

# Assess The Awareness Level Among Makkah Hospitals Regarding Occurrence Variance Reporting

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## Abstract

### Aims

This study aims to evaluate staff awareness of occurrence variance reporting (OVR) in Makkah hospitals, with a focus on patient safety incident reporting. The objective is to identify the types and frequencies of reported events, analyze the consistency of reporting over time, and examine the primary methods used to disseminate lessons learned to improve patient safety practices.

### Methods

A retrospective study was conducted over three years (2021-2023) across 10 governmental hospitals in Makkah, using OVR data categorized by incident type and severity. Data analysis was performed using Microsoft Excel to calculate frequencies, trends, and patterns across different incident categories and time periods. Reporting methods, such as alerts, meetings, and presentations, were also examined for their effectiveness in enhancing staff awareness.

### Findings

The total number of OVRs decreased annually, from 33,170 in 2021 to 24,423 in 2022, and then to 22,201 in 2023. Medication errors, patient care management, documentation issues, staff-related concerns, and laboratory-related issues were consistently the most frequently reported categories. The most effective methods for disseminating lessons learned included alerts and presentations, which were used with varying frequency over the three-year period. Catastrophic incidents, although rare, have increased, highlighting areas for further improvement in patient safety practices.

### Conclusion

The decline in reported incidents suggests potential improvements in hospital practices or changes in reporting behavior, possibly due to fear of repercussions. To sustain improvements, it is recommended to enhance communication strategies and foster a supportive reporting environment, encouraging all staff to actively participate in patient safety initiatives.

**Keywords:** Makkah, Medical Care, Patient Safety, Hospitals, Management, Occurrence Variance.

## Introduction

The healthcare sector requires specialized labor due to hazardous operations. Patient safety is the primary objective of the healthcare sector, aiming to prevent or reduce risk, errors, and harm (1, 2). Strong leadership, dedication, documentation, and a mechanism for employees to report mistakes can improve patient safety. Medical errors pose a significant threat to patients' safety and can lead to costly

and life-threatening consequences (3). The World Health Organization (WHO) aims to reduce avoidable harm related to medications by 50% by 2022 (4).

The Institute of Medicine's "To Err Is Human" emphasizes the duty of medical practitioners to enhance patient safety culture. Preserving and maintaining patient safety has been highly valued economically, humanely, and ethically in hospital environments (5). Productive resource utilization can improve the quality time spent treating patients and reduce the time spent searching for medical supplies and devices (6, 7). According to Biondi et al. (2016), higher resource utilization in hospitals is positively associated with patient satisfaction, suggesting that hospitals with higher per-patient expenditures may receive higher ratings and appear more attractive to healthcare consumers (8).

An incident reporting system, such as occurrence variance reporting (OVR), is essential for enhancing patient safety and mitigating organizational risk. The reporting system gathers and records patient safety incidents that affect families and healthcare staff, involving the voluntary reporting of events that contradict routine policies, such as prescribing, order communication, product labeling, packaging, and nomenclature (9, 10). Quick reporting among healthcare professionals helps identify causes of deviations and uses mistakes as opportunities for quality improvement and education. However, the number of reports may vary across institutions due to differences in safety culture (10, 11).

The Institute for Safe Medication Practices (ISMP) has identified ten Key Elements of the Medication Use System to identify system-based causes of medication errors (12, 13). Applying this concept in analyzing reported errors highlights system issues rather than individual pitfalls, ensuring patient safety and overall patient care. Although patient safety is a global concern, and a patient safety culture among healthcare staff is crucial, Saudi Arabia has been investing heavily in enhancing patient safety, and assessing this culture is essential for informing policymakers about future directions (14, 15). Variability in patient safety culture is evident globally, even within geographically related regions. This variability also characterizes patient safety culture in Arab countries, with potential for improvement reflecting on healthcare (16). An organizational and multidisciplinary approach is essential for making changes. In the Makkah region, an area with unique characteristics and diversity, there has been an urgent need to assess the status of patient safety culture in Makkah hospitals (17). Reporting is a crucial aspect of patient care; however, in Saudi Arabia, a patient safety culture is characterized by poor communication, inadequate personnel, a blame culture, and ineffective leadership (17). A strong organizational attitude, interunit cooperation, and managerial support are essential for promoting safety improvements and building patient confidence in treatment (18).

