

Incident reporting reduction during the COVID-19 pandemic in a tertiary Italian hospital: A retrospective analysis

GIULIA PAULETTI¹, CRISTIAN GIROTTO², GIUSEPPE DE LUCA³, and ANNA MARIA SAIIEVA²

¹Department of Molecular Medicine, University of Padova, via Gabelli 63, Padova 35121, Italy

²Department of Directional Hospital Management, Padua University Hospital, via Giustiniani 3, Padova 35128, Italy

³Department of Cardiac, Thoracic, Vascular Sciences and Public Health, University of Padova, Via Giustiniani 2, Padova 35128, Italy

Address reprint requests to: Giroto Cristian, Department of Directional Hospital Management, Padua University Hospital, Via Giustiniani 3, Padova 35128, Italy.

Tel: +00390498217372; E-mail: cristiangir8@gmail.com

Abstract

Background: Incident reporting (IR) is one of the most used systems to gain knowledge of adverse events (AEs) and to identify sources of risk. During COVID-19 pandemic, several organizational changes have been implemented to respond adequately and effectively to the emergency; this required the suspension of most deferrable activities.

Objective: The aim of this study is to investigate whether IR attitude of health workers has been reduced during the pandemic event.

Method: A retrospective analysis was conducted at the Azienda Ospedale – Università di Padova (Italy), considering IR of years 2019 and 2020. To standardize the effects of the decrease in admissions, we considered the number of incidents per 1000 admissions.

Results: Data shows that during the first (March–May 2020) and second waves (October–December 2020) of the COVID-19 pandemic there was a statistically significant reduction in the rate of IR for every 1000 admissions ($P=0.001$ —Wilcoxon test), especially for AEs and in COVID-19 units.

Conclusion: This study shows a reduction in IR especially during the first and second pandemic waves of COVID-19 in year 2020. Education and training interventions could be fundamental to raise awareness of the importance of IR in health workers, as this could provide opportunities to understand what is impacting on safety in a particular healthcare context and enable continuous improvement.

Key words: risk management, Covid-19, patient safety, incident reporting

Introduction

The World Health Organization (WHO) defined ‘Patient safety’ as the absence of preventable harm to a patient during the process of health care and reducing the risk of unnecessary injuries associated with health care to an acceptable minimum [1]. Furthermore, in the Global Patient Safety Action Plan 2021–2030, WHO affirms that patient safety can be defined as a framework of organized activities that consistently and sustainably lower risks, reduces the occurrence of avoidable harm, making errors less likely and reducing their impact when they does occur [2, 3]. The focus over the last year has also been on economic losses and access problems due to unsafe care, which potentially become major barriers to achieving Universal Health Coverage [2]. An estimation of 64 million disability-adjusted life years are lost every year due to ‘not safe’ care, worldwide, suggesting that patient harm due to adverse events could be one of the top 10 causes of death and disability in the world. In high-income countries, estimates suggest one in every ten patients is harmed while receiving hospital care [4]. In Italy, adverse events (AEs) have been identified in 5% of admissions; of these 56.7% were preventable harms [5].

One of the most widespread systems used to gain knowledge of AEs and to identify sources of risk within organizations involves filling out incident reports. Incident reporting (IR) is a tool that allows healthcare professionals to voluntarily report and describe adverse events and near misses, unintentionally caused, often due to latent criticalities, which could cause harm to the patient, or create risk situations [6, 7]. IR systems are now considered a cornerstone for improving patient safety and are applied by many hospitals accreditation programs. IR systems rely on a process by which staff-reported problems are investigated and addressed [8]. Several hospitals around the world adopted a web-based IR tool rather than a paper one: several studies reported that this organizational change led to a higher number of reports [9–11]. A Dutch study published in 2019 has shown that a web-based tool, even in the first months after its implementation, doubled the reporting rate [12]; another study stated that among non-medical professionals, who had not always had access to previously used paper forms, found IR web-based system better [13].

In December 2019, Chinese authorities reported a cluster of pneumonia cases of unknown aetiology in the city of

Wuhan (Hubei province, Mainland China). On 9 January 2020, the Chinese Centre for Disease Control and prevention identified a novel coronavirus as the causative agent for these cases. On 11 March 2020, the WHO declared that the international outbreak of coronavirus SARS-CoV-2 infection could be considered a pandemic [14]. WHO Director-General's statement announced that countries must take a global-government and global-society approach, built around a comprehensive strategy to prevent infections, to save lives, and to minimize impact [15]. Globally, as of 27 December 2020, there have been over 79.2 million cases and over 1.7 million related-deaths reported since the start of the pandemic [16].

