

British Journal of Medicine & Medical Research 8(5): 384-407, 2015, Article no.BJMMR.2015.462 ISSN: 2231-0614



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Medication Safety Unit Programs in King Saud Medical City, 2012 – 2013: Safe Medication Management and Use with a Focus on Patient Safety

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Authors' contributions

This work was carried out in collaboration between all authors. Author IAAZ designed the study, and authors DSAD, SOS and NAQ wrote the protocol, and authors IAAZ and NAQ wrote the first draft of the manuscript. Authors DSAD, SOS and NAQ managed the literature searches, and data analyses of the study. Author NAQ revised the manuscript a number of times in accordance to reviewers' healthy comments. All authors read and approved the final manuscript.

Article Information

DOI: 10.9734/BJMMR/2015/17221

Editor(s):

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Reviewers:

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Complete Peer review History: http://www.sciencedomain.org/review-history.php?iid=1117&id=12&aid=9081

Review Article

Received 3rd March 2015 Accepted 15th April 2015 Published 2nd May 2015

ABSTRACT

Background: Medication safety unit [MSU] streamlines the safe management and use of prescribed medications and reduction in all types of medication errors [MEs], and associated morbidity and mortality resulting in enhanced patient safety, better quality of healthcare services and cost saving.

Objective: This study aims to describe MSU programs together with their purposes developed in

King Saud Medical City [KSMC], Saudi Arabia and supports them with related policies and guidelines based on qualitative evidence-based research done across the world.

Methods: A mixed study was designed to define programs, roles and annual plan of MSU, which was established in year 2012. Multiple awareness campaigns and training courses were organized for highlighting the significance of MSU among healthcare providers and consumers in KSMC.

Results: The MSU developed 14 programs and annual medication safety plan of actions together with respective policies, procedures and guidelines, well supported by qualitative evidence-based research data for improving safe medication management and use associated with reported reduction in MEs, and increased patient safety and quality of healthcare.

Conclusion: MSU is a useful tool to encourage reporting of MEs, which are reported to increase patient safety and safe medication management and tends to decrease the number of MEs. Beside establishing MSU in all hospitals, this study calls for a randomized controlled study in future that will identify potential risk factors that impact safe medication management and are associated with patient safety not only in Saudi Arabia but also in other Arabian Gulf countries.

Keywords: Medication safety unit; medication safety programs; medication safety annual plan; medication errors; patient safety; Saudi Arabia.

ABBREVIATION

ADEs - Adverse Drug Events; ADRs - Adverse Drug reactions; *AHRQ - Agency for Healthcare Research and Quality; AKU- Artificial Kidney Unit; ADD - Automatic Dispensing Devices; CPR-Cardiopulmonary resuscitation; *CBAHI - Central Board for Accreditation of Healthcare Institutions; CC - Close calls; *CMS - Centers for Medicare & Medicaid Services; ET - Education & Training; ETP - Education and Training Program; EDS - Electronic Document System; EP - Electronic Prescribing; EPS - Electronic Prescribing System; FMEA - Failure Mode and Effect Analysis; FDIs - Food-Drug Interactions; HIT- health Information Technology; *HAM - High Alert Medications; HIV- Human Immunodeficiency virus; HDP - Hospital Drug Formulary; ICU - Intensive care unit; *IOM- Institute of Medicine; *IPSGs - International Patient Safety Goals; *ISMP - Institute of Safe Medication Practice; *JC - Joint Commission, KSMC - King Saud Medical City, *LASA - Look alike and Sound alike, MAP - Medication-related Action Plan: MEs - Medication errors: MMP - Medication Management Program: MMU - Medication Management and Use; MR - Medication Reconciliation; MRN - Medical Registration Number; MSU - Medication Safety Unit; MSC - Medication Safety Committee; MSCs -Medication Safety Coordinators; MUS - Medication Use System; *NCCMERP - National Coordinating Council for Medication Error Reporting and Prevention; NMs - Near misses; PMR - Personal Medication Record; P&TC - Pharmacy and Therapeutic Committee; RCA - Root Cause Analysis; *SFDA - Saudi Food and Drug Authority; and TEAAD - Training & Education Academic Affairs Department.

*Main sources for developing policy, procedures, guidelines and annual medication safety action plan.

1. INTRODUCTION

Medication errors are a public health problem. Medical mistakes, medication errors [MEs],and adverse drug events [ADEs] related to drugs use in healthcare systems are known to cause considerable damage to a significant number of patients and lead to various complications, long hospital stay, huge costs, worse outcome, poor quality of life, and increased mortality [1-5]. These drug-related problems are the major concern for patient safety. Medical professionals, allied personnel, nontechnical staff and patients themselves tend to cause these devastating drug related adverse events and MEs across multiple

specialties in a healthcare system [4-6]. About 50% of medication errors also called near misses/close calls cause no patient harm as they are corrected before they reach the patient [7]. Majority of reported unintentional MEs do not cause harm to the patient but some result in severe morbidity and mortality [2,5]. Notably, medical mistakes cause up to 98,000 deaths annually in the USA [8]. Electronic prescribing system [EPS] a strategic prevention tool reduces the ME occurrence in all medical settings and also is associated with other advantages [9-15] and also helps in safe medication management and improving quality of care across multiple disciplines of healthcare systems [16-29]. In

addition to preventing MEs, EPS lowers readmission rates, reduces the number of MErelated claims, and increases the prescription of generic medications, improves communication about medications, supports clinical activity through interaction with knowledge sources, and improves clinical decisions at the point of prescribing and administration [12-18]. When EPSs are implemented, healthcare providers and managers tend to experience higher job satisfaction as there is improvement in work efficiency [12-14]. Furthermore, atmosphere is less stressful and there is more cooperation and effective. meaningful communication between professionals, technical staff, and patients [29,30]. However, electronic prescribing introduced new types of MEs together with challenges and potential risks to patient safety [31-39].

