Operations

The COVID-19 outbreak in Saudi Arabia and the impact on patient safety incident reports: An empirical study among the medical facilities of Qassim health cluster

By Sultan Al-Shaya, MD, TQM, Ayed Al-Reshidi, MSc, CPHQ, CHS, CSSMBB, Majeda Farajat, MD, MPH, CLSSBB®, and Aliaa Elnefiely, MD, TQM, CPHQ

COVID-19 outbreak in Saudi Arabia (SA) has placed substantial challenges on its health care system, which raised our concern about the possible influence on patient safety culture. Therefore, this study aimed to provide empirical evidence on how the COVID-19 outbreak impacted patient safety incident reports (PSIRs) among the Qassim Health Cluster (QHC) in SA. This retrospective study assessed a total of 23,481 inpatient PSIRs from 22 medical facilities. We compared data on PSIRs between COVID-19 period (March–July 2020) and a comparable pre-COVID-19 period (March–July 2019). PSIRs were classified according to “Saudi Patient Safety Taxonomy.” In the COVID-19 period: inpatient admissions have significantly dropped by one-fourth, and the median score of PSIRs significantly increased to 30.6/100 inpatients. Nevertheless, there were no changes in PSIRs harm level. The top five areas of reporting were related to: patient care, medication, infection control, staff, and facility maintenance. Furthermore, there were no significant differences in the frequency rate of PSIRs by facility bed capacity. The significant increase in PSIRs at COVID-19 time can be perceived as a positive outcome. Our view considers both the COVID-19 crisis and future health crises. The lessons learned here should be employed to promote sustainable preparedness and responses to subsequent crises.
INTRODUCTION

In 2020, the emerging coronavirus (COVID-19) pandemic has been the leading cause of morbidity and mortality across most of the world. Although the first-ever confirmed case of COVID-19 was recorded on November 17, 2019 in China, Saudi Arabia (SA) experienced its first case approximately three and half months later on March 2, 2020. Since that time, an increasing number of coronavirus infections have occurred in SA. In terms of confirmed COVID-19 cases as a percentage of the population, SA has led in COVID-19 cases among other Arab countries, with cases exceeding a quarter of a million (n = 255,825) by July 22, 2020. For the Qassim province in particular, there have been 19,582 confirmed cases of COVID-19 for the period from March 2–July 31, 2020.

Health care workers (HCWs) stand at the frontline of this pandemic and carry a substantial degree of responsibility in combatting it. Their commitment to the measures of preventing and controlling the infection are integral to the safety of both patients and staff. HCWs are at a higher risk of catching COVID-19 from infected staff and patients. In their nationwide cohort study, Shah and his colleagues found that HCWs with direct patient contact had a triple risk of COVID-19 hospital admission compared with other HCWs. Moreover, the same study reported that the families of the HCWs also had higher risk (double) of COVID-19 hospital admission. Accordingly, HCWs are believed to encounter professional challenges resulting from the emerging work environment that COVID-19 has created, which is characterized by apprehension, stress, and uncertainty. Besides, this COVID-19-induced health care environment is expected to persistently raise additional issues related to patient safety and ethical and legal matters.

Central to patient safety is the provision of patient safety culture (PSC). A positive PSC is an active measure to improve patient outcomes and protect them from adverse events. A PSC consists of multiple elements, however; this study is primarily concerned with the “active reporting culture,” which proactively works to disclose the core of a problem. Active reporting systems enable the staff to identify the underlying causes of the errors, prioritize improvement opportunities, learn from their own errors, and therefore develop self-improvement plans. Moreover, having effective incident reporting systems within the health care organizations is believed to be an operative strategy to improve patient safety.

In SA, the COVID-19 outbreak has placed considerable challenges and burdens on the country’s health care system, raising concerns about how PSC can influence patient safety. As Tingle asserted, patient safety should not be abandoned during the COVID-19 crisis, and efforts to cultivate a deep-rooted PSC must be sustained. As per Saudi Ministry of Health (MOH) policy and procedures on risk management, PSIRs are an important input for a tool (risk register) to manage medical risks along with various internal and external resources. In 2018, the Saudi MOH launched a nationwide initiative to improve the taxonomy of the patient safety incident reporting system known as the Saudi Patient Safety Taxonomy (S-PST).

