Quality Improvement Project

Reducing Nonsentinel Harm Events due to Medication Errors by Using Mini–Root Cause Analysis and Action

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ABSTRACT

Introduction: A full root cause analysis (RCA) such as that required following a sentinel event is time-consuming, labor-intensive, and expensive. This quality improvement project used a similar but abbreviated process (mini-RCA and action; mini-RCA2) in response to medication errors that caused less serious harm. Methods: In 2018, all medication errors that caused harm due to system failures but were not sentinel events were investigated by mini-RCA2. The incidence of similar medication errors reported in the year before and in the year after the introduction of mini-RCA2 was compared to determine the impact of this intervention. Similar events were identified by searching the safety reporting system database for reported medication errors by drug name (e.g., Humate® P) and/or event type (e.g., prescribing error—omission of a patient’s home medications on admission to hospital). The time and labor costs of this intervention were estimated. Results: Seven medication errors were investigated by mini-RCA2. More than 48 members of staff from 11 clinical and nonclinical departments contributed to the identification of 39 system failures and made 42 recommendations, of which 22 (52%) were implemented. This reduced the recurrence of reports of similar events from 35 (0.57%) to 21 (0.36%). Although this 0.21% absolute decrease did not achieve statistical significance, recurrence of similar harm events was reduced from 7 (0.11%) to 0 (p = 0.016). Benefits were greatest when the mini-RCA2 recommendations were fully implemented. This reduced the recurrence of similar events from 9 (0.21%) to 0 (p = 0.007). A total of 251 hours (mean ± SD, 35.9 ± 16.6 hours) were required for this intervention. The associated labor cost was Saudi Arabia Riyal (SAR) 34,181 (US $8256; mean SAR ± SD, 4883 ± 1302 [mean US $ ± SD, 2102 ± 561]). Conclusion: The use of mini-RCA2 to review medication errors provided a structured process to manage reported events, monitor the implementation of recommendations, and assess the effectiveness of implemented actions. The use of this rapid process to investigate errors that cause harm but are not sentinel events reduced recurrence of similar medication errors. Although the time and cost required for this intervention is not insignificant, the cumulative benefit to patients, healthcare professionals, and the organization are greater.

Keywords: medication error, sentinel event, patient safety, root cause analysis

INTRODUCTION

Problem Description

A drug-induced injury caused by medical intervention is an adverse drug event (ADE).[1] Adverse drug events include allergic reactions, adverse drug reactions, overdoses, and medication errors. The National Coordinating Council for Medication Error and Prevention (NCCMERP) defines a medication error as: “Any preventable event that may cause or lead to inappropriate medication use or patient harm, while the medication is in the control of the health-care professional, patient, or
consumer.”\(^2\) The terms medication safety incident, medication error, and adverse drug event are synonymous and are often used interchangeably.\(^2\)-\(^6\)

A sentinel event is a patient harm event that causes death, permanent harm, or severe temporary harm that requires intervention to sustain life.\(^7\) Healthcare regulatory agencies, such as The Joint Commission on Accreditation of Healthcare Organizations, have mandated a comprehensive analysis of sentinel events since 1997.\(^7\)

ADEs are relatively common causes of sentinel events.\(^2\)-\(^6\) As such medication errors can cause considerable morbidity or mortality, inflate the cost of patient care, and burden healthcare systems with substantial legal and operational expenses.\(^2\)-\(^6\)

Alarmingly, the profligate trajectory of medication use is likely to dramatically increase the incidence of ADEs and the risk to patients.\(^6\) Yet, neither the definitions of ADEs and harm outcomes, nor the methods used to detect them, are standardized.\(^5\) So, the true incidence and cost of medication errors are indeterminable. Regardless, the drive to prevent medication errors is a critical patient safety initiative.

**Available Knowledge**

Medication errors are preventable. Determining the etiology of ADEs is critical to the formulation and implementation of successful and sustainable systems-based strategies to reduce their incidence. The most commonly used framework for the comprehensive systematic evaluation of the factors that resulted in a medical error is root cause analysis (RCA).\(^7\)-\(^9\),\(^10\) When conducting an RCA the first step involves a situation analysis to define the problem and its impact. A core team with the appropriate skill mix to address the issue must then be formed. This team must systematically collect and analyze data about the problem with the intention to identify the causes and the contributing factors. This process requires multi-disciplinary engagement to be effective.

Although complex, time-consuming, and labor-intensive, a well-conducted RCA often identifies the system failures and human factors that contributed to an error.\(^7\)-\(^9\),\(^10\) However, despite significant efforts to increase patient safety and widespread uptake of RCA, adverse event rates have remained essentially unchanged.\(^11\),\(^12\) Thus, RCA alone is not sufficient to improve patient safety. Further initiatives are required. So, in response to problems with the RCA process, the National Patient Safety Foundation (NPSF) released a report entitled “RCA²: Improving Root Cause Analyses and Actions to Prevent Harm.”\(^10\) Notably, the NPSF renamed the process “Root Cause Analysis and Action” (RCA²).\(^10\) This emphasized that the outcomes of the RCA (i.e., corrective actions and risk mitigation) are as important as the process itself.\(^10\)

Furthermore, sentinel events are just the tip of the iceberg. Many medication errors cause harm that does not achieve sentinel status. Some healthcare settings use RCA methodology to investigate errors that are not sentinel events.\(^9\),\(^13\) For example, a hospital in Western India reported that medication errors occurred in the treatment of 117 of 300 patients between June 2012 and April 2013.\(^13\) Many important observations were made after RCA was performed for each of these errors. For example, the RCA of the prescribing errors, 62 (53%) in this cohort, found that these were due to not prescribing the dosage form (33, 53%), illegible handwriting (21, 34%), and prescription of the wrong brand name (8, 13%).\(^13\)

Institutions that perform more RCA will obviously develop more recommendations to improve patient safety.\(^9\) However, the data suggesting that this approach reduces harm are limited to observational studies. So, healthcare regulators do not mandate detailed investigation and analysis of these less harmful errors. As a result, nonsentinel events are rarely investigated to the same extent. This wastes precious opportunities to expose the flaws in the system uncovered by ADEs that do not appreciably affect patient outcomes.

**Rationale**

A full, formal RCA is demanding, time-consuming, labor-intensive, and expensive. Performing a full “formal” RCA for all harm events is not feasible. However, the use of a similar but abbreviated process (eg, mini-RCA²) for errors that cause less serious harm may improve patient safety.

**Specific Aims**

The aim of the study was (1) to assess the feasibility of performing mini-RCA² for all medication errors due to system failures that caused harm but were not sentinel events and (2) to assess whether this intervention may contribute or not to reduce patient harm.

**METHODS**

This retrospective, observational study was approved by the institutional review board of the King Abdullah International Medical Research Center, Riyadh, Saudi Arabia. No patient identifiable data from individual patients are included in this paper.

**Context**

The setting for this quality improvement project is a 1600-bed academic tertiary care center that promotes a “just culture.” This emphasizes that mistakes are usually due to suboptimal systems and links discipline to behavior, not harm. Thus, in the event of a serious untoward incident, the directly involved staff are not blamed. Instead, the stakeholders focus on “what went wrong?” rather than “who did this?”\(^14\) This model allows individual accountability whilst promoting a learning culture.\(^14\) Thus, a just culture creates an environment where individuals feel comfortable report-
ing errors. This helps the organization learn from its mistakes.\textsuperscript{[14]} All reported medication errors are reviewed by Medication Safety Program (MSP) staff (one medication safety officer and two clinical auditors) within 24 hours of reporting. The medication safety officer was previously a pharmacist and the two clinical auditors were previously pharmacy technicians. However, they are now full-time staff in the department of quality and patient safety and have no other roles or responsibilities.