Despite the global recognition of OVR's importance in enhancing patient safety, there has been a notable lack of research on OVR mechanisms and patient safety culture in Saudi Arabia, particularly in Makkah City. The limited number of studies addressing OVR awareness among healthcare professionals in this region underscores a critical gap in understanding and potentially improving patient safety practices. Therefore, this study aimed to assess the awareness levels of OVR among hospitals in Makkah City, thereby providing insights into current practices and identifying areas for improvement to ensure better patient safety outcomes.

## **Materials and Methods**

A retrospective study was conducted from January 2021 to December 2023 using the data from Makkah Health Clusters (MHC), which managed 10 governmental hospitals (Appendix A). The proposal for this study was approved by the Research Ethics Committee at Makkah Health Affairs in Makkah City. The data pool was collected directly from MHC's Institutional Excellence and Quality Administration using a checklist of monthly OVRs from October 2021 to December 2023.

In this study, various approved OVR categories were utilized to assess operational efficacy and identify areas for improvement. Categories include Nursing Care Management, which addresses issues related to patient admission, transfer, and discharge; Housekeeping, focusing on facility cleanliness; Security-Related Issues, which cover incidents like assaults or missing property; and Laundry Services,

emphasizing supply and service response. Additionally, categories like Medication, Infection Control-Related Issues, and IT-Related Issues were examined to ensure proper medication handling, infection control practices, and IT service management. Other areas include Facility Maintenance, Staff-Related Issues, and Communication Issues, which collectively aim to enhance patient safety and operational efficiency (see Appendix B).

The inclusion criteria focused on completed data from 2021 to 2023 from the 10 MHC hospitals. Private and military hospitals, which did not fall under the category of MHC hospitals, were excluded from this study. The data were analyzed using a unified OVR Excel sheet that included the total number of reports per quarter, categorized by OVR categories and levels of harm. The classification of harm levels was based on the Saudi Patient Safety Taxonomy, published in 2018 by the Saudi Patient Safety Center in collaboration with the Saudi Ministry of Health. Additionally, data on lessons learned and improvement projects developed in response to OVR findings were also collected.

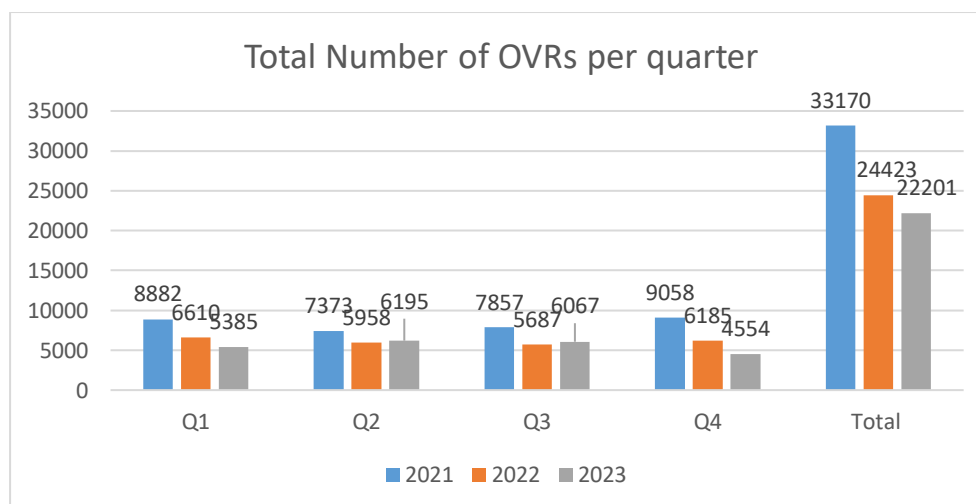
### Statistical Analysis

The data were systematically analyzed using Microsoft Excel, employing its advanced tools to ensure accurate calculations and clear visualizations. Descriptive statistics were used to summarize the frequency and distribution of OVRs across different categories and time periods. Charts and pivot tables were employed to visualize trends, while categorical data were compared across years to identify patterns in patient safety incidents and the effectiveness of improvement projects.

### Results

The findings of this study provided a comprehensive view of the OVR tendencies over three consecutive years, with distinctions in incident reporting on a quarterly basis. The Bar Chart in Figure 1 provides valuable insights into OVRs reporting per quarter at 10 hospitals in Makkah City over 3 years from 2021 to 2023. The total number of OVRs has shown a consistent decline each year, dropping from 33,170 in 2021 to 22,201 in 2023. This downward trend was most pronounced in the first two quarters of each year, while the fourth quarter consistently experienced the peak in OVR volume, reaching 22,201. The steady decrease in OVRs suggested potential changes in factors of the internal and external healthcare organizations.