To our knowledge, few studies across the world have addressed COVID-19’s impact on incident reporting. Among existing studies, a case study from an academic hospital in the UK revealed a statistically significant reduction in incident reporting during the COVID-19 crisis when compared to earlier data. As for the nature of PSIRs during the COVID-19 period, a study among US hospitals showed that the most common category of incidents included laboratory testing (47%), followed by processes/protocols (25%) and isolation integrity (22%). The present study sought to collect information on COVID-19-related PSIRs to establish priorities for effective COVID-19 service delivery and to ensure patient safety among the medical facilities of the QHC. The results of this work are expected to aid in preparation and response planning for current and future crises and outbreaks. Thus, this study aimed to address the impacts of COVID-19 on PSIRs among the QHC facilities by comparing data on PSIRs between the COVID-19 period (March 2, 2020 to July 31, 2020) and a comparable pre-COVID-19 period (March 2, 2019 to July 31, 2019). The impact was assessed based on volume, rate, and level of harm. The study further aimed at identifying the top five most frequently reported categories of PSIRs during the COVID-19 period; and assessing if there is an association between the facilities’ PSIR volume and bed-capacity volume during the pre-and COVID-19 periods.

MATERIALS AND METHODS

This is a retrospective study of a descriptive nature among the hospitals (n = 19) and the specialized centers (n = 3) of the QHC. Secondary data analysis was conducted using the database of QHC’s Performance Excellence and Quality Administration. There are advantages for utilizing secondary data sources, including being convenient, cost-effective, and time-saving. Nevertheless, the usage of secondary data might be limited by the original purpose it was collected for; in addition to the limited information of the secondary researcher about the data collection process. The ethical approval was obtained from the Qassim Region Research Ethics Committee. This study only included PSIRs relating to inpatients (treated in inpatient wards). By contrast, PSIRs relating to outpatients were excluded. The decision to exclude PSIRs from outpatient areas was based on two reasons: first, outpatient areas generally experience much lower rates of PSIRs when compared to inpatient areas; and second, after the COVID-19 outbreak in SA in March 2020, working hours decreased and the number of outpatient department (OPD) visits slowed down.

The rate of PSIRs for each of the predetermined periods was calculated as “total incidents per 100 patients.” To avoid biases due to drops in bed occupancy resulting from COVID-19 restrictions, we standardized the rate by using...
Table 1: Descriptive statistics on PSIRs related variables for the pre-COVID-19 period (March–July, 2019) and the COVID-19 period (March–July, 2020)

| Period            | Total inpatients | Total PSIRs | PSIRs median rate (range) |
|-------------------|------------------|-------------|---------------------------|
| Pre-COVID-19 period | 52,078           | 10,729      | 26.9/100 inpatients (1.0–506.3) |
| COVID-19 period   | 37,555           | 12,752      | 30.6/100 inpatients (2.5–333.0) |
| p-Value           | <0.001*          | 0.290       | 0.004*                    |

Table 2: Comparison of between the pre-COVID-19 period (March–July, 2019) and the COVID-19 period (March–July, 2020), based on the level of harm of the PSIRs

| Level of harm | Pre-COVID-19 period N (%) | COVID-19 period N (%) | p-Value* |
|---------------|---------------------------|-----------------------|----------|
| None          | 5393 (50.3%)              | 7131 (55.9%)          | 0.761    |
| Minor         | 2649 (24.7%)              | 2099 (16.5%)          | 0.223    |
| Moderate      | 1733 (16.2%)              | 3183 (25.0%)          | 0.702    |
| Major         | 875 (8.2%)                | 251 (2.0%)            | 0.122    |
| Catastrophic  | 79 (0.7%)                 | 88 (0.7%)             | 0.832    |

*significant (p-value ≤ 0.05).

