety incident, RCA = root cause analysis. *Discussion of the cases by local clinical safety leaders. †Interdisciplinary team.
## Table 3

Summary of the improvement actions (n = 1774 factor addressed) per category and type of barrier.

| Category | Type of barrier | Description | Before | After | Percentage (95% CI) | χ² test | P-value |
|----------|----------------|-------------|--------|-------|---------------------|---------|---------|
| Organization | Physical, human | Attached to the operating theater cleaning protocol | 33.3% (24.9–42.9%) | 21% (14.2–30%) | 0.047 |
| Administrative | Reinforcement of the patient’s unequivocal identification protocol | 27% (19.3–36.4%) | 18% (11.7–26.7%) | 0.149 |
| Physical, human, and administrative | Transit room for the care and follow-up of the patients in the transfer between hospitals within the complex | 15% (9.7–22.5%) | 2% (0.6–7%) | <.001 |
| Physical | Expansion of spaces and personnel in emergencies | 14.7% (9–22.2%) | 12.4% (7.4–20%) | 0.211 |
| Administrative | Patients’ identification wristbands in emergency departments | 13% (7.8–21%) | 1% (0.2–5.4%) | <.001 |
| Natural | Theoretical education program for newcomers | 12% (7.1–18.8%) | 14% (8.5–22.1%) | 0.680 |
| Natural | Procedure attached to the surgical safety checklist to reduce the risk of burns in the operating theater | 10.1% (6.4–18.1%) | 2% (0.6–7.1%) | 0.019 |
| Physical | Procedure to attend to the second and third victims of a severe adverse event | 9% (4.2–18.2%) | 2% (1.7–10.9%) | 0.275 |
| Administrative | Protocol for the organization and control of the cardiological arrest trolleys | 8.1% (2.8–21.3%) | 4.6% (1.8–11.2%) | 0.438 |
| Physical | Day hospital for patients who come to perform an invasive diagnostic test | 8% (4.1–15%) | 1% (0.2–5.4%) | 0.002 |
| Administrative | Cardiopulmonary resuscitation programs for professionals | 7% (3.4–13.7%) | 6% (2.8–12.5%) | 0.730 |
| Administrative | Protocol to attend cardiac arrests in the hospital and its environment | 6.6% (3.1–13.6%) | 0% (0–5.4%) | 0.032 |
| Physical | Reinforcement of the protocol for the care of the peripheral pathway in the children’s hospital | 2% (0.7–5.7%) | 1.4% (0.5–3.9%) | 0.630 |
| Physical | Medication information in the primary care electronic prescribing system | 65% (56.1–74.2%) | 62% (52.2–70.9%) | 0.539 |
| Medication | Instructions to improve the completion of the paper prescription in the hospital | 34% (25.5–43.7%) | 23.6% (16.7–32.4%) | 0.098 |
| Physical, human | Protocol to avoid abstinence syndrome after sedoanalgesia in the infant ICU | 27% (19.3–36.4%) | 8% (4.1–15%) | <.001 |
| Physical, natural | Standardization of noradrenaline solutions in adult and pediatric hospitalization wards | 32.4% (24.2–41.8%) | 4.2% (1.6–10.2%) | <.001 |
| Physical, human | Recommendations for the use of analgesia and antibiotics in the adult emergency department | 32% (23.7–41.7%) | 29.2% (21.2–38.9%) | 0.331 |
| Natural, human | Double control of signatures in the prescription, preparation, and administration of medication in the neonatology department | 20% (13.3–28.9%) | 3% (1–8.5%) | <.001 |
| Physical, human | Protocol for the use of high-risk medication in the hospital. | 17% (10.9–25.5%) | 6.6% (3.3–13.1%) | 0.025 |
| Physical, human | Protocol for the use of high-risk serum therapy in the hospital | 15% (9.3–23.3%) | 2% (0.5–6.7%) | <.001 |
| Physical, human | Protocol to avoid abstinence syndrome after sedoanalgesia in the neonatal ICU | 11.3% (6%–20%) | 1.9% (0.5–6.6%) | 0.007 |
| Physical | Implementation of traceability of surgical material at source and destination | 10% (5.4–17.9%) | 0% (0–1.3%) | <.001 |
| Administrative | Recommendations to strengthen safety barriers in the prescription and administration of pacemaker in the infant hospital | 21.3% (18.9–23.9%) | 13.5% (11.5–15.8%) | 0.044 |
| Communication | Safety instruction to improve the communication with primary care at the start of oral anticoagulation medication | 36% (27.3–45.8%) | 23% (15.8–32.2%) | 0.042 |
| Human | Reconciliation of medications with primary care in the emergency department | 24.6% (15.2–37.1%) | 15.3% (9.1–26.3%) | 0.291 |
| Human | Communication skills were highlighted during regular meetings. Poor communication discussed with affected team members | 16% (10.1–24.4%) | 7.1% (3.5–14.9%) | 0.250 |
| Administrative | Procedure for sending biological samples in the pediatric emergency department | 9.3% (5.6–15.1%) | 4% (1.7–9.7%) | 0.087 |
| Physical | Traceability of annotations, electronic prescribing system | 9% (4.8–16.2%) | 1.6% (0.4–5.7%) | 0.011 |
| Natural | Checklist for the transfer of care from emergency departments to hospitalization | 7.9% (3.9–15.4%) | 2% (0–2.9%) | <.001 |
| Natural | Double check of the balances at the beginning and end of nursing shift in neonatal ICU | 6.2% (3.2–11.7%) | 1.4% (0.4–5.1%) | 0.039 |
| Natural | Effective way to communicate severity diagnoses of laboratory, microbiologist, pathologist, or radiologist | 1.8% (1–2.9%) | 0.2% (0.05–0.7%) | <.001 |
| Physical | Electronic prescribing system in adults’ emergency department | 21% (14.2–30%) | 5% (2.2–11.2%) | <.001 |
| Physical | Advanced infusion pumps | 12% (7.7–19.8%) | 0% (0–3.7%) | <.001 |
| Physical | Instruction to control the opening of windows in hospitalization rooms | 10% (5.4–17.7%) | 4.2% (1.8–9.5%) | 0.094 |
| Physical | Use of limited cards in the emergency lift of the maternity hospital | 8% (4.1–15%) | 0% (0–1.9%) | <.001 |
| Physical | Implementation of traceability of surgical material at source and destination | 7.1% (3.5–14%) | 1% (0.2–5.4%) | 0.274 |
| Physical | Replaced faulty or unsuitable equipment | 4.4% (3.5–20.7%) | 1.7% (0.5–6.1%) | 0.033 |
| Physical | Call to consultation by code on screen | 3.5% (1.4–8.7%) | 0% (0–3.1%) | 0.036 |
| Total | | 9.4% (7.7–11.4%) | 3.9% (2.9–5.3%) | 0.009 |