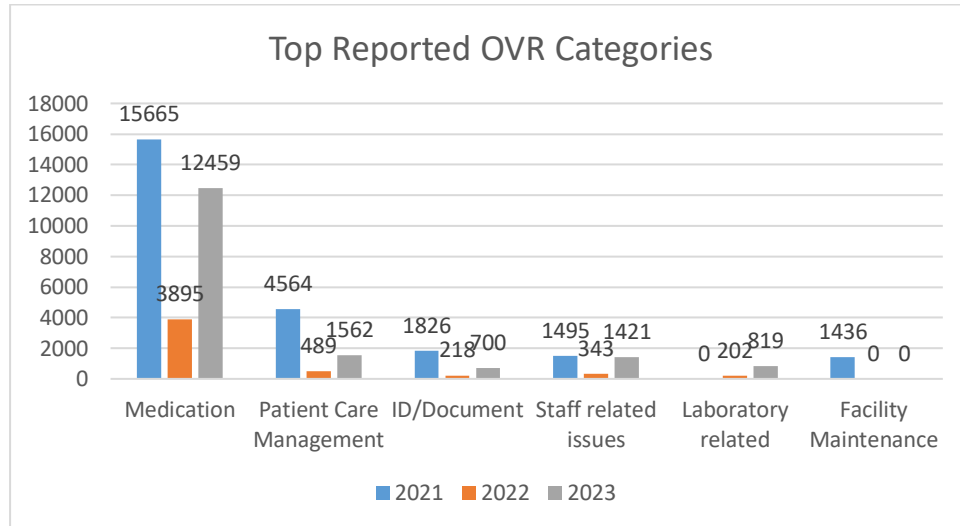
**Figure 1: Total Number of OVRs per quarter**



In 2021, the most frequent categories of OVR were medication-related issues ( $n = 15,665$ ), patient care management ( $n = 4,564$ ), identification or documentation problems ( $n = 1,826$ ), staff-related issues ( $n = 1,495$ ), and facility management issues ( $n = 1,436$ ). In 2022, the predominant categories shifted significantly, with medication issues declining to 3,895, while patient care management (489) and identification or documentation issues (218) became more prominent. Staff-related issues also

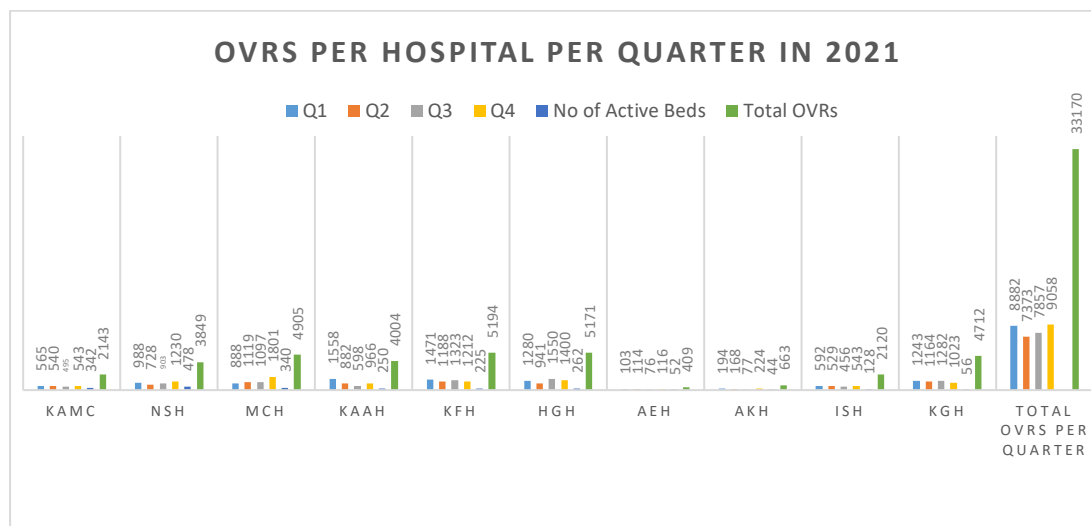
decreased to 343, and laboratory-related issues emerged with 202. By 2023, medication issues had surged again to 12,459, with patient care management rising to 1,562 and identification or documentation issues at 700. Staff-related issues remained relatively stable at n = 1,421, while laboratory-related issues increased to n = 819. As shown in Figure 2.