There are many opportunities and challenges to electronic prescribing. EPSs facilitate the patientcentered role of pharmacists in medication review and treatment plans, review of patient response, identification of optimum dosage forms, patient education and counseling, improving accuracy of medication dispensing on hospital discharge, and communication of ongoing pharmaceutical care needs [40-42]. Thus, EPSs help to improve pharmacists' contributions to the clinical care of patients. As a result, pharmacists are able to spend more time serving patients in in-and out-patient settings [43-45]. Challenges and weaknesses of EPSs need to be addressed. For instance, those first beginning to use EPSs tend to experience difficulties with formulary checks and RxH documentation, which are associated with prescriber distrust and unwillingness to rely on EP-based information [46]. Greater accuracy and completeness must be assured if EPSs are to meet their objective of improving the efficiency and safety in PHCs and other settings [46]. Another example concerns faxed eprescriptions. If computer software such as Sure Scripts sends prescription faxes to community pharmacies [40], those pharmacies may not accept these prescriptions because they have not seen a computer-faxed prescription with an electronic signature before. This problem, however, can be easily addressed through widespread education programs.

The importance of staff training and increasing public awareness of EPSs cannot be overemphasized. The public and patients need continuing awareness campaigns about EPSs.

Initially, the country that adopts EPS needs to make a huge investment not only for the purchase of a comprehensive, qualified and fully functional EPS software but also for the continued training of health staff, systems changes and the mounting of public-awareness campaigns [40,47-50]. Returning to pharmacist's handling of prescriptions, rather than searching through faxes and voicemails, pharmacy staff could check e-prescriptions directly sent to their computers and dispense medications to the patient. Another challenge for EPSs concerns medical errors. MEs have detailed taxonomies [44-46,51], multiple etiologies [52,53], and relevant pre- and post-EP era issues. The development of EPSs to capture all forms of MEs, then, is a daunting task. However. continuing advancements information technology offer strategies that can help to implement clinical practice guidelines [54]. Furthermore, an interesting tool has been built to develop collaboration between patients and physicians that allows the physician to make well-informed and safe EP decisions based on personal medication records contributed by the patient [55].

The Institute of Medicine [IOM] reports [43-44] galvanized the interconnected issues of medication safety, patient safety and quality of life, medication safety management guidelines, ADEs and MEs, poor outcomes and their costs burden [8,44]. IOM reports further focused benefits of electronic health records [EHRs] and electronic healthcare systems. EPSs identify and prevent clinically significant MEs coupled with medication use across six critical processes [18,56-60]. Notably, there are several ways of categorizing MEs [44,61-63], and their prevention strategies and cost projections vary across the western world [44,64-66]. Medication errors that result in harm to patients are mostly caused by incorrect administration of medication, selecting wrong route, and dispensing wrong medications, and HAM are the most frequently reported medication in ADEs [67]. Medication errors occur at a variable magnitude in any step of medication use process that are medication selection and procurement, storage, ordering and transcribing, preparing and dispensing, administration, and monitoring and evaluating [68-70].

Medication error reporting is important from a number of perspectives including knowing its trends, causes, systems' failure, patients safety, medication safety and prevention strategies [71,72]. However, MEs are less likely to be

reported due to fear of punishment in punitive culture that holds error maker responsible irrespective of root cause. On the other hand, the blame free culture encourages reporting of errors but falls short in punishing intentional error makers including negligent and careless prescribers of medication. The "just culture" mainly focuses on the sequence of events rather than the person who made the error and punishes negligent / reckless behaviors of error makers, thus results in better error reporting, helps in preventing MEs and ADEs and also seeks to understand risk [73,74].

1.1 King Saud Medical City

King Saud Medical City is a tertiary care and referral hospital in Riyadh capital city, KSA. This medical city has 1400 bed capacity and comprises of general, pediatric and maternity hospitals together with intensive care unit (ICU), artificial kidney unit (AKU), human immunodeficiency virus (HIV) centre and dental clinics. The campaign for improving medication safety and patient safety in KSMC were formally started in Jan 2012. Pharmaceutical care staff assessed strength, weaknesses, opportunities and threats [75] of present pharmacy scenario for bringing about change that is designed to help healthcare professionals to identify potential risks to medication safety, prevent medication errors, ensuring patient safety and improving quality of healthcare. Medication Safety Coordinators [MSCs] especially pharmacists from Pharmacy Department and Drug Poisoning and Information Center (DPIC) used relevant materials and tools to pinpoint specific system weaknesses (lack of awareness campaigns about prescribing system, error reporting, medication errors makers and barriers to error reporting, role of HIT) in the medication-use processes in order to provide a starting point for successful organizational improvements. The newly formed team started initiatives to improve medication safety by collaborative approach [76] based on stakeholders including multidisciplinary physicians, nurses, pharmacists and healthcare users after baseline assessment for safe medication management at King Saud Medical City [KSMC]. Medication therapy management service model 2.0 have five core elements in version 1.0 including medication therapy review, personal medication record [PMR], a medication-related action plan [MAP], intervention and referral, and documentation and follow-up with redesigning of the PMR and MAP to be more "patient friendly," effective, and

efficient for patients to use in medication selfmanagement [76] and possibly this model is equally applicable to hospital pharmacies.