The NCCMERP classification\textsuperscript{[2]} is used to classify the severity of the reported ADEs. The MSP officer validates and initiates intervention for all ADEs that caused harm. Sentinel events are escalated to the director of the Department of Quality and Patient Safety who initiates and leads the immediate response. Other harm events were investigated at the discretion of the MSP officer.

**Intervention**

In January 2018, the MSP at King Abdulaziz Medical City (KAMC) started a quality improvement project designed to fully investigate all medication errors due to system failures that caused harm but were not sentinel events. All ADEs were assessed to determine whether any latent system failures contributed to the incident and whether hospital policies on medication use were followed. If policies were not followed, no latent failures were identified, and the incident was considered to be due to human error alone by the medication safety officer and the staff involved; further independent comprehensive systematic assessment was considered unnecessary. In accordance with established hospital policies, these events were addressed at the departmental level. Therefore, ADEs caused by human error alone were excluded from this initiative.

Mini-RCA\textsuperscript{2} methodology was used by the MSP to investigate nonsentinel events due to system failures as soon as possible after the event. This initiative complemented the preexisting protocolized pathway for investigation of sentinel events. The methodology of full RCA\textsuperscript{2} has been described previously.\textsuperscript{[8,10]} A mini-RCA\textsuperscript{2} is essentially an informal, abbreviated RCA\textsuperscript{2}. The differences between a full RCA\textsuperscript{2} and a mini-RCA\textsuperscript{2} conducted in our organization are described in Table 1. Similar to RCA\textsuperscript{2}, the mini-RCA\textsuperscript{2} process involves identifying the root causes of the ADE. It integrates system thinking and involves all relevant stakeholders to identify potential improvements that could decrease the risk of recurrence of the ADE.

After the initial analysis, a preliminary report is prepared by using a standardized template (Fig. 1). This initial report includes all of the root causes that were identified during the mini-RCA\textsuperscript{2} and is shared with all stakeholders. It also recommends interventions to prevent the recurrence of the incident (ie, an action plan). Within 72 hours of the initial analysis the

| Table 1.—Differences between root cause analysis and mini–root cause analysis and action at our organization |
|----------------------------------|----------------------------------|----------------------------------|----------------------------------|----------------------------------|
| **Root Cause Analysis** | **Mini–Root Cause Analysis and Action (Mini-RCA\textsuperscript{2})** |
| Response to sentinel events | Response to events that cause harm but are not sentinel events |
| The Joint Commission on Accreditation of Healthcare Organizations recommends that response to a sentinel event should include RCA. | Medication safety program initiative to use mini-RCA after nonsentinel events |
| This is included in hospital policy. | Informal process guided by medication safety program initiative |
| Formal process guided by administrative policy and procedure document | |
| Led by higher management staff | Led by medication safety officer |
| Involves higher management staff | Involves stakeholders |
| Mandatory literature review | Literature review not required but may be performed |
| First meeting conducted after the approval of the task force released from medical services | Meeting organized as soon as event recognized and reported |
| Members of RCA Task Force are trained and certified in performance of RCA. | |
| Investigations are conducted by a multi-disciplinary team. | |
| Staff involved in the event are formally interviewed by an independent member of RCA Task Force using a structured questionnaire. | |
| Multiple meetings and reviews are required as staff involved in incident and some stakeholders are excluded from some meetings. | |
| RCA: root cause analysis. |

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| Contributing factors / root causes | Recommendations | Time line | Responsibility | Measures of Effectiveness |
|----------------------------------|----------------|---------|----------------|-------------------------|
|                                   |                |         |                |                         |

**Figure 1.—Template for immediate summary report of mini-RCA\textsuperscript{2}. RCA\textsuperscript{2}: Root Cause Analysis and Action.**
medication safety officer prepares the final report of the mini-RCA\textsuperscript{2} in collaboration with the MSP Chairman. The final report may include other recommendations deemed appropriate. Each report specifies a time frame for implementation of each recommendation. Specific departments are made accountable for either implementing or rebutting each recommendation.

The medication safety officer sends the final mini-RCA\textsuperscript{2} report to all departments involved in the incident and uploads the report to a database to facilitate follow-up (Access, Microsoft). The medication safety officer contacts each department to ensure that the recommendations have been actioned as specified in the final report.

If recommendations have not been implemented the medication safety officer informs the chairman of the MSP. At our institution the chairman of the MSP is currently also the director of the Department of Quality and Patient Safety. In this latter capacity he expedites implementation of the recommendations by contacting the relevant stakeholders, resolving any conflicting opinions, and informing the higher administration. The effectiveness of the action plan is assessed by monitoring the recurrence of similar ADEs through the ongoing assessment of reported medication errors.

Study of the Intervention

The database of mini-RCA\textsuperscript{2} reports was reviewed to determine the number of medication errors that were investigated with this methodology between January 1, 2018, and December 31, 2018. The number, specialty, and grade of healthcare professionals involved in each mini-RCA\textsuperscript{2} were determined. The total number of recommendations made and the number that had been implemented were determined.

Measures

The numbers of similar ADEs reported 12 months before and after each mini-RCA\textsuperscript{2} were compared. All reported medication errors are classified by specific event type in the Safety Reporting System database. Similar ADEs events were identified by searching the Safety Reporting System database for reported medication errors by drug name (eg, Humate P) and/or event type (eg, prescribing error—failure to order a patient’s home medications on admission to hospital). These data were then aggregated to provide summary statistics.

To determine the time required for this intervention the authors created a framework to identify the tasks performed during a mini-RCA\textsuperscript{2}. These tasks included reviewing the incident report, conducting the investigation, the mini-RCA\textsuperscript{2} meeting, the preparation of the report, reviewing the report, communicating actions, and follow-up. Most of the work was performed by the medication safety officer and the MSP Chairman who were involved with most of these tasks. They were asked to recall the time they spent on each mini-RCA\textsuperscript{2}. The other participants only reviewed the incident report, attended the mini-RCA\textsuperscript{2} meeting, and reviewed the final report. The duration of the single mini-RCA\textsuperscript{2} meeting for each incident was strictly limited to 1 hour. The time that the other participants spent reviewing the incident report and the final mini-RCA\textsuperscript{2} report was extrapolated from the time the MSP Chairman spent on these tasks. All times were rounded up to 15-minute intervals.

An economic analysis was then performed. To estimate the labor cost, the time spent by each member of staff involved was multiplied by their average hourly salary (based on the midpoint of the salary scales).

Analysis

Data are presented as frequency and percentage and were compared by using Fisher exact test. All statistical analyses were performed with Excel 2016 (Microsoft). The time required for each mini-RCA\textsuperscript{2} is presented in hours and the associated financial cost is presented in Saudi Arabia Riyals (SAR) and US dollars ($). The exchange rate is pegged at 3.75 SAR to $1.

RESULTS

Harm Events Investigated Using the Mini-RCA\textsuperscript{2} Methodology

Of the 2927 medication errors reported in 2018, 13 errors (0.44%) caused harm but were not sentinel events. Six ADEs were due to human error, while seven (54%) resulted from system failures and were investigated by using mini-RCA\textsuperscript{2} methodology (Table 2). For contextualization, in 2018, a total of 2912 events did not cause harm, one sentinel event was investigated by higher administrative personnel using the full RCA methodology, and another sentinel event was investigated by the medication safety officer, under the supervision of higher administrative personnel, using the full RCA methodology.