In Italy, on January 30, 2020, the Italian National Institute of Health (ISS) confirmed the first two cases of COVID-19 [17]. Between February and November 2020, 1 651 229 positive cases of COVID-19 have been reported to the National Integrated Surveillance System of the ISS. The epidemic spread scenario can be summarized in three phases. The first phase, covering the period from March to the end of May 2020 (First wave), was characterized by a very rapid diffusion of cases and deaths and a strong territorial concentration mainly in Northern Italy. During the summer season, from June to mid-September (transition phase), the spread was initially very limited. As of the beginning of October 2020 (Second wave) cases increased again rapidly with an exponential rate over a large part of the country; only in mid-November a decline in incidence was observed [18].

Since the first cases of COVID-19, several organizational changes have been implemented to respond adequately and effectively to the emergency and to the needs of citizenship [19, 20]. A crisis management plan was fundamental to face the pressure caused by the pandemic on the entire healthcare system [21]. A lot of space and resources were dedicated to assisting COVID-19 affected patients; this hospital reorganization required the suspension of most deferrable activities that led to a consequent decrease in the number of admissions [19, 22].

In the current SARS-CoV-2 pandemic, it is important for health care providers to be diligent and careful about IR to assure both patients and health workers safety. IR also contributes to maintaining a heightened awareness, to address all sources of potential harm and to understand if the organizational changes implemented, due to the emergency, have had an impact on safety in the healthcare context.

The aim of this study is to investigate whether IR attitudes of health workers have been altered during the pandemic event, particularly during the first and second waves.

Methods and materials

Study

For this research, a retrospective analysis was conducted, approved by the hospital institutional director.

Setting

This research was conducted in the Azienda Ospedale – Università di Padova (AOUP), a highly specialized tertiary hospital of national importance situated in North-Eastern Italy, in the Veneto Region. AOUP is a public, acute care hospital with 1700 beds, serving approximately 1 million people a year. The health care provided includes any type of medical

specialties, surgery and transplantation activities, and every year outpatient facilities count more than 7 million specialist visits.

The AOUP guarantees all care activities in a process that inseparably includes teaching and research activities. There is a specific unit dedicated to Clinical Risk and Patient Safety, whose goal is to develop an internal risk management system to increase the safety of patient care and that of all staff, to support professional activity, to guarantee the hospital's image and patient confidence and to reduce the possibility of litigation between the patient and the hospital [23].

The approval of the ethics committee was not requested because no sensitive data (neither of patients nor of health workers) have been used for this retrospective analysis.

Instrument

To conduct this research, the 'Claims and clinical risk management' portal ('Gestione sinistri e rischio clinico'—GSRC), a web-based tool adopted in the Clinical Risk and Patient Safety Unit of AOUP, was used and analyzed. In the Veneto region there has been a significant increase in rates of IR, which coincides with the introduction of the GSRC Portal in year 2018, a web-based reporting system that replaced the paper one. In this portal, where all adverse events and near misses reported by hospital employees are combined, it is possible to analyze data of interest and to monitor the use of the tool, the occurrence of incidents and, subsequently, to implement improvement actions.

In AOUP, the introduction of this new technology had been preceded by a training course given to health workers conducted by the Clinical Risk and Patient Safety Unit, to encourage reporting, to foster the utilization of the new tool and to promote the culture of Clinical Risk. The collection and analysis of adverse events and near miss constitutes an essential pool of data and information for mapping the areas at greatest risk, both at hospital and regional levels; the analysis of an adverse event or a near miss are essential to monitor the safety level of the organization and to acquire essential information for the management of clinical risk [6].

Data analysis

From the GSRC, data of IRs of years 2019 and 2020 were analyzed. The total number of incidents registered in the portal were extracted divided by year and month: then, adverse events and near misses were considered differently. Subsequently, to mitigate the effects of the decrease in admissions, especially during pandemic waves in year 2020, we considered the number of IRs per 1000 admissions. Then, statistical analysis was conducted to evaluate whether the difference in the IR rate between year 2019 and 2020 had statistical significance (Wilcoxon test). Subsequently, each month of year 2019 was compared with the corresponding month of year 2020 to verify in which ones the reduction in the IR rate was significant. The analyses were conducted using R (version 3.5.3).

Results

The rate of total incidents reported per 1000 admissions in years 2019 and 2020 are summarized in [Table 1](#).