**RESULTS**

The total number of inpatient admissions in the pre-COVID-19 period (March–July 2019) was 52,078, whereas in the comparable COVID-19 period (March–July 2020) the total number of inpatient admissions has statistically significantly dropped to 37,555, that is by one-fourth. Concerning the count of PSIRs, there was a nonstatistically significant increase from 10,729 reports in the pre-COVID-19 period to 12,752 reports in the COVID-19 period (Table 1). The median score of PSIRs was 26.9/100 inpatient admissions in the pre-COVID-19 period, the rate statistically significantly increased to 30.6/100 inpatient admissions in the COVID-19 period; that is about 31% of inpatients had a PSIR (Table 1). Concerning the impact of COVID-19 on the level of harm caused to patients by the reported PSIR, no significant changes were found (Table 2). As shown in Figure 1, the top five most frequently reported categories of PSIRs at pre-COVID-19 period were inpatient care management, medication, infection control related issues, staff-related issues, and facility maintenance, whereas the top five most frequently reported categories of PSIRs at COVID-19 period were medication, patient care management, infection control related issues, laboratory-related issues, and medical equipment issues. As shown in Table 3, there were no associations between the volume of PSIRs and the size of the facility (bed capacity) neither at the pre-COVID-19 period nor the COVID-19 period.

**DISCUSSION**

Our study aimed to answer central questions about how the COVID-19 outbreak has influenced PSIRs and related variables among Saudi medical facilities, particularly, facilities within the QHC. The significance of the obtained results can be summarized in five main points. First, the COVID-19 outbreak impacted inpatient volume (admissions), which decreased by one-fourth. The occurring drop in admissions could be attributed to the national effort to reduce non-COVID admissions by limiting admissions to urgent and emergency cases during the COVID-19 period (March to July 2020). Second, the COVID-19 outbreak impacted the frequency of PSIRs, which caused an increase in total PSIRs and the median rate of PSIRs. We view the increase in the PSIRs as a positive outcome since our staff has remained aware of the importance of incident reporting during the COVID-19
Figure 1:
Distribution of PSIRs by nature, pre and post COVID-19 times

Table 3: Differences in PSIRS Median Rate by facility’s size, for the pre-COVID-19 period (March–July, 2019) and the COVID-19 period (March–July, 2020)

| Facility’s size          | N  | Mean rank | p-Value* |
|--------------------------|----|-----------|----------|
| Pre COVID-19 time        |    |           |          |
| Small (<50 Beds)         | 7  | 13.50     | 0.55     |
| Medium (50–99 Beds)      | 7  | 9.71      |          |
| Large (100+ Beds)        | 8  | 11.31     |          |
| Post-COVID-19 time       |    |           |          |
| Small (<50 Beds)         | 7  | 13.14     | 0.55     |
| Medium (50–99 Beds)      | 7  | 9.43      |          |
| Large (100+ Beds)        | 8  | 11.88     |          |

*Significant (p-Value ≤ 0.05).

period. Moreover, this increase in incident reporting practices had created a successful environment for learning, which may help in planning responses to future outbreaks and crises. Indeed, in a recent article published in 2020, a group of diverse researchers agreed that the COVID-19 pandemic may result in many positive changes in health care, such as upgraded coordination and quality. These changes could be realized through strong commitments to a shared goal, building innovative solutions, and transforming failures into lessons and motivators to achieve future success. Our results are inconsistent with the results of the data from a UK study, which reported a statistically significant reduction in PSIRs after the COVID-19 crisis. The authors attributed this reduction to overworked staff who had less time to issue PSIRs and the perception of a decreased importance in error reporting.

Third, in our investigation of COVID-19’s impact on the levels of harm caused to patients by the reported PSIRs, we found no statistically significant differences in the five levels of harm between the pre-COVID-19 and the COVID-19 periods. Our results are in line with a previous study by the British National Health Service that reported consistent patterns of harm throughout the pre-COVID-19 and the COVID-19 periods. Because COVID-19 infection is linked to elevated harms, we view the “no change” in the harm levels between the pre and the COVID-19 periods as a positive sign. Indeed, for patient safety incidents not to be more harmful at the critical time of COVID-19 there must have been the adoption of good...
practices against nosocomial COVID-19 infection among the HCWs. This is not unexpected since the health care authorities in SA have responded rapidly and effectively to contain the viral outbreak. The Saudi Center for Disease Prevention and Control (Saudi CDC), in cooperation with the MOH, has provided continuous updates/versions of guidelines and tools designed for the management of COVID-19.19 In its turn, the Saudi Central Board for Accreditation of Healthcare Institutions “CBAHI” has developed a self-assessment tool for COVID-19 preparedness among health care facilities.20 Moreover, the Saudi Patient Safety Center (SPSC) has focused on releasing updates on safety guidelines for the HCWs.21