The patient affected by the error involving Humate P was critically ill and was receiving treatment in the pediatric intensive care unit at the time of the incident. The clinician reporting the incident suggested that the ADE had caused harm. So, this incident was included in the initiative, and mini-RCA\textsuperscript{2} was performed. Although the patient subsequently died, during the course of the mini-RCA\textsuperscript{2} it became clear that the error did not harm the patient. Whilst ultimately the medication error was not thought to have harmed the patient, this was not clear at outset.

Engagement of Healthcare Professionals in Mini-RCA and Root Causes Identified

The mini-RCA\textsuperscript{2} for seven ADEs involved 48 healthcare professionals (median, 6; range, 3–13) from 11 clinical and nonclinical departments (Table 3). This initiative identified a total of 39 system failures that were the root

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Table 2.—Medication errors that caused harm due to system failures and were assessed by using the mini–root cause analysis and action methodology

| Medications                        | Errors                                | Event Types             | Process Stages | Specific Event Type | Consequences of Error                                      | Intervention                                           | Classification of Harm                      |
|-----------------------------------|---------------------------------------|-------------------------|----------------|--------------------|------------------------------------------------------------|--------------------------------------------------------|--------------------------------------------|
| Bisoprolol                        | Home medication not ordered            | Dose omitted            | Prescribing    | Prescribing error  | Fast AF developed in patient with paroxysmal AF            | Treatment of fast AF required                       | E-Temporary harm, required intervention    |
| Exforge HCT (Amlodipine, Valsartan, Hydrochlorothiazide) |                                       |                         |                | Home medications not ordered                |                                                            |                                                        |                                            |
| Rivaroxaban                       |                                       |                         |                |                                  |                                                            |                                                        |                                            |
| Midazolam infusion                | Midazolam infusion stopped during operation under general anesthesia | Medication stopped     | Prescribing    | Administering       | Dose omitted                                               | Patient required treatment for status epilepticus, and midazolam infusion was restarted on return to the neonatal intensive care unit. | E-Temporary harm, required intervention    |
| Humate P (Antihemophilic factor [500 IU]/von Willebrand factor [1200 IU]) | 4800 units given instead of 2000 units | Dose Incorrect          | Prescribing    | Dispensing          | Humate P dose incorrect                                   | No harm was caused by the error. The patient subsequently died. The death was not related to the medication error. | D-No harm, additional monitoring required |
| Subcutaneous Enoxaparin           | 60 mg given instead of 35 mg           | Dose incorrect          | Dispensing     | Monitoring          | Incorrect preparation dispensed on discharge               | Pharmacist told patient to go to ER to check the anti–factor Xa level on October 30, 2018 but patient did not go until surgery follow-up visit on November 4, 2018. Patient developed nosebleed. | E-Temporary harm, required intervention    |
| Subcutaneous Enoxaparin           | Adult patient received 160 mg in less than 24 h | Dose incorrect          | Prescribing    | Dose/frequency incorrect | Postoperative bleeding 24 h after abdominoplasty | Emergency exploration of wound under anesthesia required to control bleeding | F-Temporary harm, required hospitalization |
| Intravenous immunoglobulin        | Incorrect infusion rate programmed into pump | Incorrect infusion rate | Dispensing     |                   | Dispensing error due to brand substitution                 | Patient developed breathlessness secondary to acute bronchospasm. | E-Temporary harm, required intervention    |
| Levetiracetam Hydralazine         | Levetiracetam dispensed instead of Hydralazine | Medication incorrect    | Dispensing     |                   | Discharge medication dispensing error                      | Patient was admitted to another hospital.            | E-Temporary harm, required hospitalization and intervention |

AF: atrial fibrillation; ENT: ear, nose, and throat; ER: emergency room.
Table 3.—The outcomes of the mini–root cause analysis and action investigations of medication errors that caused harm but were not sentinel events

| Medications                  | Person Affected | Locations and Departments | Date of the Event | Departments Involved in Mini- RCA | Causal and Contributing Factors                                                                 | Recommended Actions                                                                 | Time Scale        | Follow-Up         |
|------------------------------|-----------------|----------------------------|-------------------|----------------------------------|--------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------|-------------------|------------------|
| Bisoprolol                   | Exforge HCT (Amlodipine, Valsartan, Hydrochlorothiazide) | Adult Inpatient ward     | February 8, 2018   | MSP Chairman, QID Task Force Chairman ADCN Surgery, Nursing Member QI Pharmacist, Pharmacy Member Pharmacist 1, Pharmacy Member QIM, QID Member MSO, QID Member | Hospital policy on patients’ own medications was not multi-disciplinary. Nurses not aware of the need to send patients’ own medications to pharmacy for inspection, relabelling, and appropriate dispensing. The policy on nonformulary drug requests did not describe procedure for the physician to enter nonformulary medications in the CPOE system. | Develop multi-disciplinary policy for “Medications Brought into Hospital by Patients.” Ensure staff awareness of revised multi-disciplinary policy. Update policy on nonformulary drug requests to include clear guidance on how to create (nonformulary) medication code in the CPOE system to facilitate physician entry. | Short term (1–3 months) | Implemented      |
|                              | Rivaroxaban      | Adult Inpatient ward      |                   |                                   |                                                                                                  |                                                                                      |                   |                  |
| Midazolam infusion           | Neonate         | Inpatient ward Operating theater Neonatal intensive care unit | December 31, 2018  | MSO, QID Task Force Chairman Pediatric Anesthetist, Anesthesia Member NM-NICU, Nursing Services Member | Anesthetist stopped midazolam infusion during the operation, did not resume it at the end of surgery, and disposed of the midazolam infusion in theater. Incomplete endorsement of critically ill patient to anesthetist by critical care team | Add question “Do any medications need to be restarted?” to the sign-out of the WHO safer surgery checklist. Formal communication between critical care, anesthesia, and surgery is required for all critically ill patients who need surgery. This should include a huddle meeting with a checklist to discuss and document critically ill patients’ needs during the operation. | Long term (6–12 months) | Pending implementation |