**Figure 2: Top Reported OVR Categories**



Over the three years, hospital performance in OVRs varied notably by quarter. In Year 1 (2021), as shown in Figure 3, NSH led with peak OVRs of 1230 in Q4, and MCH reached 1801 in the same quarter, reflecting high activity. Year 2 (2022), as shown in Figure 4, saw NSH excel again, with Q2 achieving 1333 OVRs, while KAAH experienced its highest OVRs in Q4 at 1527. Conversely, MCH's performance declined sharply in the fourth quarter. In Year 3 (2024), as shown in Figure 5, NSH and KAAH maintained strong figures, with NSH hitting 1404 in Q2 and KAAH 1314 in Q3. MCH's OVRs fluctuated significantly, demonstrating variable quarterly performance across the hospitals.

**Figure 3: OVRs per hospital per Quarter in 2021**



**Figure 4: OVRs per hospital per Quarter in 2022**

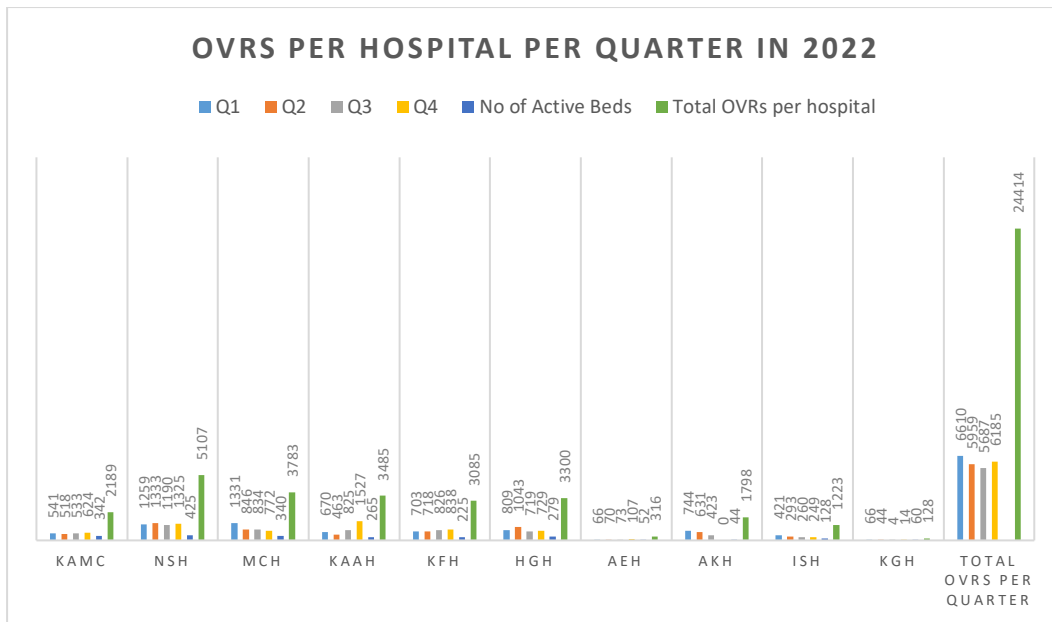
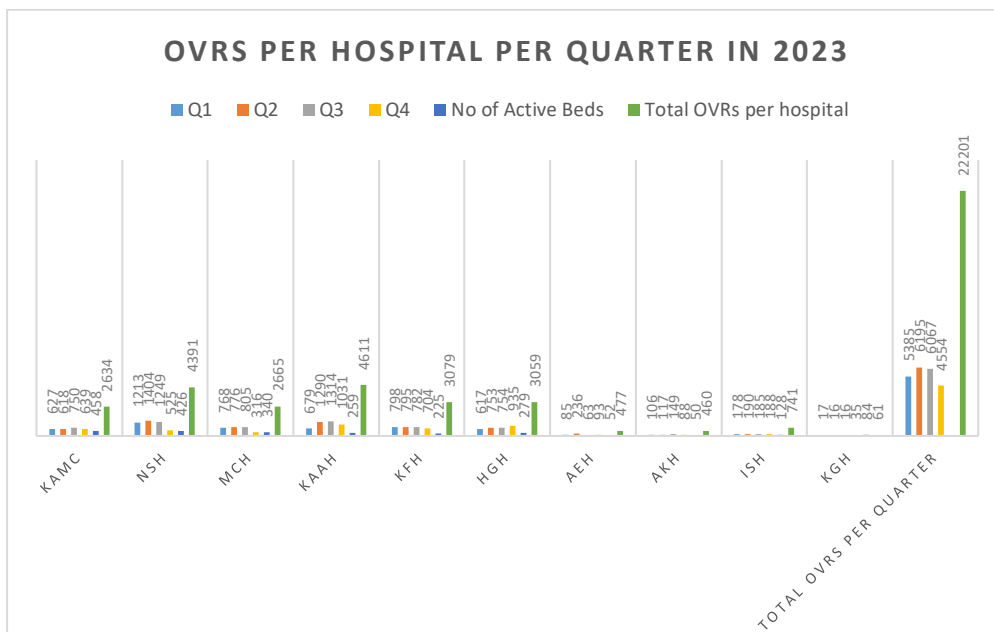
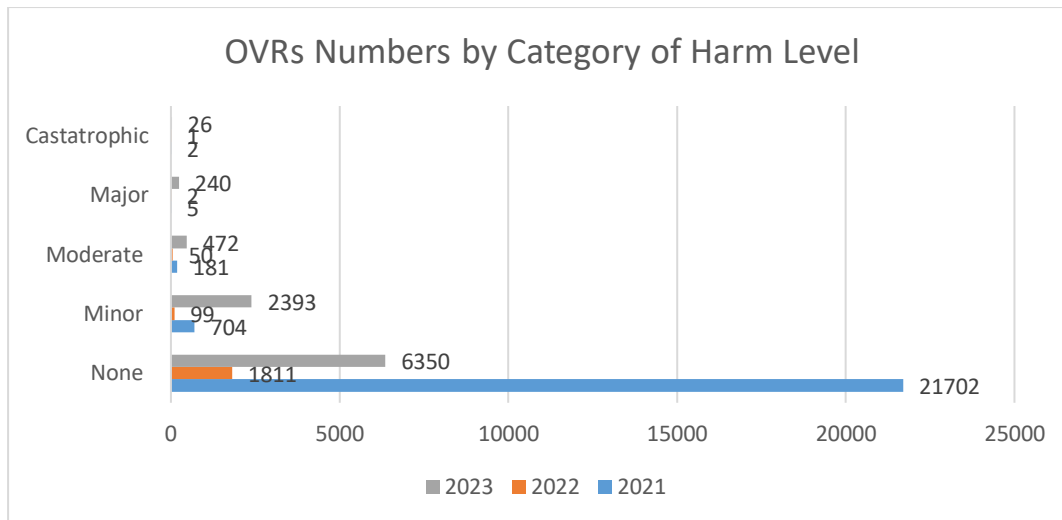