The percentage (95% CI) represents the frequency of near misses or adverse events observed (real-time observations) before and after the improvement actions were implemented. The last column shows if the improvement actions were or were not statistically significant in the reduction of the frequency of near misses or adverse events.

χ² test

Q = confidence interval. ICU = intensive care unit.

† Medical devices and vaccines were also included.
Table 4
Factors, characteristics of PSIs, and method of analysis, included in the initial univariate regression model and significant results in the multivariate analysis.

| Factors included in the initial univariate regression model | OR    | 95% CI   | P-value |
|-------------------------------------------------------------|-------|----------|---------|
| Phase                                                       |       |          |         |
| Surgical procedure                                          | 0.98  | 0.79–1.23| 0.913   |
| Medication or vaccine                                       | 1.33  | 1.01–1.76| 0.039   |
| Care and monitoring of the patient                         | 0.93  | 0.70–1.25| 0.619   |
| Diagnostic test                                             | 1.30  | 0.88–1.92| 0.169   |
| Therapeutic procedure                                       | 0.99  | 0.68–1.46| 0.989   |
| Continuity of care                                          | 2.38  | 1.46–3.90| <0.001  |
| Others                                                      | 1.15  | 0.74–1.78| 0.521   |
| Infrastructure                                              | 1.22  | 0.77–1.96| 0.379   |
| Medical device, equipment or furniture                      | 1.58  | 0.92–2.72| 0.077   |
| Organizational management/citations                         | 0.88  | 0.54–1.44| 0.597   |
| Patient identification                                      | 1.84  | 1.05–3.28| 0.024   |
| Clinical documentation/information/informed consent         | 0.82  | 0.49–1.38| 0.431   |
| Clinical evaluation/diagnosis                               | 0.98  | 0.50–1.92| 0.954   |
| Patient accident                                            | 0.93  | 0.40–2.22| 0.860   |
| Infection related to health care                            | 3.88  | 1.09–16.46| 0.019   |
| Preventive activities                                       | 5.24  | 1.17–32.77| 0.013   |
| Blood and blood products                                    | 1.16  | 0.32–4.61| 0.805   |
| Type of PSI                                                 |       |          |         |
| Near-miss PSIs                                              | 0.99  | 0.85–1.15| 0.883   |
| Adverse event PSIs                                          | 5.20  | 3.18–8.59| <0.001  |
| Method analysis                                             |       |          |         |
| Discussion of cases                                         | 1.04  | 0.88–1.23| 0.680   |
| Discussion groups                                           | 2.15  | 1.72–2.69| <0.001  |
| RCA                                                         | 2.75  | 1.52–5.06| <0.001  |
| Review of medical records                                   | 1.59  | 0.95–2.68| 0.077   |
| Not registered                                              | 1.03  | 0.46–2.16| 0.934   |
| FMEA (Failure mode and effects analysis)                    | 2.91  | 0.79–12.68| 0.900   |
| Interviews                                                 | 0.87  | 0.28–2.77| 0.797   |
| Briefing                                                   | 1.46  | 0.42–5.53| 0.526   |
| Focus groups                                                | 2.04  | 0.39–14.22| 0.366   |
| London protocol (causal model of accidents)                 | 2.33  | 0.25–54.81| 0.096   |
| Significant events audits                                   | Inf   | Inf      |        |
| Factors retained in the multivariate regression model        | OR    | 95% BCa CI| P-value |
| Adverse event (PSI type)                                    | 3.67  | 1.93–5.75| <0.001  |
| Discussion group (method analysis)                         | 2.45  | 1.56–3.80| 0.002   |
| RCA (method analysis)                                       | 2.32  | 1.31–4.02| 0.025   |