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| Medications                  | Person Affected | Locations and Departments | Date of the Event | Departments Involved in Mini- RCA | Causal and Contributing Factors                                                                                                                                  | Recommended Actions                                                                                       | Time Scale      | Follow-Up |
|-----------------------------|-----------------|---------------------------|-------------------|-----------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------|-----------------|------------|
| Antihemophilic factor (500 IU)/von Willebrand factor (1200 IU) (Humate P) Pediatrics Inpatient ward | April 19, 2018  | MSP Chairman, QID Task Force Chairman PICU Consultant, PICU Member RI Pediatric, Pediatric Member QM, Pharmacy Member Clinical Pharmacist, Pharmacy Member QI Pharmacist, Pharmacy Member Pharmacist 1, Pharmacy Member Assistant NM PICU, Nursing Services Member Nurse Coordinator Specialist PICU, Nursing Services Member Application analysts, CCIMS Member QI Specialists II, QID Member MSO, QID Member MSO, QID Member | Drug information on the packaging is confusing and incomplete. It only includes information on Humate P (500 IU). It does not include information on von Willebrand factor (1200 IU). Error-prone design of order for Humate P in CPOE system (mL/min option missing from infusion rate menu) Printed drug label was incomplete as limited space is allocated to the generic name. The generic name of Humate P is a long combination of two generic names. Humate P dosing not specified by indication in CPOE system (Antihemophilic factor [500 IU] or for von Willebrand factor [1200 IU]). As Humate P is expensive and its stability is low, pharmacy did not use the IV Admixture Medication Service to prepare it. This increases the risk of preparation errors. | Contact manufacturer/vendor to inform them that labeling is confusing and request resolution (see attached). Redesign of Humate P entry in CPOE system to add mL/min infusion option in the rate drop-down menu. Increase size of space on drug labels for generic names to accommodate the complete name and concentration information (i.e., Antihemophilic factor [500 IU]/von Willebrand factor [1200 IU]). Add full dosing specification through CPOE system by redesign of Humate P medication labeling system. Educate, train, and remind staff about hospital policy and guidelines on dosing and preparation of Humate P. These can be accessed via the CPOE system’s intranet site. Important areas to receive this education include pharmacy, all pediatric care areas, hematology care areas, and the emergency care center. Pharmacy to prepare Humate P in IV Medication Admixture Services AFTER charge nurse requests due dose | Short term (1–3 months) Implemented | |
| Medications | Person Affected | Locations and Departments | Date of the Event | Departments Involved in Mini-RCA | Causal and Contributing Factors | Recommended Actions | Time Scale | Follow-Up |
|-------------|-----------------|---------------------------|-----------------|---------------------------------|--------------------------------|----------------------|------------|-----------|
| Enoxaparin  | Pediatrics      | Inpatient ward Discharge from hospital | October 9, 2018 | MSO, QID Task Force Chairman Pediatric Clinical Pharmacist, Pharmacy Member NM, Nursing Services Member Pharmacist I, Pharmacy Member Resident Pediatric, Orthopedic Surgery Member QIM, Pharmacy Member | Error-prone design of the patient instruction field of enoxaparin prescription in CPOE system, so patient instruction label on enoxaparin dispensed from pharmacy did not include dose to be administered in mL. Adult enoxaparin syringes are given to children. So small doses are difficult to administer, increasing the risk of overdose. Pharmacy practices for preparing and dispensing enoxaparin for pediatric patients inconsistent between inpatient and discharge pharmacies Lack of knowledge of the Discharge Medication Process workflow | Automatically redefine dose in mL in instruction field for enoxaparin prescription in CPOE system so that this is printed on patient instruction label. Procurement to purchase enoxaparin syringes designed for children Standardize practice of preparing and dispensing enoxaparin within pharmacy. Ensure all nurses are aware of the Discharge Medication Process workflow. New nurses must be supervised to ensure compliance with this workflow especially during their initial 3-month probationary period. Develop workflow for the Discharge Medication Counseling Process for pediatric units. Add force function in the EMR to ensure patients discharged on anticoagulation get medication counseling before discharge. | Intermediate term (3–6 months) | Pending implementation Short term (1–3 months) | Rejected Short term (1–3 months) | Implemented Long term (6–12 months) | Implemented Short term (1–3 months) | Pending implementation Short term (1–3 months) | Pending implementation |
### Table 3.—Continued

| Medications | Person Affected Locations and Departments | Date of the Event | Departments Involved in Mini-RCA | Causal and Contributing Factors | Recommended Actions | Time Scale | Follow-Up |
|-------------|------------------------------------------|------------------|----------------------------------|---------------------------------|---------------------|-----------|-----------|
| **Enoxaparin** | **Adult Inpatient ward** | November 2, 2018 | MSO, QID Task Force Chairman Consultant Plastic Surgery, Surgery Member Ward NM, Nursing Services Member HIS Analyst, CCIMS Member QI Pharmacist, Pharmacy Member | Physicians' lack of knowledge of enoxaparin dosing for postoperative prophylaxis Lack of knowledge of the “Guideline for Prevention of Thromboembolism in Adults” | Update “Guideline for Prevention of Thromboembolism in Adults.” Train staff on the updated “Guideline for Prevention of Thromboembolism in Adults” with physicians, pharmacy, and nursing. Link the “Guideline for Prevention of Thromboembolism in Adults” to the order set for DVT prophylaxis in the CPOE system. | Intermediate term (3–6 months) | Pending implementation |
| **Intravenous human immunoglobulin** | **Adult Inpatient ward** | August 11, 2018 | MSP Chairman, QID Task Force Chairman MSO, QID Member ICU Consultant, ICU Member Pediatric Clinical Pharmacist, Pharmacy Member Critical Care Clinical Pharmacist, Pharmacy Member QI Pharmacist, Pharmacy Member Pharmacists 1, Pharmacy Member Pharmaceutical Planner, Pharmaceutical Planning Member Clinical Resource Nurse Medical Ward, Nursing Services Member Staff Nurse I Medical Ward, Nursing Services Member Staff Nurse I Medical Ward, Nursing Services Member | Brand of human immunoglobulin is not included in the ordering field of the human immunoglobulin prescription in the CPOE system. Brand of human immunoglobulin is not included on the printed medication label when dispensing human immunoglobulin. Brand of human immunoglobulin is not included in smart IV infusion pumps for administration. Dispensing pharmacist's confirmation bias of generic drug name inhibited medication appropriateness review. Lack of information on brands of human immunoglobulin in the IV manual and hospital guidelines Inadequate communication of the availability of different brands of human immunoglobulin in the pharmaceutical care services to physicians, pharmacists, and nurses | Change human immunoglobulin prescription in CPOE system to include all human immunoglobulin brands approved by the Saudi Food and Drug Authority. Ensure that brand of human immunoglobulin and its concentration are included on the printed medication label for human immunoglobulin. Add all brands of human immunoglobulin approved by the Saudi Food and Drug Authority to the drug libraries of the smart IV infusion pumps. Educate, train, and remind pharmacists to perform the medication dispensing appropriateness review. Update hospital IV manual and guidelines for all human immunoglobulin brands approved by the Saudi Food and Drug Authority. Pharmaceutical planning to use multimodal communication pathways to inform physicians, pharmacists, and nurses when new brands of human immunoglobulin are available in the pharmaceutical care services | Intermediate term (3–6 months) | Implemented |

**Note:** The actions are categorized based on the time scale: short term (1–3 months), intermediate term (3–6 months), and intermediate term pending implementation.
| Medications | Person Affected | Date of the Event | Departments Involved in Mini-RCA | Causal and Contributing Factors | Recommended Actions | Time Scale | Follow-Up |
|-------------|----------------|-------------------|---------------------------------|---------------------------------|----------------------|------------|----------|
| Levetiracetam | Adult Inpatient Discharge | January 25, 2018 | MSP Chairman, QID Task Force Chairman NM Nephrology Ward Nursing Services Member QI Pharmacist, Pharmacy Member MSO, QID Member | Suboptimal design of the machine-readable bar-coding system Similarity of the packaging of the two medications Inadequate training and supervision of the junior pharmacy technician involved | Add bar code to drug label and the bottle of the drug Inform manufacturer/vendor of the similarity of the packaging of these medications and request changes Ensure junior pharmacy technicians are supervised when preparing medications especially during the initial 3-months probationary period | Long term (6–12 months) Long term (6–12 months) Short term (1–3 months) | Implemented Pending implementation Implemented |
| Hydralazine | | | | Suboptimal design of discharge pharmacy | Isolate the discharge pharmacy area from other sections of pharmacy. And restrict the access to the discharge pharmacy to the discharge pharmacy staff. | Long term (6–12 months) | Pending implementation |
| | | | | Discharge counselling pharmacists not available after normal working hours and during the weekends | Provide on-call discharge counselling pharmacist cover after working hours and during the weekend. | Long term (6–12 months) | Pending implementation |
| | | | | Hospital policies state that discharge orders (prescriptions, follow-up appointments, etc.) should be written at least 24 h before discharge. However, this is rarely done. Underutilization of the scheduled discharge orders in the CPOE system | Educate, train, and remind physicians to follow hospital policies on discharge planning and discharge medications. Heads of each division to monitor and report each consultant’s rate of scheduled discharges and incorporate these data into physicians’ annual evaluation | Short term (1–3 months) Short term (1–3 months) | Implemented Implemented |
| | | | | | Set up a multi-disciplinary task force involving physicians, the Department of Bed Management and Pharmacy to improve discharge planning, increase the use of scheduled discharge orders in CPOE system, and increase compliance with hospital policies on discharge medications. | Long term (6–12 months) | Pending implementation |