Fourth, as illustrated in Figure 1, the top five most frequently reported categories of PSIRs during the pre-COVID-19 period included: patient care management, medication, issues related to infection control, staff-related issues, and facility maintenance. By comparison, the top five most frequently reported categories of PSIRs during the COVID-19 period included: medication, patient care management, issues related to infection control, laboratory issues, and medical equipment issues. The top three categories, which were medication, patient care management, and infection control, remained the same. Yet, there have been greater medication-related PSIRs. An opposite pattern was described by the UK’s National Pharmacy Association, which reported that PSIRs diminished by 45% during the COVID-19 period.22 The rise in medication errors in Saudi medical facilities might be attributed to the fact that within a relatively short period of time HCWs who have the privilege to prescribe, administer, or dispense medications have gone through multiple versions of a protocol on management of “patients suspected or confirmed with COVID-19.” Given the scope of this study, detailed analysis (subcategorization) of the PSIRs was not performed. Therefore, a further examination of PSIRs is recommended for future studies. Furthermore, two new areas of study, namely issues related to laboratories and medical equipment, have arisen among the top five PSIRs during the COVID-19 period. In agreement with this finding, laboratory testing was reported by a study among US hospitals to be the most common PSIR during the COVID-19 period.13 This focus on reporting about laboratory-related incidents could be explained by the intense interest HCWs have taken in preventing themselves from contracting laboratory-acquired COVID-19 infections. Moreover, the increased reporting on medical equipment may reflect HCWs’ awareness of the availability, adequacy, and function of medical devices when securing them.

Fifth, we found no relationship between the frequency of the PSIRs and the size of the facility (bed capacity) during the pre or the COVID-19 periods. This finding is supported by evidence from an earlier study in the same setting (QHC) that indicated that the overall perception of PSC is not associated with hospital variables.23 Moreover, our results are in line with a British report that analyzed more than 5 million PSIRs and concluded that the rate of incident reporting is not connected to the size of hospitals.23

CONCLUSION

This study provided empirical evidence about how the COVID-19 outbreak in SA impacted PSIRs within the QHC. COVID-19 has significantly contributed to an increased frequency in PSIRs, supporting the presence of PSC, which promotes reporting and investigation into PSIRs. Indeed, if a culture of reporting is built effectively, crises (of whatever nature) cannot act as barriers to continued reporting. Our view considered both the COVID-19 crisis and any future health crises. As such, lessons learned in this paper should be employed to promote sustainable preparation and responses to forthcoming crises. Moreover, given the modest published data on this topic, we expect our study to advance the regional and international literature by presenting a model from the Middle East, specifically from the Gulf Cooperation Council region.

LIMITATIONS AND STRENGTHS

The primary limitation of this study concerns the difficulty in confirming the causality between the COVID-19 outbreak and increased PSIRs in SA. Therefore, further prospective, longitudinal research is recommended to confirm the causality relationship between COVID-19 and PSIRs. Another limitation is related to the study’s timeliness which only covered the first five months of the COVID-19 outbreak in SA. Additionally, although analyzing PSIRs by category did not fall within the scope of this study, we acknowledge that it would have proven interesting to closely examine the incidents’ details. Accordingly, a further analysis (subcategorization) of the PSIRs, particularly for incidents related to medication, is recommended to reveal a clearer picture of their pattern.

Our study contained several strengths. First, at the time of this work’s submission, few articles about the impact of COVID-19 on PSIRs were published worldwide. Second, the study covered every medical facility (n = 22) within the QHC without applying exclusion or sampling. Third, the study was performed on a validated data set, which was extracted from the QHC’s database for Performance Excellence and Quality Administration.

ACKNOWLEDGMENT

The authors would like to acknowledge and thank the Directors of Quality Management and Patient Safety Departments of the medical facilities of Qassim Health Cluster (QHC) along with the Administration of Performance Excellence and Quality for data collection and validation. Additionally, we are grateful to the higher
management of the QHC for granting permission to use this dataset for secondary analysis.