1.2 Principles of Safe Medication Management and Use

Safe medication management should include safety of patient, access to appropriate medication. electronic prescribing svstem. effective communication among staff, and availability of competent healthcare professionals including pharmacy workforce [76-78]. Several approaches to safe medication management include: access to appropriate medicines, good decision support and defined risk management steps, integrated and standardized system tools and software, good processes to support staff at each step in medication management pathways, and staff training and pharmacy capacity building with multiple competencies [76-79]. Medication use processes in which MEs are reported to occur were identified; medication selection and procurement, storage, ordering, transcribing, preparing and dispensing, administration, monitoring and evaluation [68-70]. Medication safety coordinators identified the medication safety initiatives [8,44,79] in a couple of formal meetings, discussions and workshops then they collaboratively developed a comprehensive action plan. Subsequently. medication safety committee (MSC) conducted education and orientation sessions for healthcare professionals on monthly basis. This was to ensure that a better medication safetv environment [80] associated with better health quality outcome is nurtured at KSMC. Safe medication milieu is characterized by a healthy reporting culture, regular discussions of near misses. MEs and ADEs, education strategies. well designed delivery and storage processes. and renovated environment [80]. In addition, medication safety management staff conducted regular rounds of wards and outpatient clinics for assessing the compliance of healthcare professionals regarding MSU programs.

1.3 Medication Safety Unit and Programs

The medication safety unit supported by a team of medical, pharmacy, nursing and administrative staff was established in KSMC in year 2012. This developmental national agenda was driven by health issues especially patient safety, safe medication management, quality of care, patient and health provider satisfaction, observational research results, rising medication errors

occurrence, incident analysis, and continual stakeholders' input [47-49,76-80]. Notably, MSU is reported to increase patient safety through collaboration and systems improvement in medication management processes across the healthcare continuum [68-70,80]. MSU developed the following activities / tasks; 1) to deal with and monitor ME occurrence and reporting through EPS, 2) adverse drug events (ADEs) reporting and documentation, 3) to manage HAMs and prohibited abbreviations, 4) documentation of patient allergy, 5) to develop educational materials, posters and brochures for training and campaign awareness purpose, 6) to make checklist of MSU for weekly inspection, and 7) to create a blame free culture for reporting medical incidents-ME and near misses [18,56-60,67,71-74]. These activities of MSU will have an impact on medication safety and improve patient safety and quality of health care services [68-70,80].

Medication safety unit developed the following programs; 1) medication safety program proposal, 2) medication safety committee time reference, 3) data statistics of medication error rate before and after implementation of medication safety program in May 2012, 4) annual medication safety action plan to improve safe medication management and this plan has been reviewed and approved by pharmacy and therapeutic committee [P&TC] in KSMC, 5) medication error reporting program, 6) a tool to analyze sentinel events. Briefly these programs are highlighted in below section. Overall, pharmacy department of KSMC developed processes and identified behaviors related to medication management system that determines the way that medications are used or handled by patients, pharmacy personnel, and healthcare organizations [79-80]. Consequently, pharmaceutical medication services galvanized to maximize benefit and substantially minimize harm to patients as a result of safe medication management [76-78]. Multi-faceted approach was used to reduce harm with standardization of specific high risk medicines or processes, risks at interfaces of care, staff medication management skills development, and use advanced health information technology to support safe pharmacy practice and pharmaceutical care [71-74,78-80]. In a related development, four common methodologies in terms of incident report review. direct observation, chart review, and trigger tool were identified for the assessment of safe medication management [81].

1.4 Programs Objective

The medication safety unit program objective are: 1) to establish an organizational authority for identifying responsible individuals and groups. 2) establish criteria, guidelines, treatment protocols and standards for patient safety and safe medication management, 3) to educate health care professionals including pharmacists, physicians, and nurses to promote the use of criteria, guidelines, and standards of patient and medication safety, 4) to reduce MEs and medication-related serious conditions through a systematic approach, 5) to develop good interprofessional coordination and collaboration and implementation of a continuing improvement approach to enhance patient safety and proper reduce management, 6) medication to medication-related morbidity and mortality, 7) to improve patient care by identifying, analyzing, and reducing the risks of ME and medication related injury or impairments to in-and out-patient population.

These objectives were linked with multiple purposes of medication safety program utilization by pharmacy department and DPIC, 1) to initiate a risk assessment process to identify systembased medication safety improvements in the hospital setting, 2) to use Institute of Safe Medication Practices (ISMP) key elements of the Medication Use System™ and other medication tools received from the Central Board for Accreditation of Healthcare Institutions (CBAHI) accreditation to help identify and prevent risk in daily practice. 3) to examine flow diagrams and flow phases of medication processes to identify variability in current medication-use in different areas of patient care, 4) to select effective medication error reduction strategies that can prevent patient harm, 5) to collect data for identifying medication error trends, 6) to apply all key elements underlying medication safety to identify breakdowns / failures in the system that have contributed to the medication errors / near misses, and 7) utilization of collected data for medication errors or near misses since 2012 for improving safe medication management processes and publication of reports in international. The MSU programs aligned with international data were tailored to achieve various objectives that focused mainly on patient safety, safe medication management and risk assessment, training of staff, and reduction in MEs associated with ADEs in healthcare settings [4-79-12,9,43,66,77,82-87].