ADCN: Acting Director Clinical Nursing; CCIMS: Corporate Clinical Information Management System; CPOE: computerized prescriber order entry; DVT: deep vein thrombosis; EMR: electronic medical record; HIS: Health Informatics System; ICU: Intensive Care Unit; IV: intravenous; MSO: Medication Safety Officer; MSP: Medication Safety Program; NM: Nurse Manager; NM-NICU, Nurse Manager – Neonatal Intensive Care Unit; PICU: Pediatric Intensive Care Unit; QI: quality improvement; QID: Quality Improvement Department; QIM: Quality Improvement Manager; R1: Postgraduate Year 1 Resident; RCA: root cause analysis; WHO, World Health Organization.
causes of the harm events investigated (median, 6; range, 2–10).

**Recommendations Made Following the Mini-RCA²**

The recommendations made after each mini-RCA² and their stage of implementation on January 7, 2020, are shown in Tables 3–5. Several recommendations were made after each mini-RCA² (median, 6; range, 2–10). Of the 42 recommendations made following the mini-RCA², 22 (52%) had been implemented by January 7, 2020. The time scale within which each recommendation should have been implemented was defined by the team conducting each mini-RCA². Of 22 recommendations (52%) that should have been implemented within 1–3 months (short term), 16 (73%) had been. Of 12 recommendations (29%) that should have been implemented within 3 to 6 months (intermediate term), four (33%) had been. Of eight recommendations (19%) that should have been implemented within 6 to 12 months (long term), two (25%) had been. After extensive discussion, two of the recommendations (5%) were ultimately rejected by the stake holders and the higher administration. Thus, on January 7, 2020, a median of three recommendations had been implemented after each mini-RCA² (range, 0–6) and 18 recommendations were still pending.

Major changes to systems, policies, guidelines, work flow, awareness, and training were made. However, despite regular follow-up with the departments responsible for each recommendation, many important medication safety initiatives are outstanding. Recommendations were fully implemented for only two events (prescribing error—omission of a patient’s home medications on admission to hospital and Humate P dose incorrect; see Tables 3 and 4). The implementation of some recommendations was delayed because they were incorporated into larger ongoing quality improvement projects. For example, the recommendations made after the omission of the midazolam infusion have been incorporated into a large multi-disciplinary initiative to enhance medication safety within the operating theaters.

**Analysis Used to Determine the Impact of Mini-RCA² on the Recurrence of Medication Errors**

The data from the SRS database on the number of medication errors that occurred 1 year before and 1 year after each index event is summarized in Table 4. The first
event occurred on January 25, 2018, and the last event occurred on December 31, 2018. To determine the total number of medication errors reported during the periods under consideration the SRS database was interrogated for events from January 25, 2017, until December 30, 2018 (“before”) and January 26, 2018, until December 31, 2019 (“after”). This was used as the denominator for the aggregate data below.

**Impact of Mini-RCA² on the Recurrence of Medication Errors**

In the years before each index event a total of 6124 incidents were reported. Including the seven index events, 35 similar events (0.57%) occurred. In the years after each index event, a total of 5885 incidents were reported. Twenty-one similar events (0.36%) occurred. The reduction in the recurrence of similar reported events (14, 0.24%; \( p = 0.11 \)) did not achieve statistical significance. However, consideration of the impact of this initiative on incidents that caused harm is of great interest.

**Impact of Mini-RCA² on the Recurrence of Harm Events**

In the years before each index, seven of the 35 similar incidents (0.11%) caused harm but were not sentinel events. These seven incidents were the harm events that were included in the present quality improvement initiative (ie, mini-RCA² was performed). However, none of the 21 similar events reported in the years after each index event caused harm. The statistically significant absolute decrease in recurrence of similar harm events (7, 0.11%, \( p = 0.016 \)) represented a relative risk reduction of 1 (Table 4).

**Effect of Implementation of the Mini-RCA² Recommendations on Event Recurrence**

When the recommendations from the mini-RCA² had been fully implemented, the benefits were greater. In the years before the two index events for which all mini-RCA² recommendations were implemented, a total of 4344 ADE reports were submitted. Including the two index events, 11 similar events (0.25%) occurred. In the years after each index event, a total of 3323 incidents were reported. No similar events were reported. This represents a statistically significant absolute decrease (11, 0.25%) in recurrence of similar events (\( p = 0.007 \)), with relative risk reduction of 1 (Tables 4 and 5).