Figure 5: OVRs per hospital per Quarter in 2023



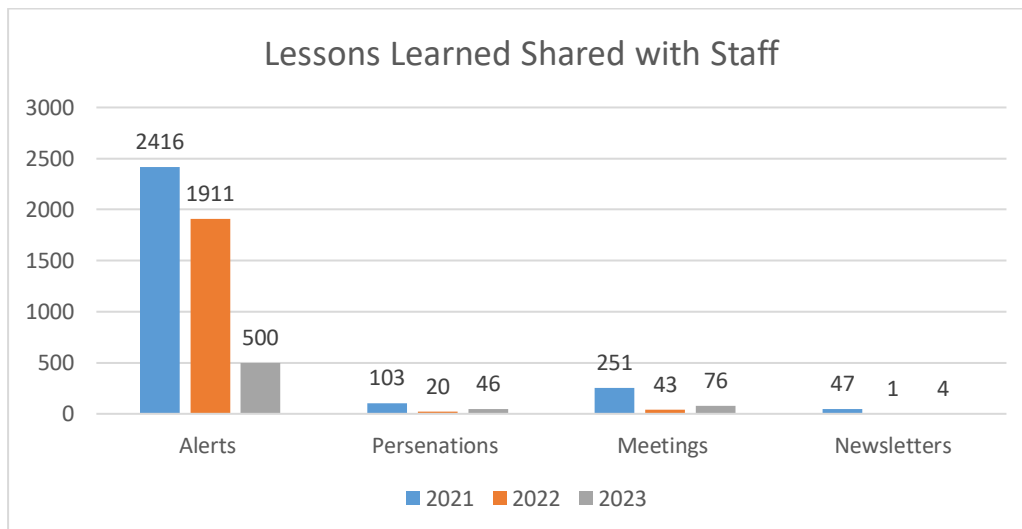
The OVR data categorized incidents based on their impact on patients or individuals, as shown in Figure 6. The "None" category, indicating incidents with no harm, was reported 21,702 times in 2021, 1,811 times in 2022, and 6,350 times in 2023. The "Minor" category, involving incidents that required non-invasive diagnostic tests and increased monitoring but did not alter vital signs, had 704 reports in 2021, 99 in 2022, and 2,393 in 2023. "Moderate" incidents, which involve changes in vital signs, decreased consciousness, and the need for medication or invasive procedures, were reported 181 times in 2021, 50 times in 2022, and 472 times in 2023. The "Major" category, representing unexpected incidents causing permanent or long-term harm, showed a notable increase from 5 reports in 2021 and 2 in 2022 to 240 in 2023. Lastly, the "Catastrophic" category, which denotes incidents resulting in death, recorded 2 cases in 2021, 1 in 2022, and 26 in 2023.