1.4.1 Medication safety program - designed guidelines

The pharmacy staff, DPIC technical workers, nursing personnel, and medical professionals searched the relevant literature collaboratively developed guidelines for the following components of safe medication management; 1) medication use system, 2) high alert medications, 3) LASA medications, 4) drug drug interactions and drug-food interactions. 5) storage of medications. 6) medication administration. 7) multi-doses medication stability, 8) IV medications administration, 9) medication use through IV drips and IV push, 10) minimize medication errors to bγ computerized physician order entry (CPOE) support system, 11) handling of hazardous medications, 12) medication safety data sheet and nutrition stability during administration, and 13) drug and pregnancy [9-10,25,31,68-71,79-80,86,88-98]. The respective guidelines are the core components of MSU annual plan described briefly in subsequent section [detailed policies, guidelines and annual medication safety action plan are available from IAAZ and DSAD upon request].

2. METHODS

2.1 Search Method

Computer searches were made using keywords, which included medication safety unit, and safe medication management, and these words were combined with patient safety, quality care, pharmacy care, medication errors, quidelines. medication error reporting, computerized physician order entry, and outcome. We used PubMed, Google Scholar, and Ovid SP search engines and retrieved more than 15,600 articles published over a period of 15 years, from 2000 to 2014. Two authors [NAQ & DSD] qualitatively reviewed these articles and selected 140 articles based on the following criteria; published in local and international English literature; available abstract or full article or both; articles' focus on medication safety management and medication safety unit in hospitals; book chapters; good quality papers; systematic reviews, metaanalysis and randomized clinical trials (RCTs). The studies were excluded due to: duplication; neither abstract nor full article available; editorials, case reports, and correspondences; unrelated articles; and published in non-English literature. Thus, a total of 136 sources were included for supporting our medication safety unit programs and roles / purposes and annual plan

together with adaptation and development of policies, procedures and guidelines for safe management and use of medications, safety of patients, good quality healthcare and outcomes. So this was a qualitative systematic review, which finally included 136 studies. Notably, the research team retrieved the collected data from pharmacy department / MSU for patients counseled in pharmacy clinics (3-month data of 2012) and medication errors reporting over a period of 4 years (2010-2013). In addition, KSMC medication safety systems were assessed using ISMP Medication Safety Self-Assessment tool [99]. The related detailed methodology of collecting ME reporting and analyzing data is described elsewhere [47-49]. Overall, the design of this study reflects a mix-method, qualitative and quantitative.

3. RESULTS

3.1 Medication Safety Management Programs

3.1.1 ISMP medication safety self-assessment® for hospitals [99]

This assessment, carried out in July 2011, was the baseline for Medication Safety Initiatives in KSMC. The assessment was conducted to assess the Medication Safety System at King Saud Medical City. Subsequently, based on assessment results the medication safety programs and improvement projects were developed. Table 1 summarizes the ISMP Self -Assessment Report of KSMC. Notably, the USA Institute for Safe Medication Practices (ISMP) is highly committed to ME prevention and safe medication use. Overall, the assessment of medication safety at KSMC was below the standard especially for the following highlighted issues: patient information related to medication safety drug monitoring and pharmacovigilance: drugs, drug concentration, dose and administration time; procurement, maintenance, use and standardization of medication, devices for medication deliverv: use and staff competency and education. Consequently, the implementation of medication safety programs impressively improved these elements in KSMC.

3.1.2 ISMP medication safety selfassessment® for antithrombotic therapy

Using ISMP, self-assessment was conducted to evaluate the antithrombotic therapy [71-74,78-80,

96,100], as one of the important medication safety issues at King Saud Medical City in July 2011. The overall score of the assessment was 16.5% (139 out of 838). Some of the key elements scored 0% such as pharmacy staff competency, education and training, quality processes, and risk management. The result of the core characteristics of each key element helped pharmacy team to implement the following at KSMC: 1) develop an antithrombotic program at KSMC, 2) establish inpatient and outpatient antithrombotic expert team, implementation of the developed program, among others, by at least one clinical pharmacist, 4) develop and implement guideline for antithrombotic therapy, and 5) monitor and evaluate the progress.

3.1.3 Proper handling of high alert medication [HAM] program

A number of meetings attended by medical staff and allied personnel including pharmacists, nurses and administrators were organized for high alert medications. Accordingly a list of HAM was prepared, to be regularly updated by pharmacy coordinators. Safe cabinets were provided for HAM storage so that HAMs are separated from other medications. For further enhancing medication safety, proper labeling systems were used, which include; red label, special red flag, and using of Tallman lettering [101]. Electronic prescribing system already in place in KSMC incorporated red warning messages and alerts, which help substantially in preventing ME [16,71]. Besides automated dispensing cabinets, Bar code technology is reported to considerably reduce ADEs [102,103].

3.1.4 Look alike and sound alike (LASA) drug program

Similar procedures including meetings and 2-mini workshops were used in identifying and listing LASA drugs and responsible pharmacists made a LASA list using Tallman lettering [101]. In addition, special labels were used to differentiate and identify LASA medications. Furthermore, physical separation was also done for look-alike medications. Notably, LASA medications cause confusion among dispensers and also result in MEs and near misses [101.104]. One in four MEs (25%) is caused by LASA medication confusion [104]. Notably, patient safety is compromised and medication mismanagement happens if LASA medications are not separated physically medications. Furthermore. from other

pharmacists double check LASA medications, a ME preventive strategy, and other technological (systems group) and risk management solutions before dispensing them to patients discharged from hospitals [105]. It is to make sure that correct medication is given to the patient and preventing any drug related adverse problems.