**Resource Utilization and Economic Analysis**

Table 6 displays the time and the labor costs of each mini-RCA². A total of 251 hours (mean ± SD, 35.9 ± 16.6 hours) was required for this intervention. Most of the time was spent on the investigations by the medication safety officer (99 hours, 39.4%). Fifty hours of other healthcare professionals’ time was required for
| Medication Error                                                                 | Team Member                              | Review Incident Report | Investigation | Mini-RCA<sup>2</sup> Meeting | Preparation of Report | Review Report | Communicating Actions and Follow-Up | Total | SAR and USD ($) per h | Total Cost  |
|--------------------------------------------------------------------------------|------------------------------------------|------------------------|---------------|-----------------------------|----------------------|--------------|-----------------------------------|-------|------------------------|-------------|
| Bisoprolol                                                                      | MSO                                      | 0.25                   | 16            | 1                           | 4                    | 2            |                                   | 23.25 | SAR 36                 | SAR 837      |
| Exforge HCT (amlodipine, Valsartan, Hydrochlorothiazide)                        | MSP Chairman                             | 0.25                   | 1             | 2                           | 1                    | 2            |                                   | 6.25  | SAR 325                | SAR 1218.75  |
| Rivaroxaban                                                                     | ADCN Surgery, Nursing Member              | 0.25                   | 1             | 0.5                         |                       |               |                                   | 1.75  | SAR 59.5               | SAR 325      |
| Prescribing error – home medications not prescribed on admission                | QI Pharmacist, Pharmacy Member           | 0.25                   | 1             | 0.5                         |                       |               |                                   | 1.75  | SAR 34                  | SAR 224      |
|                                                                                  | Pharmacist 1, Pharmacy Member            | 0.25                   | 1             | 0.5                         |                       |               |                                   | 1.75  | SAR 11                | SAR 224      |
|                                                                                  | QIM, QID Member                          | 0.25                   | 0.5           |                             |                       |               |                                   | 1.75  | SAR 45                 | SAR 224      |
|                                                                                  | Total                                    | 1.5                    | 16            | 6                           | 6                    | 3            | 4                                 | 36.5  | SAR 36                 | SAR 978.75   |
| Midazolam infusion                                                              | MSO, QID                                 | 0.25                   | 3             | 1                           | 2                    | 1            |                                   | 7.25  | SAR 36                 | SAR 135      |
|                                                                                  | Task Force Chairman                      |                        |               |                             |                       |               |                                   |       | SAR 36                 | SAR 78.75    |
|                                                                                  | MSP Chairman                             | 0.25                   | 1             | 1                           |                       |               |                                   | 2.25  | SAR 52                 | SAR 438.75   |
|                                                                                  | Pediatric Anesthetist, Anesthesia Member  | 0.25                   | 1             | 0.5                         |                       |               |                                   | 20.8  | SAR 341.25             | SAR 117      |
|                                                                                  | NM-NICU, Nursing Services Member         | 0.25                   | 1             | 0.5                         |                       |               |                                   | 13    | SAR 136.5              | SAR 1895.25  |
|                                                                                  | Total                                    | 1.3                    | 3             | 3                           | 2                    | 2            | 2                                 | 13    | SAR 221                | SAR 505.4    |
| Antihemophilic factor (500 IU) VWF (1200 IU) Humate P                          | MSP Chairman, QID                        | 0.25                   | 1             | 1                           | 2                    | 1            |                                   | 4.25  | SAR 36                 | SAR 78.75    |
|                                                                                  | Task Force Chairman                      |                        |               |                             |                       |               |                                   |       | SAR 36                 | SAR 221      |
|                                                                                  | MSO, QID Member                          | 0.25                   | 24            | 1                           | 8                    | 2            |                                   | 35.25 | SAR 36                 | SAR 4758.75  |
|                                                                                  | PICU Consultant, PICU Member             | 0.25                   | 1             |                             | 0.5                   |               |                                   | 1.75  | SAR 341.25             | SAR 117      |
|                                                                                  | R1 Pediatric, Pediatric Member           | 0.25                   | 1             | 0.5                         |                       |               |                                   | 1.75  | SAR 136.5              | SAR 117      |
|                                                                                  | QIM, Pharmacy Member                     | 0.25                   | 1             | 0.5                         |                       |               |                                   | 1.75  | SAR 136.5              | SAR 117      |
|                                                                                  | Clinical Pharmacist, Pharmacy Member     | 0.25                   | 1             | 0.5                         |                       |               |                                   | 1.75  | SAR 136.5              | SAR 117      |
|                                                                                  | QI Pharmacist, Pharmacy Member           | 0.25                   | 1             | 0.5                         |                       |               |                                   | 1.75  | SAR 136.5              | SAR 117      |
|                                                                                  | Pharmacist 1, Pharmacy Member            | 0.25                   | 1             | 0.5                         |                       |               |                                   | 1.75  | SAR 341.25             | SAR 117      |
|                                                                                  | Assistance NM PICU, Nursing Services Member | 0.25             | 1             | 0.5                         |                       |               |                                   | 1.75  | SAR 136.5              | SAR 117      |