Figure 6: OVRs Numbers by Category of Harm Level



The most common methods for sharing lessons learned with staff to enhance overall knowledge and practices were alerts, meetings, newspapers, and presentations. Alerts were the most frequently utilized method, with 2,416 instances in 2021, 1,911 in 2022, and 500 in 2023, as shown in Figure 7. Presentations were given 103 times in 2021, 20 times in 2022, and 46 times in 2023. Meetings were held 251 times in 2021, 43 in 2022, and 76 in 2023. Newspapers were the least used method, with 47 distributions in 2021, 1 in 2022, and 4 in 2023, as shown in the visual representation of these trends.

**Figure 7: Lessons Learned Shared with Staff**



## Discussion

This cross-sectional study aimed to assess staff members' level of OVR knowledge at MHC hospitals. From the study, it is clear that reports increased in 2021 compared to 2022 or 2023. The reduced number may be related to hospital improvement initiatives that could help address patient safety issues. But this decrease may be associated with perceived leader support or perceived risk of sanctions. These findings are consistent with the survey conducted by Albarrak et al. (2020), which revealed that half of the participants from the emergency department reported a non-punitive environment, while the other half experienced disciplinary action after filing a complaint ( $p < 0.001$ ). These outcomes indicated that organizational culture and leadership are significant factors influencing staff reporting behaviors. Additionally, 54% stated that while the OVR executive did approach reports systemically rather than individually, the condition was not satisfied (statistical significance identified,  $p = 0.002$ ) (9). Moreover, Mohammad et al. (2016) found that time restraints, work pressure, unclear instructions, forgetfulness,

non-confidential and/or complex reporting systems, peer pressure, fear of losing employment or disciplinary action, and a lack of feedback were factors that prevented healthcare providers from engaging in OVR (19).

According to Al-zain and Althumairi (2021), understanding these barriers might help in developing effective strategies to address these reporting problems (20). According to Poku et al. (2024), interventions to improve adverse event reporting in the emergency department include enhancing reporting rates, identifying areas for improvement, and incorporating new approaches (21). Moreover, an electronic reporting system might improve practices among the healthcare providers. Albarrak et al. (2020) found that 80% of participants considered computer-based reporting more accessible than traditional paper methods, underscoring the potential benefits of modern reporting systems (9).

However, Brondial et al. (2019) and Elsayed et al. (2023) suggested that a well-designed e-OVR system significantly improves the efficacy and efficiency of any healthcare risk management system, provided that healthcare organizations ensure all practitioners are aware of reporting procedures and incidence variations (22, 23). The lack of clear policies, excessive workload, and reports with insufficient feedback might negatively impact the perception of OVR (24).

In this study, 7 out of 10 hospitals were accredited by the Saudi Central Board for Accreditation of Healthcare Institutions, while three were not. Accreditation status influenced staff awareness of overall visit reports. For instance, a study in Egypt by Elsehrawy et al. (2023) found that healthcare providers in accredited hospitals had a statistically significantly higher mean awareness of OVR (224.53) compared to those in non-accredited hospitals (153.47), with a p-value of  $<0.001$  ( $P < 0.001$ ) (25). Accredited hospitals have additional structured procedures to support safe cultural behaviors, such as regular training sessions on the significance of incident reporting and the production of structured occurrence variance reports (26, 27). For instance, according to Liana (2024), various accredited hospitals implemented a safety culture during the COVID-19 pandemic through six indicators, including leadership, safety communication, regulations, work environment, participation, and training (28).