Bootstrap for variables in the equation

| Factors retained in the multivariate regression model | OR    | 95% BCa CI | P-value |
|------------------------------------------------------|-------|------------|---------|
| Adverse event (PSI type)                              | 3.67  | 1.93–5.75 | <0.001  |
| Discussion group (method analysis)                    | 2.45  | 1.56–3.80 | 0.002   |
| RCA (method analysis)                                 | 2.32  | 1.31–4.02 | 0.025   |

BCa = bias-corrected and accelerated; Inf = infinite; PSI = patient safety incident; RCA = root cause analysis.

*Based on 10,000 bootstrap samples.

reported behavior rather than their real-time observations. In this sense, this study measured PSIs in 2 different ways: to assess patient safety awareness of health professionals, we used the notifications of PSIs in our IRS and we observed that notifications increased through the period of study. To assess the efficacy of the measures we implemented, we performed real-time observations before and after the improvement actions. External staff recorded events directly observed in the location of each PSI notified by the IRS. The impact of the interventions by PSIs rates (before and after) was obtained through direct observations. The reduction of near misses or adverse events could not be due to the decrease of awareness and willingness to report such events, given that the information was obtained through real time observation.

But when real-time observations were made the explanations for noncompliance with hand hygiene provides a coherent way to design better interventions. In this study, this study measured PSIs in 2 different ways: to assess patient safety awareness of health professionals, we used the notifications of PSIs in our IRS and we observed that notifications increased through the period of study. To assess the efficacy of the measures we implemented, we performed real-time observations before and after the improvement actions. External staff recorded events directly observed in the location of each PSI notified by the IRS. The impact of the interventions by PSIs rates (before and after) was obtained through direct observations. The reduction of near misses or adverse events could not be due to the decrease of awareness and willingness to report such events, given that the information was obtained through real time observation.

The study of the near misses as a surrogate for adverse events is relevant because incidents constitute a population in which the adverse event is a subset. Analysis of these reports indicates that both human and systemic factors contributing to human errors can be identified. According with the results of the study, nurses and other non-health staff groups (e.g., cooks, maintenance technicians, clerks, cleaning personnel) reported more incidents ending with no harm to the patient. Near-miss was the type of PSI with more improvement measures pending implementation in the hospital (207 measures).
focus on practical skills as communication, leadership, and teamwork. There is a growing body of literature supporting the use of simulation as a more effective educational tool to promote practical abilities among physicians and nurses in clinical practice. Thus, the implementation of this educational method in patient safety could help reduce PSIs [13,34].

There are also questions about the effectiveness and cost of IRSs. Renshaw et al. [11] estimated that “the cost of the system was equivalent to 1184 UK National Health Service (NHS) employees spending all their time each month completing incident forms,” which were time-consuming to complete. [16] For this reason, this IRS aims to take less time to complete, a median of 10 minutes (159 reports evaluated, range from 3 to 20 minutes).

Our study was performed at a single tertiary hospital. In addition to being a single-center project, there are some other possible conditions limiting generalizability. One area of possible bias was that no comparison with other IRSs has been made. A direct comparison of 2 different IRS methods would provide valuable information regarding success factors, and to facilitate the choice between different IRSs.

5. Conclusion

In conclusion, the implementation of a hospital IRS, together with the systematization of the method and analysis of IRSs by local CSLs has led to improvement measures for over 1774 contributing or latent factors (median of 1.34 per PSI). The analysis showed a statistically significant reduction of near-miss or adverse events observed in 63.15% of the improvements implemented. The variables associated with significant improvement measures were “adverse events” type of PSI, “discussion group,” and RCA type of analysis. There was also a significant correlation between the patient safety workshops and the number of reports per month. All contribute directly to safer care, which is an important boost to the consolidation of the patient safety culture in the hospital.

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