3.1.5 Crash cart inventory program

Pharmacists, DPIC staff, nurses and physicians discussed a number of times Federal Emergency Management Agency (FEMA) [106] projects for understanding its underlying principles for crash cart inventory checklist. Designated pharmacists with the help of the Code Blue Committee daily update the crash cart medications list. At the same time, a comprehensive crash cart checklist was developed for use by pharmacy and nursing staff for daily and monthly checking of crash cart. Simultaneously, a number of workshops were organized for training pharmacy staff, nurses and administrators for the new processes and changes concerning crash cart inventory checklist and related safe medication issues during times of disasters, crises emergencies in hospitals [107]. According to this study, both human factor engineering (HFE) and usability in context of code cart design are effective and can affect patient safety by saving valuable time and reducing wasted effort including errors during code situations [107].

3.1.6 Approved and prohibited abbreviations program

A number of meetings among designated staff pharmacy, nursing, medicine administration were held to discuss and make a list of approved and prohibited abbreviations with a recommendation to update it regularly. The prepared list was distributed among all concerned staff of KSMC. The concerned team also developed special cards with the list of prohibited abbreviations placed at the notice board of various departments and distributed among prescribers and dispensers medications in KSMC. There are seven evidence-based dangerous prohibited abbreviations (Table 2) should never be used in clinical practice; use of such abbreviation is discouraged through education rather than enforcement. Ultimately avoidance of prohibited abbreviations by 75% as advocated by the Joint Commission (JC) and ISMP is associated with reduced MEs, better outcome and enhanced patient safety [108].

Table 1. Summary of the ISMP self-assessment report of KSMC

| Key elements | Core characteristic | Score | T. score |
|---------------------------------------|---|----------------|-----------------|
| 1.Patient info | Core Characteristic #1Essential patient information is obtained, readily | 63/166 (38%) | 63/166 (38%) |
| | available in useful form, and considered when prescribing, dispensing, | | |
| | and administering medications and monitoring its effects | | |
| 2.Drug info | Core Characteristic #2 Essential drug information is readily available in | 73/176 (41%) | 127.5/252 (51%) |
| | useful form and considered when prescribing, dispensing, and | | |
| | administering medications, and monitoring the effects of medications. | | |
| | Core Characteristic #3 A controlled drug formulary system is established to | 54.5/76 (72%) | |
| | limit choice to essential drugs, minimize the number of drugs with which | | |
| | practitioners must be familiar, and provide adequate time for designing | | |
| | safe processes for the use of new drugs added to the formulary. | | |
| 3.Communication of drug orders and | Core Characteristic #4 Methods of communicating drug orders and other | 77/114 (68%) | 77/114 (68%) |
| other drug info | drug information are streamlined, standardized, and automated to minimize | | |
| | the risk for error. | | |
| 4. Drug labeling , packaging, and | Core Characteristic #5Strategies are undertaken to minimize the | 25.5/52 (49%) | 43.5/92 (47%) |
| nomenclature | possibility of errors with drug products that have similar or confusing | | |
| | manufacturer labeling/packaging and/or LASA drugs. | | |
| | Core Characteristic #6 Readable labels that clearly identify drugs are on | 18/40 (45%) | |
| | all drug containers, and drugs remain labeled up to the point of actual | | |
| | drug administration. | | |
| 5. Drug standardization, Storage, and | Core Characteristic #7 IV solutions, drug concentrations, doses, and | 4/42(10%) | 86.5/224 (39%) |
| Distribution | administration times are standardized whenever possible. | | |
| | Core Characteristic #8 Medications are provided to patient care units in a | 19/36 (53%) | |
| | safe and secure manner and available for administration within a time | | |
| | frame that meets patient essential needs. | | |
| | Core Characteristic #9 Unit stock is restricted. | 55.5/123 (42%) | |
| | Core Characteristic #10 Hazardous chemicals are safely sequestered | 8/14 (57%) | |
| | from patients and not accessible in drug preparation areas. | | |
| 6.Medication device acquisition, use | Core Characteristic #11 The potential for 'human error' is mitigated | 33/140 (24%) | 33/140 (24%) |
| and monitoring | through careful procurement, maintenance, use, and standardization of | | |
| | devices used to prepare and deliver medications. | | |
| 7.Environmental factor, workflow, & | Core Characteristic #12 Medications are prescribed, transcribed, | 31.5/54 (58%) | 89.5/138 (65%) |
| staffing patterns | prepared, dispensed, and administered within an efficient and safe | | |

| | workflow and in a physical environment that offers adequate space and lighting, and allows practitioners to remain focused on medication use without distractions. Core Characteristic #13 The complement of qualified, well-rested practitioners matches the clinical workload without compromising patient safety. | 58/84 (69%) | |
|--|---|---------------|---------------|
| 8.Competency & staff education | Core Characteristic #14 Practitioners receive sufficient orientation to medication use and undergo baseline and annual competency evaluation of knowledge and skills related to safe medication practices. | 51/92 (55%) | 75/162 (46%) |
| | Core Characteristic #15 Practitioners involved in medication use are provided with ongoing education about ME prevention and the safe use of drugs that have the greatest potential to cause harm if misused. | 24/70 (34%) | |
| 9.Patient education | Core Characteristic #16 Patients are included as active partners in their care through education about their medications and ways to avert errors. | 47/70 (67%) | 47/70 (67%) |
| 10.Quality processes & risk management | Core Characteristic #17 A safety-supportive 'just culture' and model of shared accountability for safe 'system design' and making safe 'behavioral choices' is in place and supported by management, senior administration, and the Board of Trustees/Directors. | 81.5/198(41%) | |
| | Core Characteristic #18 Practitioners are stimulated to detect and report ADEs, MEs and close calls, hazards, and observed 'at-risk behaviors', and interdisciplinary teams regularly analyze these reports as well as reports of MEs that have occurred in other organizations to mitigate future risks. | 107/158(68%) | 248/492 (50%) |
| | Core Characteristic #19 Redundancies that support a system of 'independent double checks' or an automated verification process are used for vulnerable parts of the medication system to detect and correct serious errors before they reach patients. | 47.5/108(44%) | |
| | Core Characteristic #20 Proven infection control practices are followed when storing, preparing, and administering medications. | 12/28(43%) | |