Non-accredited hospitals need to improve their policies to reduce issues such as healthcare workers' guilt, ignorance, and fear of punishment. Therefore, implementing a potential training program may significantly increase hospital staff awareness of the OVR system and its importance for patient, staff, and hospital safety (25). The analysis of this study revealed that medication errors were the most frequently reported OVR type in 2021, 2022, and 2023, with incidents numbering 15665, 3895, and 12459, respectively. These results were followed by issues related to patient care management, documentation, staff, and laboratory concerns. Althobaiti et al. (2022) found that nursing care management issues accounted for 60.4% of all OVR types, with identification/document/consent issues coming in second at 9.4%. Significantly, 2, 1, and 26 catastrophic-level events were reported in 2021, 2022, and 2023, respectively. Among the various OVR types, housekeeping concerns (0.2%) and laundry service issues (0.1%) were the least commonly reported (29).

Several studies have identified the categories and proportions of errors in healthcare systems. Based on the study's findings, procedural errors were identified as the most common type of medication-related error, accounting for 38%, followed by pharmaceutical errors (16%), documentation errors (13%), and communication errors (12%) (30). However, a survey conducted by the Netherlands Federation of University Medical Centres (2020) revealed that patient safety issues, communication, and culture were the main reasons identified by five of the eight hospitals as the causes of recurring complications (31). Additionally, a study conducted in Saudi Arabia found that poor regulations and guidelines, inadequate communication, staff shortages, and a lack of competencies were the main factors contributing to the underreporting of patient safety incidents in hospitals (32).

Consequently, reporting systems and patient safety activities could be enhanced by eliminating barriers and establishing a non-punitive, non-blaming learning organization environment (33, 34). These factors

were consistent with our idea that the most valuable way to communicate lessons learned from patient safety events to personnel is to increase their awareness and improve their activities, which can be accomplished through alerts, meetings, newspapers, and presentations.

This study lacked data on reporters' job titles, which prevented us from determining awareness levels across different types of reporters. According to Albarrak et al. (2020), nurses had significantly more understanding of how to access the OVR system to file a report, with 98% awareness ( $p < 0.001$ ), compared to 45.8% among physicians (9). This outcome has been attributed to pharmacists' strong commitment to safety and their efforts to reduce errors. According to Sikora (2023), pharmacists typically engage in indirect patient care following the direct care provided by nurses (35). This allows them to focus more on detecting and preventing various mistakes. These findings suggest that future studies should explore different types of reporters and their levels of awareness to understand better the factors influencing reporting behavior, including who is most likely to file reports and the reasons behind their actions.

### **Conclusion**

This retrospective study evaluated OVR awareness across MHC hospitals, analyzing reports filed in 2021 (33,170), 2022 (24,423), and 2023 (22,201). The decline in reports from 2021 to 2023 may be due to practical improvement projects or issues such as a lack of leadership support, time constraints, unclear policies, and fear of repercussions. The top five reported issues were consistent across all three years: medication errors, patient care management, documentation, staff-related issues, and laboratory concerns. Given the recurrence of these issues, improvement projects need revision. To enhance communication and patient safety culture, studying reporter types and factors affecting OVR was suggested to better understand and improve reporting behavior.

### **Ethical Statement**

This study was approved by the Research Ethics Committee at Makkah Health Affairs, Makkah City, Saudi Arabia. The ethical approval reference number is H-02-K-076-0621-436. All data were collected and analyzed in accordance with ethical research standards and with full respect for the confidentiality and privacy of the research process, and no personally identifiable information was used in the analysis.

### **Consent to Participate**

Not Applicable – This study was a retrospective analysis using de-identified administrative data. No direct contact with human subjects was made, and therefore, informed consent was not required.

### **Consent for Publication**

Not Applicable – No individual-level data, images, or personal details are presented that would require consent for publication.

### **Funding Declaration**

This research received no specific grant from any funding agency in the public, commercial, or not-for-profit sectors.

### **Declaration of Conflicting Interest**

The authors declare no potential conflicts of interest with respect to the research, authorship, and/or publication of this article.