Data shows that during year 2020, compared to year 2019, the reduction in rate of IR every 1000 admissions

Table 1 Rate of incident reporting per 1000 hospitalizations/month in year 2019 and 2020 and analysis of monthly difference

Month	2019	2020	P-value
January	20.3	17.4	
February	19.0	19.2	
March	20.9	17.7	0.012
April	19.1	14.1	<0.001
May	20.6	13.7	<0.001
June	19.7	15.1	<0.001
July	19.2	17.6	
August	15.2	15.4	
September	15.0	12.8	
October	15.9	8.7	<0.001
November	16.1	10.3	<0.001
December	13.8	5.8	<0.001
Whole year	215.0	167.9	0.001

has been statistically significant ($P = 0.001$ —Wilcoxon test). Furthermore, we noticed that the reduction was statistically significant especially during the first (March–May 2020) and second waves (October–December 2020) of the COVID-19 pandemic; in the other months no statistically significant differences were found.

From Figure 1 we can see that the reduction in IR was different if we consider adverse events or near misses. The trend rate in reduction of reporting was more remarked in AE reporting.

Subsequently, the departments in which the incidents were reported, were compared with each other to investigate whether the reduction was greater in COVID-19 wards than in the others. To conduct this analysis, the total number of incidents of each ward in 2019 was compared with the total number of incidents in 2020 in the same wards. The average percentage reduction in IR in COVID-19 departments in 2020, compared to 2019, was 27.94%. Some wards, such

Table 2 Mean of incident reporting in COVID-19/non- COVID-19 wards in year 2019 and 2020

	Mean of IR in COVID-19 wards	Mean of IR in non-COVID-19 wards
Year 2019	19	13.92
Year 2020	13.69	11.66
Percentage reduction	27.94%	16.24%

as the intensive care units and the emergency room, had been transformed into COVID-19 departments during year 2020 to assist COVID patients. In the previous year, those wards were dedicated to the usual clinical activity. The reduction in IR in non-COVID-19 departments, in the same year, was 16.24%. (Table 2).

Finally, from the GSRC database, we investigated how many incident reports were correlated to COVID-19 infections and how many were not in year 2020.

Considering a total of 1037 IR collected in 2020, 233 of them were related to COVID-19 (about 22% of the total). Of these, about 80% of IR ($n = 197$) occurred in the wards involved in the assistance of COVID-19 affected patients (e.g. emergency wards), concerned, for example, errors in drug administration or delays in assistance. The remaining 20% ($n = 36$) were related to IR reported in other wards or services and include anomalies in COVID-19 testing or in the management of non-COVID-19 patients.

Discussion

Statement of principal findings

This research shows a great variability in the attitude of IR in AOUP among different pandemic periods, with a reduction during the moment of greatest incidence of cases of COVID 19. This reduction was predominant in AE while near miss IR reports were constant.

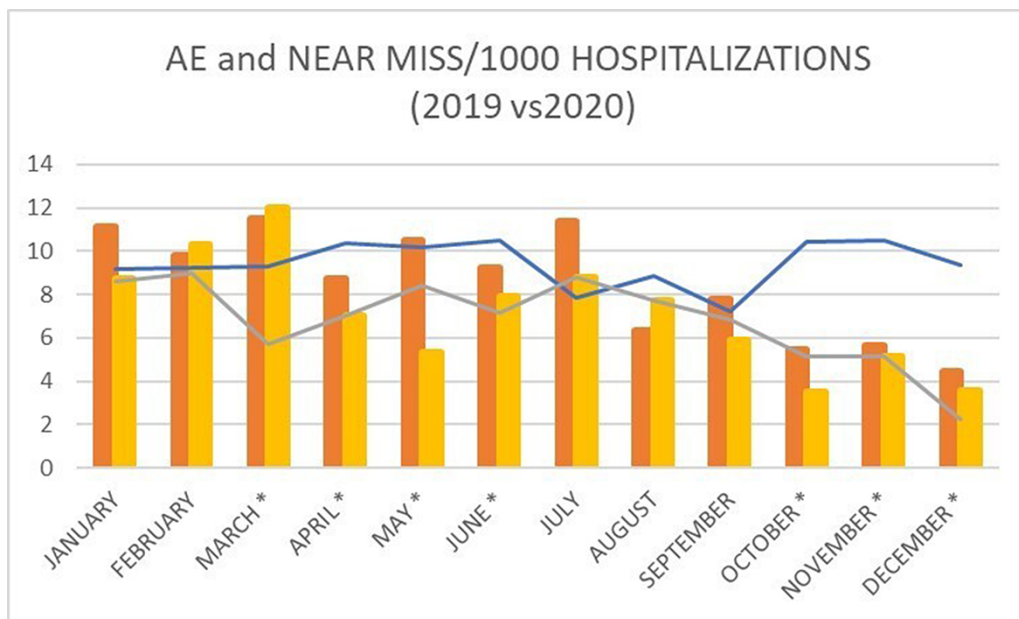


Figure 1 Rate of adverse event and near miss per 1000 hospitalizations (year 2019 and 2020).