Key elements highlighted in gray and light gray color need improvement; 2011 Self-Assessment Total (KSMC) = 890/1850 (48%)

3.1.7 Medication errors and near misses program

Medication errors encountered in all age groups due to unsafe management of medications, lack of HIT integration in health system, and the lack of medication safety and quality assurance programs cause serious disturbance in patient safety [109-113]. Electronic prescribing system [EPS], one of the main preventive strategies in this direction is in place in KSMC since 2006 [47-49]. Notably, handwritten prescription errors are prevented by 50% using EPS [114]. The pharmacy team, DIPC staff and administrators developed a process for MEs and NMs reporting and trending. The salient features of this system include: voluntary reporting MEs to MSU in a blame free culture and safe management of medications (Fig. 1). For this purpose, there is a special ME / NMs reporting template; data collection related to MEs and NMs from pharmacy and inpatient care units; monthly data analysis with a focus on knowing the trend, stages and the areas for further improvement; develop and execute an action plan to prevent the occurrence of MEs and NMs / CCs across multiple stages. In addition, the concerned staff collaboratively develops educational posters to demonstrate the trend in MEs and NMs to be shared among all healthcare providers for further improving medication management and patient safety. Every reported ME is investigated by a multidisciplinary team that uses root cause analysis [RCA]. Furthermore, research team published a number of papers on MEs and NMs / CCs in KSMC in international journals [47-49,114].

3.1.8 Adverse drug reactions (ADRs) program

The ADRs differ from ADEs; adverse drug events (preventable) are medical occurrences temporally associated with the use of a medicinal product, but not necessarily causally related whereas ADR (non preventable), included in manufacturer's prescription information, means an (injurious) response to a drug which is noxious and unintended, and which occurs at doses normally used in man for the prophylaxis. diagnosis, or therapy of disease, or for the modifications of physiological function [115] and more detailed information about the definition of these terms are discussed here [44,70,116]. The pharmacy team developed a program for ADRs with the following objectives: voluntary reporting of ADR to pharmacy department; to collect the data using the adverse drug reaction template; to analyze the data on monthly basis to know the trend; to communicate with Saudi Food and Drug Authority (SFDA) if required; to develop educational materials for training concerned personnel and posters to be placed on notice board at KSMC. This program is included in the policy and procedures of KSMC.

Table 2. Seven prohibited abbreviations

| Dangerous prohibited abbreviations | Approved use |
|------------------------------------|----------------------|
| IU | Unit |
| U or u | Unit |
| QD or qd | Daily |
| QOD or qod | Every other day |
| Zero after decimal | 1 mg (never use |
| point, i.e., 1.0mg | zero after decimal) |
| No zero before decimal | 0.6mg (always use |
| point, i.e., .6mg | zero before decimal |
| | point |
| Drug name | Always write |
| abbreviations | complete spelling of |
| | generic drug name |

More info: <u>www.intranet.Capitalhealth.ca/rgo</u> [108]

3.1.9 Drug storage program

The pharmacy team with the help of designated physicians, nurses and administrators developed a new Inventory Control Policy for automatic dispensing and restoring medications safely in KSMC, which is associated with smooth dispensing medications, a reduction in MEs, easy costing of services, less financial burden, and enhanced patient safety and this is in line with recommendations of this survey [117]. Another study from Canada reported similar but limited benefits and recommended that to realize the full impact of decentralized automatic dispensing devices [ADD], hospitals need to assess their current systems and the benefits before implementing any change [118]. The pharmacy key leaders assigned Quality Pharmacy Team (QPT) to conduct weekly check of medication store and storage of medications in KSMC. Furthermore, team key leaders also distribute key tasks among members of QPT. Notably the QPT members collaboratively developed multi-dose medication stability guidelines auidelines. and prevent transmission of blood borne pathogens / diseases or other microbial agents contaminants to patients as a result of unsafe injection, infusion, and medication vial handling practices [119]. In a related development, drugs administration aids [DAAs] that use repackaged drugs in stable form in patients with chronic diseases help in enhancing adherence, associated with good outcomes like glycemic control and reduction in MEs in health settings [120].

3.1.10 Handling Pro Re Nata [p.r.n] program

The pharmacy team discussed with assigned physicians, nurses and administrators the use of p.r.n. orders given by physicians in hospital settings including emergency departments. ICUs p.r.n. inpatients. Notably. orders unintentionally create confusion and misunderstanding among patients [121] and pharmacy staff often contacts physicians for p.r.n. clarifications and thus efficiency of pharmaceutical work is decreased. Therefore, the pharmacy team developed a p.r.n. order policy and procedures [all guidelines, policies and procedures about all programs available from IAAZ upon request] for appropriate prescribing of medications and decreased use of p.r.n. A study found that a significant decrease in p.r.n. use of psychotropic and non psychotropic mediations can be achieved safely based on clinical feedback of relevant data. Furthermore, this decreased p.r.n. use was associated with decreased seclusion and restrain events but no change in violent events in a state psychiatric hospital [122] and other researchers called for more research as evidence for benefits of p.r.n. use of medications are limited [123]. The designated pharmacy staffs educate and orient regularly new medical staff and nurses on p.r.n. policy and procedures. Furthermore, pharmacy staff developed monitoring mechanisms for preventing routine and overuse of p.r.n. orders, which are often associated with polypharmacy. However. p.r.n. psychotropic medications is reported to be effective in managing violent patients having severe psychiatric disorders including intellectual disabilities [124]. Arguably, p.r.n. orders are reported to cause MEs, retard the work of nurses and pharmacists and result in patient harm [125]. Several studies have reported cautious use of p.r.n. medications across healthcare settings [121.125].