### **Data Availability Statement**

The data used in this study were obtained from the Institutional Excellence and Quality Administration at the Makkah Healthcare Cluster. These data are not publicly available due to privacy restrictions, but they will be available from the corresponding author upon reasonable request and with permission from the relevant authority.

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## APPENDIX-A

| S. No | Acronym | Full Form                         |
|-------|---------|-----------------------------------|
| 1     | KAMC    | King Abdullah Medical City        |
| 2     | NSH     | Noor Specialist Hospital          |
| 3     | MCH     | Maternity and Children's Hospital |
| 4     | KAAH    | King Abdulaziz Hospital           |
| 5     | KFH     | King Faisal Hospital              |
| 6     | HGH     | Hera General Hospital             |
| 7     | AEH     | Ajyad General Hospital            |
| 8     | AKH     | Alkamel Hospital                  |
| 9     | ISH     | Ibn Sina General Hospital         |
| 10    | KGH     | Khulais General Hospital          |

## APPENDIX-B

| Category                        | Description                                                                                                                                                                   |
|---------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Nursing care management</b>  | Patient disposition such as delay in admitting patient, delay in transferring patient, improper patient discharge, left against medical advice.                               |
| <b>Housekeeping</b>             | Poor cleanliness of facilities or poor housekeeping response.                                                                                                                 |
| <b>Security-related issues</b>  | Physical assault, verbal assault, missing property, or no security staff in the building.                                                                                     |
| <b>Laundry services</b>         | Lack of laundry service supplies or poor laundry service response.                                                                                                            |
| <b>Pressure ulcer</b>           | Localized damage to the skin and/or underlying soft tissues, usually over a bony prominence, related to a medical or other device.                                            |
| <b>Procedural</b>               | Pre-procedural issues like cancellation of surgery; intra-procedural issues like incorrect medical records, incomplete procedure on surgery schedule.                         |
| <b>Skin lesion/integrity</b>    | Abrasion, hematoma, redness, rash, skin tear, blister, or cellulitis.                                                                                                         |
| <b>Facility maintenance</b>     | Disruption of power supply, HVAC failure, generator failure, malfunction of automated doors, medical gas leaks, overflow of sewage, or water leaks.                           |
| <b>Staff-related issues</b>     | Refusal to perform assigned tasks, non-performance of duty, unfair workload, ethical issues, or lack of professional development.                                             |
| <b>Occupational health</b>      | Contact with hazardous substances, sharps injury, accidents caused by internal/external projects, or slips, trips, and collisions.                                            |
| <b>ID/Document/Consent</b>      | Illegible writing, wrong name, wrong patient, or wrong Medical Record Number (MRN).                                                                                           |
| <b>Medication</b>               | Adverse drug reaction, medication delivery delay, wrong dose, high alert label missing, wrong patient, wrong method of preparation, wrong storage, or unavailable medication. |
| <b>Behaviour</b>                | Uncooperative behaviour, inappropriate behaviour, aggressive behaviour, or family interfering with patient care.                                                              |
| <b>Fall</b>                     | Incidents involving a patient nearly or fully falling.                                                                                                                        |
| <b>Medical equipment issues</b> | Electrical items not tested, broken medical equipment, medical equipment misuse, medical device unexpected failure, or medical device violating safety standards.             |

|                                         |                                                                                                                                                                                                      |
|-----------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Infection control-related issues</b> | Device product or fluid-associated infections, hand-hygiene process issues, improper infection control practices, improper waste collection, or sharp container unavailability.                      |
| <b>Communication issues</b>             | Inappropriate communication between staff and patients, poor communication among staff/teams/departments, poor call center response, or failure of the telephone system.                             |
| <b>Laboratory-related issues</b>        | Delayed blood/blood product delivery, delayed feedback on rejected specimen, incomplete blood/blood product request, lost sample, wrong patient's MRN, transfusion reaction, or delayed test result. |
| <b>Intravenous</b>                      | Extravasation, occlusion, infiltration, phlebitis, leaking, or wrong insertion.                                                                                                                      |
| <b>Supply chain issues</b>              | Unavailability of medical items in store, unavailability of non-stock items, lack of stationery supply, damaged items on delivery, or medication out of stock.                                       |
| <b>IT-related issues</b>                | Abuse of system authorities, disruption of IT services, information leakage due to software errors, spreading of viruses, lack of IT supplies, or poor IT response.                                  |