*Significant difference in AE 2019 versus 2020. Orange column: 2019 NEAR MISS. Yellow column: 2020 NEAR MISS. Blue line: 2019 ADVERSE EVENT. Gray line: 2020 ADVERSE EVENT.

Our data shows that the reduction in IR was greater in COVID-19 departments than in others. The comparison conducted between years 2019 and 2020 suggests that working in a COVID-19 area may have a negative impact on IR. The reduction in IR, as an average percentage, was more significant in wards that were dedicated to the care of COVID-19 patients during the year 2020. Especially during the first and second waves, IR may not have been the priority for healthcare professionals due to continuous organizational changes and a climate of uncertainty about the disease, its specific behavior, treatment, impact and evolution.

Strengths and limitations

This study presents some limitations that need to be mentioned. Incidents are voluntary and they can be reported later in time in the health portal; therefore, data obtained from our research could be not fully representative of the totality of IR which occurred, especially for year 2020.

The reduction of outpatient visits in 2020, compared to year 2019, and how many IR were usually connected to that kind of health performance, were not considered. Patient falls and aggression towards health care workers were not considered in our analysis.

For our study, we did not consider the turnover of healthcare workers and other variables as, for example, bed turnover; such variables could be related to the IR reduction observed within this research.

Interpretation within the context of the wider literature

Denning *et al.* [24] confirmed the same trend in the overall reduction rate of IR during the COVID 19 pandemic. The same authors reported that this reduction of IR may be explained by the increased workload, change in perceived importance of error reporting or even organizational changes that led to an effective reduction of events [24].

As reported in the international literature IR is extremely important during a particular healthcare context, such as a pandemic, to understand what is impacting on safety and which additional organizational changes are required [24, 25].

Patient safety should always remain the priority in a healthcare context and the contribution of workers must be constant to allow continuous organizational improvements. Moreover, other studies described that during a pandemic event, risk management has a fundamental role to support organizations and to assure patient safety, even with the contribution of patient safety teams. Learning opportunities as well as innovations could be improved, capturing crisis-related incidents [25, 26].

Strategies to inform health professionals have been implemented in AOUP to involve them in organizational changes aimed at enhancing patient and workplace safety.

Implication for policy, practice and research

What emerges from our results suggests that there was a decrease in the rate of IR that does not allow us to have a complete view of the systemic errors that occurred within the hospital. This made it impossible for our GSRC Unit to understand and manage the criticalities of the system, increasing the risk of damage to the patient.

Further research is needed to investigate if the lower trend-rate in IR in year 2020 is correlated to an effective reduction of adverse events and/or near misses in clinical practice. For example, a review of medical records or a survey with health workers could be done. Moreover, it could be investigated whether the lower propensity to report is present, for example, more in doctors than in nurses. Such a study has already been planned by our group.

Leadership is essential during a pandemic crisis, at all levels, but constant feedback from the bedside is needed to guide organizational changes. Moreover, in this context, it is important to support educational strategies and clinical risk management: learning both from goals rather than from incidents is more important than ever [25].

Additional research is required to understand if the lower rate of IR in year 2020, compared with data of the previous year, is directly related to Covid-19 pandemic or if other variables, such as workers turnover, could have affected this trend.

Conclusions

In conclusion, this study shows a reduction in IR especially during the first and second pandemic waves of COVID-19 in year 2020. A decrease in the rate of IR may increase the risk of damage to the patient and may not allow the unit to carry out its mission within the hospital.

Education and training interventions could be fundamental to raise awareness of the importance of IR by health workers, as this could provide opportunities to understand what is impacting the safety, in a particular healthcare context, and enable continuous improvement.

Funding

None declared.

Data availability

No new data were generated or analysed in support of this review.

Ethics and other permissions

This study has been approved by the hospital institutional director because according to the Italian ethic guidelines the project does not need ethical authorization as it does not employ patients' identification and no possibility of tracing patients is foreseen.

References

1. World Health Organization (WHO) Geneva. *Patient safety*. www.who.int/teams/integrated-health-services/patient-safety (21 March 2021, date last accessed).
2. World Health Organization (WHO) Geneva. *Global Patient Safety Action Plan*. www.who.int/teams/integrated-health-services/patient-safety/policy/global-patient-safety-action-plan (21 March 2021, date last accessed).
3. World Health Organization. WHO global action on patient safety. World Health Organization, 2019.
4. World Health Organization. WHO patient safety: global action on patient safety: report by the director-general. World Health Organization, 2019.