3.1.11 Patient medication counseling program

Pharmaceutical Care Department in collaboration with DPIC and KSMC administration established a patient counseling program. The primary aim of this program is to provide counseling services to patients who demonstrate many concerns about

medication use, with or without problems. Initially this program is supported by 10 clinical trained in counseling pharmacists. designated to cover specific inpatient units in and discharged patients from general hospital. Later, this program was expanded to cover outpatient services and counseling team included trained clinical pharmacists affiliated to pharmaceutical care. For achieving this purpose, a number of counseling clinics were opened in pharmacy and outpatient settings. Notably, patients collecting prescribed medications often have some queries. doubts and need clarifications and discussion with the competent pharmacy staff. The consulting counseling clinics and related staff subserve formally this function. Seventy eight male and female patients were counseled during three month period (Figs. 2 & 3) in 2012. Notably, MEs tend to occur frequently at discharge, making discharge counseling a vital component of medication reconciliation. Furthermore, counseling to discharge inpatients and by extension to outpatients with prescribed drugs, a recognized patient safety initiative for which pharmacists have appropriate expertise is associated with a variety of advantages including reduced MEs, enhanced patient satisfaction, decrease in post-discharge readmission and good adherence and better outcomes [126-128]. Nonetheless, in Canadian healthcare context several barriers to discharge counseling to be overcome strategically reported in one study were time constraints, and failure to notify pharmacist about impending discharge and the former related to clarification of prescriptions, creation of a medication list, and faxing of prescriptions [129].

3.1.12 Standard drug administration schedule

The designated pharmacy team which included pharmacists, physicians, nurses, administrators developed policy and procedures for standard drug administration schedule, which include doses, frequency, route, continuous versus intermittent, and timing. The related guidelines are included in the policy and procedure document. The team regularly updates standards administration time schedule for medications during holy month of Ramadan (Fasting) annually. There are many reported advantages of drug administration schedule; adherence to medication is better with once-daily than more frequently scheduled medication regimens in patients with chronic disease [130]: drug scheduling models in the quest for a cancer cure [131]; minimize the development of acquired resistance to therapy [132]; optimal effectiveness of a drug and avoidance of toxic or adverse effects [133]; confer prophylactic benefits and prevention of drug-induced complications like polyuria [134]; and adequate control of disease such as hypertension with no adverse CVD events such as stroke, and end-organ damage [135] and others.

3.1.13 Implementation of medication safety program - annual action plan 2012

This medication safety action plan (Table 3) was prepared with the help of experts drawn from different departments of KSMC. In addition, the team used human resources for executing all 14 components of this MSU action plan. The main active players in planning and executing this plan are acknowledged at the end of this paper. The annual action plan focuses on how to manage safe medication use, to reduce MEs and NMs by

95% in 2013, to increase NMs / MEs reporting by 50% in the first quarter of 2013, to train concerned staff for enhancing their knowledge in safe medication management, related policy and procedures, and guidelines, to educate patients and their families in safe use of medications at home. This medication action plans operational from February 2013 and would be fully implemented over a period of one year. Members of Medication Safety Unit conducted staff education and orientation programs for the implementation of all the projects as per the annual Action designed Plan. Subsequently, both designated personnel from medication safety unit and total quality management department monitored progress, solved obstacles encountered and evaluated the implemented projects and accordingly applied modifications if required.

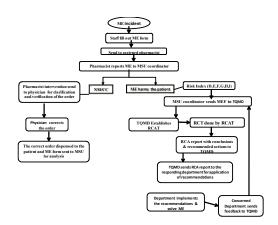
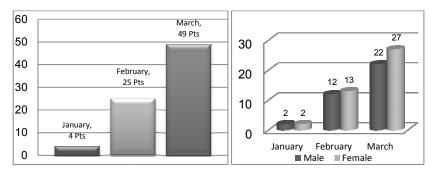


Fig. 1. ME reporting and RCA flow chart



Figs. 2 & 3. Number of patients and distribution by gender counselled, Jan to March 2012