|                                                                                  | QI Specialists II, QID Member            | 0.25                   | 1             | 0.5                         |                       |               |                                   | 1.75  | SAR 136.5              | SAR 117      |
|                                                                                  | MSO, QID Member                          | 0.25                   | 1             | 0.5                         |                       |               |                                   | 1.75  | SAR 136.5              | SAR 117      |
|                                                                                  | Total                                    | 3.25                   | 24            | 13                          | 8                    | 6.5          | 4                                 | 58.75 | SAR 36                 | SAR 7680.5   |
|                                                                                  | Downloaded from http://meridian.allenpress.com/innovationsjournals-JQSH/article-pdf/4/1/27/2829242/i2589-9449-4-127.pdf by guest on 29 November 2021 | | | | | | | | | | Quality Improvement Project |
| Medication Error    | Team Member                                  | Time Required to Conduct Mini-RCA², h | Financial Cost |
|---------------------|----------------------------------------------|--------------------------------------|----------------|
|                     | Review Incident Report | Investigation | Mini-RCA² Meeting | Preparation of Report | Review Report | Communicating Actions and Follow-Up | Total | SAR and USD ($) per h | Total Cost |
| Enoxaparin Pediatric| MSO, QID                                     | 0.25  | 16 | 1 | 5 | 2 | 24.25 | SAR 135 | SAR 3273.75 | SAR 36 | SAR 873 | SAR 243.25 | SAR 828.75 | SAR 221 | SAR 64.75 | SAR 136.5 | SAR 36.4 | SAR 175 | SAR 45.5 | SAR 136.5 | SAR 36.75 | SAR 221 | SAR 63 | SAR 5030 | SAR 1340.4 | SAR 1038.4 |
|                     | Task Force Chairman                           | 0.25  | 1  | 1 | 2 | 4.25 | SAR 195 | SAR 828.75 | SAR 221 | SAR 64.75 | SAR 136.5 | SAR 36.75 | SAR 221 | SAR 63 | SAR 828.75 | SAR 221 | SAR 64.75 | SAR 136.5 | SAR 36.75 | SAR 221 | SAR 63 | SAR 828.75 | SAR 221 | SAR 64.75 | SAR 136.5 |
|                     | MSP Chairman                                  | 0.25  | 1  | 0.5 | 1.75 | SAR 135 | SAR 3273.75 | SAR 36 | SAR 873 | SAR 243.25 | SAR 828.75 | SAR 221 | SAR 64.75 | SAR 136.5 | SAR 36.75 | SAR 221 | SAR 63 | SAR 828.75 | SAR 221 | SAR 64.75 | SAR 136.5 |
|                     | Pediatric Clinical Pharmacist, Pharmacy Member| 0.25  | 1  | 0.5 | 1.75 | SAR 135 | SAR 3273.75 | SAR 36 | SAR 873 | SAR 243.25 | SAR 828.75 | SAR 221 | SAR 64.75 | SAR 136.5 | SAR 36.75 | SAR 221 | SAR 63 | SAR 828.75 | SAR 221 | SAR 64.75 | SAR 136.5 |
|                     | NM, Nursing Services Member                   | 0.25  | 1  | 0.5 | 1.75 | SAR 135 | SAR 3273.75 | SAR 36 | SAR 873 | SAR 243.25 | SAR 828.75 | SAR 221 | SAR 64.75 | SAR 136.5 | SAR 36.75 | SAR 221 | SAR 63 | SAR 828.75 | SAR 221 | SAR 64.75 | SAR 136.5 |
|                     | Pharmacist 1, Pharmacy Member                | 0.25  | 1  | 0.5 | 1.75 | SAR 135 | SAR 3273.75 | SAR 36 | SAR 873 | SAR 243.25 | SAR 828.75 | SAR 221 | SAR 64.75 | SAR 136.5 | SAR 36.75 | SAR 221 | SAR 63 | SAR 828.75 | SAR 221 | SAR 64.75 | SAR 136.5 |
|                     | Resident Pediatric, Orthopedic Surgery Member| 0.25  | 1  | 0.5 | 1.75 | SAR 135 | SAR 3273.75 | SAR 36 | SAR 873 | SAR 243.25 | SAR 828.75 | SAR 221 | SAR 64.75 | SAR 136.5 | SAR 36.75 | SAR 221 | SAR 63 | SAR 828.75 | SAR 221 | SAR 64.75 | SAR 136.5 |
|                     | QIM, Pharmacy Member                          | 0.25  | 1  | 0.5 | 1.75 | SAR 135 | SAR 3273.75 | SAR 36 | SAR 873 | SAR 243.25 | SAR 828.75 | SAR 221 | SAR 64.75 | SAR 136.5 | SAR 36.75 | SAR 221 | SAR 63 | SAR 828.75 | SAR 221 | SAR 64.75 | SAR 136.5 |
|                     | Total                                         | 1.75  | 16 | 7  | 5  | 3.5 | 4.25 | SAR 135 | SAR 3273.75 | SAR 36 | SAR 873 | SAR 243.25 | SAR 828.75 | SAR 221 | SAR 64.75 | SAR 136.5 | SAR 36.75 | SAR 221 | SAR 63 | SAR 828.75 | SAR 221 | SAR 64.75 | SAR 136.5 |
| Enoxaparin Adult     | MSO, QID                                     | 0.25  | 8  | 1  | 5  | 2 | 16.25 | SAR 135 | SAR 2193.75 | SAR 36 | SAR 585 | SAR 828.75 | SAR 221 | SAR 341.25 | SAR 91 | SAR 136.5 | SAR 36.4 | SAR 196 | SAR 52.5 | SAR 136.5 |
|                     | Task Force Chairman                           | 0.25  | 1  | 1  | 2 | 4.25 | SAR 195 | SAR 828.75 | SAR 221 | SAR 64.75 | SAR 136.5 | SAR 36.75 | SAR 221 | SAR 63 | SAR 828.75 | SAR 221 | SAR 64.75 | SAR 136.5 |
|                     | MSP Chairman                                  | 0.25  | 1  | 0.5 | 1.75 | SAR 135 | SAR 2193.75 | SAR 36 | SAR 585 | SAR 828.75 | SAR 221 | SAR 341.25 | SAR 91 | SAR 136.5 | SAR 36.4 | SAR 196 | SAR 52.5 | SAR 136.5 |
|                     | Consultant Plastic Surgery, Surgery Member    | 0.25  | 1  | 0.5 | 1.75 | SAR 135 | SAR 2193.75 | SAR 36 | SAR 585 | SAR 828.75 | SAR 221 | SAR 341.25 | SAR 91 | SAR 136.5 | SAR 36.4 | SAR 196 | SAR 52.5 | SAR 136.5 |
|                     | Ward 39 NM, Nursing Services Member           | 0.25  | 1  | 0.5 | 1.75 | SAR 135 | SAR 2193.75 | SAR 36 | SAR 585 | SAR 828.75 | SAR 221 | SAR 341.25 | SAR 91 | SAR 136.5 | SAR 36.4 | SAR 196 | SAR 52.5 | SAR 136.5 |
|                     | HIS Analyst, CCIMS Member                     | 0.25  | 1  | 0.5 | 1.75 | SAR 135 | SAR 2193.75 | SAR 36 | SAR 585 | SAR 828.75 | SAR 221 | SAR 341.25 | SAR 91 | SAR 136.5 | SAR 36.4 | SAR 196 | SAR 52.5 | SAR 136.5 |
|                     | QI Pharmacist, Pharmacy Member                | 0.25  | 1  | 0.5 | 1.75 | SAR 135 | SAR 2193.75 | SAR 36 | SAR 585 | SAR 828.75 | SAR 221 | SAR 341.25 | SAR 91 | SAR 136.5 | SAR 36.4 | SAR 196 | SAR 52.5 | SAR 136.5 |
|                     | Total                                         | 1.5  | 8  | 6  | 5  | 3  | 27.5 | SAR 135 | SAR 2193.75 | SAR 36 | SAR 585 | SAR 828.75 | SAR 221 | SAR 341.25 | SAR 91 | SAR 136.5 | SAR 36.4 | SAR 196 | SAR 52.5 | SAR 136.5 |
| Medication Error | Team Member | Time Required to Conduct Mini-RCA², h | Financial Cost |
|------------------|-------------|---------------------------------------|----------------|
|                  |             | Review Incident Report | Investigation | Mini-RCA² Meeting | Preparation of Report | Review Report | Communicating Actions and Follow-Up | Total | SAR and USD ($) per h |
| Intravenous human immunoglobulin | MSP Chairman, QID | 0.25 | 1 | 1 | 2 | 4.25 | SAR 195 | SAR 828.75 |
| Task Force Chairman | 0.25 | 24 | 1 | 8 | 2 | 35.25 | SAR 135 | SAR 4758.75 |
| MSO, QID Member | $56 | $1269 | $341.25 | SAR 195 | $52 | SAR 135 | SAR 4758.75 |
| ICU Consultant, ICU Member | 0.25 | 1 | 0.5 | 1.75 | SAR 135 | $47.5 | SAR 243.25 | SAR 243.25 |
| Pediatric Clinical Pharmacist, Pharmacy Member | 0.25 | 1 | 0.5 | 1.75 | SAR 135 | $47.5 | SAR 243.25 | SAR 243.25 |
| Critical Care Clinical Pharmacist, Pharmacy Member | 0.25 | 1 | 0.5 | 1.75 | SAR 135 | $47.5 | SAR 243.25 | SAR 243.25 |
| QI Pharmacist, Pharmacy Member | 0.25 | 1 | 0.5 | 1.75 | SAR 135 | $47.5 | SAR 243.25 | SAR 243.25 |
| Pharmacist 1, Pharmacy Member | 0.25 | 1 | 0.5 | 1.75 | SAR 135 | $47.5 | SAR 243.25 | SAR 243.25 |
| Pharmaceutical Planner, Pharmaceutical Planning Member | 0.25 | 1 | 0.5 | 1.75 | SAR 135 | $47.5 | SAR 243.25 | SAR 243.25 |
| Clinical Resource Nurse Ward 16, Nursing Services Member | 0.25 | 1 | 0.5 | 1.75 | SAR 135 | $47.5 | SAR 243.25 | SAR 243.25 |
| Staff Nurse I Ward 16, Nursing Services Member | 0.25 | 1 | 0.5 | 1.75 | SAR 135 | $47.5 | SAR 243.25 | SAR 243.25 |
| Staff Nurse I Ward 16, Nursing Services Member | 0.25 | 1 | 0.5 | 1.75 | SAR 135 | $47.5 | SAR 243.25 | SAR 243.25 |
| Total | 2.75 | 24 | 11 | 8 | 5.5 | 4 | 55.25 | SAR 7314.75 | SAR 1952 |
| Levitiracetam | MSP Chairman, QID | 0.25 | 1 | 1 | 2 | 4.25 | SAR 195 | SAR 828.75 |
| Task Force Chairman | 0.25 | 8 | 1 | 4 | 2 | 15.25 | SAR 135 | SAR 4758.75 |
| MSO, QID Member | $52 | $221 | SAR 2058.75 | SAR 2058.75 | $549 | SAR 135 | SAR 4758.75 |
| QI Pharmacist, Pharmacy Member | 0.25 | 1 | 0.5 | 1.75 | SAR 135 | $549 | SAR 196 | SAR 135 |
| NM Ward 12, Nursing Services Member | 0.25 | 1 | 0.5 | 1.75 | SAR 135 | $549 | SAR 196 | SAR 135 |
| Total | 1 | 8 | 4 | 4 | 2 | 4 | 23 | SAR 322 | SAR 7314.75 |
| Hydralazine | 12.75 | 99 | 50 | 38 | 25.5 | 26 | 251.25 | SAR 34181.25 | SAR 9115 |