5. Tartaglia R, Albolino S, Bellandi T *et al.* Adverse events and preventable consequences: retrospective study in five large Italian hospitals. *Epidemiol Prev* 2012;36:151–61.
6. Regione del Veneto, Italy. *Gestione Rischio Clinico e Sicurezza del Paziente e Incident Reporting*. <https://salute.regione.veneto.it/web/gsrc/incidentreporting> (21 March 2021, date last accessed).
7. Albolino S, Tartaglia R, Bellandi T *et al.* Patient safety and incident reporting: survey of Italian healthcare workers. *Qual Saf Health Care* 2010;19:i8–12.
8. Tricarico P, Castriotta L, Battistella C *et al.* Professional attitudes toward incident reporting: can we measure and compare improvements in patient safety culture? *Int J Qual Health Care* 2017;29:243–9.
9. Archer G, Colhoun A. Incident reporting behaviours following the Francis report: a cross-sectional survey. *J Eval Clin Pract* 2018;24:362–8.
10. Dixon JF. Going paperless with custom-built web-based patient occurrence reporting. *Jt Comm J Qual Improv* 2002;28:387–95.
11. Okafor NG, Doshi PB, Miller SK *et al.* Voluntary medical incident reporting tool to improve physician reporting of medical errors in an emergency department. *West J Emerg Med* 2015;16:1073–8.
12. de Vos MS, Hamming JF, Chua-Hendriks JJC *et al.* Connecting perspectives on quality and safety: patient-level linkage of incident, adverse event and complaint data. *BMJ Qual Saf* 2019;28:180–9.
13. Sendlhofer G, Eder H, Leitgeb K *et al.* Survey to identify depth of penetration of critical incident reporting systems in Austrian healthcare facilities. *Inquiry* 2018;55:46958017744919.
14. Istituto Superiore di Sanità (ISS) Italy. *Coronavirus*. <https://www.epicentro.iss.it/en/coronavirus/sars-cov-2-international-outbreak> (21 March 2021, date last accessed).
15. World Health Organization (WHO) Switzerland. *WHO Director-General's opening remarks at the media briefing on COVID-19 - 11 March 2020*. <https://www.who.int/director-general/speeches/detail/who-director-general-s-opening-remarks-at-the-media-briefing-on-covid-19-11-march-2020> (21 March 2021, date last accessed).
16. World Health Organization (WHO) Switzerland. *Weekly epidemiological update - 29 December 2020*. <https://www.who.int/publications/m/item/weekly-epidemiological-update-29-december-2020> (21 March 2021, date last accessed).
17. Istituto Superiore di Sanità (ISS) Italy. *ISS per COVID-19*. <https://www.iss.it/coronavirus> (21 March 2021, date last accessed).
18. Istituto Superiore di Sanità. *Impatto Dell'epidemia Covid-19 Sulla Mortalità Totale Della Popolazione Residente Periodo Gennaio-Novembre 2020- Rapporto Iss E Istat Del 30 Dicembre 2020*. Istituto Superiore di Sanità, 2020.
19. De Filippis G, Cavazzana L, Gimigliano A *et al.* Covid-19 pandemic: a frontline hospital reorganization to cope with therapeutic and diagnostic emergency. *Pharmacol Res* 2020;161:105160.
20. Meschi T, Rossi S, Volpi A *et al.* Reorganization of a large academic hospital to face COVID-19 outbreak: the model of Parma, Emilia-Romagna region, Italy. *Eur J Clin Invest* 2020;50:e13250.
21. European Centre for Disease Prevention and Control. *ECDC checklist for hospitals preparing for the reception and care of coronavirus 2019 (COVID-19) patients*. European Centre for Disease Prevention and Control, 2020.
22. Willan J, King AJ, Jeffery K *et al.* Challenges for NHS hospitals during covid-19 epidemic. *BMJ* 2020;368:m1117.
23. Azienda Ospedale Università di Padova. *UOS Rischio Clinico*. <https://www.aopd.veneto.it/sez,263> (21 March 2021, date last accessed).
24. Denning M, Goh ET, Scott A *et al.* What has been the impact of covid-19 on safety culture? A case study from a large metropolitan healthcare trust. *Int J Environ Res Public Health* 2020;17:7034.
25. Staines A, Amalberti R, Berwick DM *et al.* COVID-19: patient safety and quality improvement skills to deploy during the surge. *Int J Qual Health Care* 2021;33:mzaa050.
26. Gurses AP, Tschudy MM, McGrath-Morrow S *et al.* Overcoming COVID-19: what can human factors and ergonomics offer? *J Patient Saf Risk Manage* 2020;25:49–54.