**CONFLICT OF INTEREST**

None

**REFERENCES**

1. Saudi Ministry of Health-MOH News. MOH Reports First Case of Coronavirus Infection. March 20, 2020. Accessed June 11, 2020. https://www.moh.gov.sa/en/Ministry/MediaCenter/News/Pages/News-2020-03-02-002.aspx

2. UNESCWA (United Nations Economic and Social Commission for Western Asia). Prevalence of COVID-19 in the Arab Region. 2020. Accessed August 13, 2020. https://www.unescwa.org/prevalence-covid-19-arab-region

3. Shah AS, Wood R, Gribben C, et al. Risk of hospital admission with coronavirus disease 2019 in healthcare workers and their households: nationwide linkage cohort study. *BMJ*. 2020;28;371:m3582.

4. Tingle J. COVID-19 safety in maternity care: lessons for the whole NHS. *Br J Nurs*. 2020;29(8):486-487.

5. Hessels AJ, Paliwal M, Weaver SH, Siddiqui D, Wurmsr TA. Impact of patient safety culture on missed nursing care and adverse patient events. *J Nurs Care Qual*. 2019;34(4):287-294.

6. Kristensen S. Patient safety culture: measurement-leadership improvement. Doctoral dissertation. Aalborg University; 2016. https://doi.org/10.5278/VBN.PHD.MED.00063.

7. Hazan J. Incident reporting and a culture of safety. *Clin Risk*. 2016;22(5-6):83-87.

8. AlReshidi A, Farajat M, Ibrahim T, Alresheedi A, Elnefiely A, Alforaith F. Current status and predictors of patient safety culture in hospitals of Qassim region, Saudi Arabia. *HMG*. 2020;2(2):76-82.

9. Tingle J. Patient safety reports round-up during the COVID-19 pandemic. *Br J Nurs*. 2020;29(10):582-583.

10. Saudi Ministry of Health, Quality and Patient Safety Directorate. Risk management and patient safety policies and procedures manual. 1st ed. Saudi Arabia: Ministry of Health, Saudi Arabia; 2018: 9–47.

11. Saudi Ministry of Health. Saudi patient safety taxonomy. 2018. https://www.moh.gov.sa/en/Ministry/MediaCenter/Ads/Documents/Saudi-Patient-Safety-Taxonomy.pdf. Accessed June 23, 2020.

12. 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(19): 7034.

13. Taylor M, Kepner S, Gardner LA, Jones R. Patient safety concerns in COVID-19–related events. *Patient Safety*. 2020;2(2):12-12.

14. Johnston MP. Secondary data analysis: A method of which the time has come. *QQML*. 2017;3(3):619-26.

15. Trinh QD. Understanding the impact and challenges of secondary data analysis. *Urol Oncol*. 2018;36(4):163-164.

16. Razali NM, Wah YB. Power comparisons of shapiro-wilk, kolmogorov-smirnov, lilliefors and anderson-darling tests. *J Stat Model Anal*. 2011;2(1):21-33.

17. Saudi Ministry of Health. ICU Triage, Admission, and Discharge Criteria during the COVID 19 pandemic V2. 2020. https://www.moh.gov.sa/Ministry/MediaCenter/Publications/Documents/ICU-Criteria-during.p. Accessed February 7, 2021.

18. Wu AW, Sax H, Letaief M, et al. COVID-19The dark side and the sunny side for patient safety. *J Patient Saf Risk Manag*. 2020;25(4):137-141.

19. Saudi Center for Disease prevention and Control (Weqaya) and MOH. COVID-19 Coronavirus Disease Guidelines, Version 1.3. https://www.moh.gov.sa/Ministry/MediaCenter/Publications/Documents/Coronavirus-Disease-2019-Guidelines-v1.2.pdf. Accessed 19 January, 2021.

20. Saudi Central Board for Accreditation of Healthcare Institutions (CBAHI). Self-Assessment Tool for COVID-19. 2020. https://resources.rldatix.com/i/1229229-cbahi-self-assessment-tool-for-covid-19/1? Accessed 18 January, 2021.

21. The Saudi Patient Safety Center. COVID-19 Safety Guide for Healthcare Professionals (version 3.0). 2020. https://spsc.gov.sa/English/PublishingImages/Pages/COVID-19. Accessed 19 January, 2021.

22. Robinson, J. Reported patient safety incidents fell by almost half during COVID-19 pandemic. *Pharm J*. 2020.

23. Howell AM, Burns EM, Bouras G, Donaldson LJ, Athanasiou T, Darzi A. Can patient safety incident reports be used to compare hospital safety? Results from a quantitative analysis of the English National Reporting and learning system data. *PLoS One*. 2015;10(12).