All incidents for which mini-RCA² was used

ADCN: Acting Director Clinical Nursing; CCIMS: Corporate Clinical Information Management System; HIS: Health Informatics System; ICU: Intensive Care Unit; MSO: Medication Safety Officer; MSP: Medication Safety Program; NM: Nurse Manager; NM-NICU: Nurse Manager – Neonatal Intensive Care Unit; PICU: Pediatric Intensive Care Unit; QI: quality improvement; QID: Quality Improvement Department; QIM: Quality Improvement Manager; R1: Postgraduate Year 1 Resident; RCA²: Root Cause Analysis and Action; SAR: Saudi riyal; USD: United States dollar.
the mini-RCA\textsuperscript{2} meetings. The total cost of the labor required for this quality improvement project was SAR 34,181 (US $8256; mean SAR \pm SD, 4883 \pm 1302 [US $ \pm SD, $2102 \pm $561]). However, the cost varied considerably. The mini-RCA\textsuperscript{2} for the ADE involving Humate P was complex, took the most time (58.75 hours; 23.4%), and was the most expensive (SAR 7681, US $2048; 22.5%). The mini-RCA\textsuperscript{2} for the ADE involving levetiracetam required the least work (13 hours; 5.2%). However, the labor costs were lowest for the mini-RCA\textsuperscript{2} for the ADE involving the midazolam infusion (SAR 1895, US $505; 5.5%).

Feasibility and Sustainability

Mini-RCA\textsuperscript{2}'s were conducted by the medication safety officer for all ADEs that caused harm but were not sentinel events in 2018. All preliminary reports were submitted within 72 hours of the mini-RCA\textsuperscript{2}. However, the final reports were submitted between 6 and 84 days after the incident (mean, 47.5 days). Delays were usually related to requests for minor modifications to the report from the MSP Chairman and individual stakeholders.

It would not be feasible for this number of medical errors to be investigated by higher administrative personnel using the full RCA methodology. However, unless the incidence of ADEs that cause harm increases significantly, investigation with mini-RCA\textsuperscript{2} led by the medication safety officer is feasible and sustainable.

DISCUSSION

Summary

A structured mini-RCA\textsuperscript{2} response to all ADEs that caused harm (ie, not just those that resulted in sentinel events) significantly reduced the recurrence of similar reported events. The benefit was greatest if all of the recommendations of the mini-RCA\textsuperscript{2} were implemented. Although the costs associated with conducting a mini-RCA\textsuperscript{2} were considerable, the impact on patient safety far outweighed this.

Interpretation

Although medication errors are common, harm is rare. In 2018, 2927 ADEs were reported at KAMC, but only 15 (0.51%) caused harm. Two of these ADEs were sentinel events. Six errors that caused harm but were not sentinel events were due to human error alone. So, seven ADEs due to system failures were investigated with the mini-RCA\textsuperscript{2} methodology. The identification of 39 system failures by this initiative generated a huge amount of knowledge about suboptimal systems that would otherwise have been lost.

Identification of these system failures prompted several interventions to improve the safety of our organization. While some similar events recurred despite mini-RCA\textsuperscript{2}, this intervention significantly reduced the incidence of recurrence of similar events and eliminated harm from similar events. Simply going through the motions of RCA and developing an action plan without implementing the recommendations will have no benefit. In the present study, the benefit to patient safety was greatest if all of the mini-RCA\textsuperscript{2}'s recommendations were implemented. In some cases, the recurrence of similar errors was eliminated completely after the implementation of the recommendations of the mini-RCA\textsuperscript{2}. Furthermore, it is possible that this initiative may have reduced the recurrence of other events. This observation reinforces the need for follow-up to ensure that the recommendations made following RCA\textsuperscript{2} are fully implemented.

Furthermore, many system failures occurred (and recurred) because of suboptimal operating procedures or lack of awareness of established/updated policies. Thus, when an ADE occurs or policies and operating procedures are developed or updated, it is important to educate the relevant stakeholders about the changes to practice required. Our institution uses a multi-modal approach to rapidly disseminate this information. This includes email, intranet banners, computer screen savers, wall-mounted screens, presentation at departmental meetings, and awareness campaigns.

When considering the recurrence of events following RCA\textsuperscript{2}, it is important to reflect on the quality of the recommendations made. In terms of the hierarchy of effectiveness, force functions and automation or computerization of processes are most likely to prevent errors.[14] Guidelines, policies, education, and reminders are less likely to successfully and sustainably improve patient safety.[14]

Previous studies have questioned the efficacy of RCA.[10–12] Indeed, the NPSF attempted to address this by developing RCA\textsuperscript{2}.[10] Our study reiterates that merely identifying causes of errors does not reduce their recurrence or prevent harm to patients. However, we demonstrate that when appropriate recommendations are made and implemented with the mini-RCA\textsuperscript{2} methodology, recurrence of similar errors can be reduced and harm may be prevented.

Substantial resources were required for this intervention. It consumed 250 hours of staff time at an estimated cost of more than SAR 34,181 (US $8256). For comparison, in an academic center in the United States the average cost of using RCA to investigate a serious reportable event due to an ADE was US $10,930 in 2013.[15] While the calculation of cost differed from that used in the present study, this illustrates the potential savings in terms of finances and staff time that may be achieved by using the mini-RCA\textsuperscript{2} methodology rather than a full RCA.

Medication errors cause great harm to patients and burden healthcare systems with considerable legal and operational expenses.[2–6] So, whilst the absolute impact may seem small, the overall benefit of this intervention to patients, healthcare professions, and the hospital is of great clinical and operational importance.
Furthermore, the insights gleaned through RCA can occasionally provide significant benefits above and beyond improvements in patient safety. For example, one mini-RCA² found that the medication error involving Humate P did not harm the affected patient. However, this was not clear at the outset. This finding was extremely comforting to the staff involved in the incident and the patient’s family.

Thus, while the full benefit of this intervention is unquantifiable, the present study demonstrates the feasibility and impact of using mini-RCA² methodology to investigate medication errors that cause harm. Our observations are similar to those from other organizations that use RCA methodology to investigate all medication errors that cause harm.¹⁰,¹³ However, no previous studies have described the impact of using an abbreviated RCA² strategy to investigate ADEs.

**Limitations**

The present study describes the investigation of a relatively small number of ADEs that caused harm in a single center. The culture at KAMC encourages and rewards the reporting of errors, and nearly 3000 ADEs were reported in 2018 alone. However, not all medication errors are reported. Furthermore, each mini-RCA² was led by an experienced medication safety officer trained to perform RCA. This ensured internal validity. However, this in turn limits external validity and generalizability to centers that do not have medication safety officers or personnel besides higher administrative staff who can perform RCA. The economic analysis did not include the nonlabor direct costs (ie, the costs of the infrastructure required to operate the MSP), hospital overheads, or the time taken to implement the recommendations of the mini-RCA². So, the total costs associated with this intervention are underestimated. However, most of the cost is associated with staff time, so the true cost is unlikely to be significantly different from the data provided above.

**Conclusion**

Using mini-RCA² to investigate medication errors that cause harm but are not considered sentinel events can reduce ADEs. This may improve patient safety and reduce the operational costs of healthcare systems. These benefits far outweigh the cost of implementing this intervention. Beyond the reduction in operational hazards, some mini-RCA²s may ultimately conclude that the patient was not actually harmed by the ADE. In this situation, the relief for all stakeholders is of incalculable value above and beyond that of the systems-level improvements made by the organization.

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