Table 3. Annual medication safety action plan 2012

| Action/steps* | Status |
|---|--|
| 1- ME reporting and documentation, | 1) Educational sessions for MEs documentation and reporting were given to all physicians and pharmacists, 2) MSU and DPIC staff delivered lectures on ME program to old and new nurses weekly, 3) A blame-free culture is established with annotation "No blame & no punishment" on the top corner of MEs form, supported by CEO and legal department. |
| 2- CCMs Guidelines. | 1) The quality pharmacist check CCMs and CC checklists monthly, 2) Nurses check CCMs daily and replace both used drugs after blue code and expired drugs monthly, 3) New medication crash trolley were distributed to all departments with no trolleys, 4) CPR committee approved emergency prefilled syringes added to the CCMs list in June 2012. |
| 3- MEs | 1) Policies and procedures of Medication Management and Use [MMU] developed and implemented, 2) Prohibited abbreviations, HAMs and LASA lists distributed to all departments, 3) Education sessions to all healthcare providers continued monthly, and 4)1- day symposium on MMU was organized in April 2013. |
| 4. Education and Information dissemination. | 1) New staff received orientation and in-service mandatory Education &Training on safe MUS, 2) Safe MUSM annual was distributed to all nursing units and also placed in the electronic document system [EDS], 3) One day safe MUS training for concerned staff and family members started in March 2013. |
| 5- KSMC | KSMC Pharmacy Services Newsletter was launched in April 2013. |
| Newsletter. 6. Drug Protocols and Standard Order Forms. | 1) A team standardized the drug protocols and standard order forms, 2) Drug protocols for HAMs were developed, and 3) standard dosing for HAMs were developed. |
| 7- Independent Double Check Systems. | 1) Policy, manual redundancies and checklist were developed in February 2013, 2) New nurses, pharmacists, and physicians received orientation, education and training on competency skills, 3) verification of the policy, manual redundancies and checklist. |
| 8- Rules, Policies, and Guidelines. | 1) Current medication safety policies and procedures were reviewed and revised, 2) New policies and procedures for medication reconciliation [MR] were developed, 3) All new and re-contracted staff received orientation, education and training on competency skills, 4) verification and check off on the policies and procedures. |
| 9 - Automation and computerization. | 1) Set a meeting with the Board of Directors, CEO, and Senior Managers and HIT directors for developing online computerized drug information systems and CPOE guidelines, MEs and ADEs monitoring, 2) Set a meeting with biomedical engineers regarding smart IV infusion pumps, automation dispensing devices [ADDs] and bar coding products. |
| 10 - Medication Safety Program. | 1) Interdisciplinary Patient Safety teams were formed to prevent harm from HAMs, ADEs, MEs, verbal and telephone orders, and concentrated electrolytes using MR tool, 2) Teams developed implementation toolkits based on evidence practices. |
| 11- FMEA Tool. | The team has performed FMEA for concentrated electrolytes. |
| 12- Forcing Functions and Constraints. | A meeting with nursing staff on monthly bases since 2013. |
| 13- DHP. | Hospital drug formulary updated. |
| 14- Staffing plan. | All department heads submitted the plan of staff and scope of services to the TQMD in March 2013. |

*highlighted in below sections

3.1.14 ME reporting and documentation guideline / action

The following recommendations were made to increase MEs documentation and reporting; 1) Implementation and monitoring of MSU in KSMC; 2) Establish BLAME FREE culture or just culture; 3) Educational and awareness sessions for all healthcare providers to improve MEs detection and reporting; 4) Healthcare providers should be motivated to report MEs; and 5) ME report flow chart developed and implemented in KSMC. The reporting of medication errors / adverse events. post MSU establishment, increased substantially over a period of three years; year 2010 (n=121); year 2011 (n = 305), year 2012 (n = 3491) and year 2013 (n = 12982) (Fig. 4) attributed to effective functioning of MSU and organized campaigns for MSU programs on multiple occasions within KSMC.

3.1.15 Cart crash medication guidelines / action

Implement system for improving the CCMs for the following, 1)- Identify and update appropriate drugs in prefilled syringes used in emergency situations, 2) keep the CCMs complete after each code blue, 3) Standardization of all CC Checklists in all patients settings using mapping system, 4) Designated nurses check CC checklists for its completeness and expiry date every shift with legible signature together with random check by the code blue committee, 5) All drawers must be kept locked, 6) Medications for the need of pediatric and maternity hospital added to CCMs.

3.2 Medication Error Guidelines / Actions

3.2.1 For prescribers

Prescribers should write; 1) a complete prescription, clear, unambiguous order that must include patient three names, drug name, dosage form, strength, dose, route, diagnosis, weight for pediatric orders, frequency and rate of medication administration, 2) They should not use all prohibited abbreviations or unofficial drug names listed by KSMC, 3) they should write the indication, duration and frequency for p.r.n. medication orders, 4) avoid illegible handwriting, 5) Minimize to the least telephone and verbal orders excepting emergency or life-saving situations, 6) document drug allergies in patient file and in electronic prescription, 7) notify the clinical pharmacist for follow up of patients on

drugs with narrow therapeutic index and dosage adjustment for renal or hepatic failure patients.

3.2.2 For pharmacists

Pharmacists should do; 1) independent double checking, 2) label medications properly, 3) use auxiliary red labels for HAMs, 4) take extra care while dispensing HAMs, 5) increase awareness among users and providers about "LASA" medications, 6) minimize floor stock medications, 7) remove concentrate electrolytes from floor stock. 8) carry out monthly inspection of crash cart medications and floor stock drugs, 9) check expiry date of drugs and use the rule - first expired first dispensed, 10) identify the patient by using three names and file number, i.e., medical registration number (MRN), 11) avoid dispensing incomplete prescriptions and orders containing abbreviations, 12) prepare prohibited chemotherapy medications in the pharmacy.

3.2.3 For nurses

Nurses should follow; 1) confirm patient identity by three names & MRN, 2) check the identity and integrity of dispensed medications, 3) compare the prescribed and used medications with doctor's order and the medication sheet. 4) use and restrict to standard administration time, 5) always double check calculations and action rates of critical and HAMs, 6) document all administered drugs in nurse medication sheet, 7) label all prepared syringes with the patient name, drug name and total dose, or prepare the syringe at bedside and administer its contents immediately and never use any unlabeled product, 8) do not carry out verbal orders and follow the policy and procedure of telephone and verbal orders.

3.2.4 Training and information dissemination guidelines / actions

MSU designated staff should do; 1) collaborate with the Training & Education Academic Affairs Department (TEAAD) to include the medication management programs (MMP) for orientation to all new staff in the hospital, 2) update education and training program [ETP] calendar annually and incorporate medication use system (MUS) in the monthly ETP, 3) develop learning modules for each topic related to safe MUS, 4) compile all the learning modules to develop a safe MUS manual for distribution among nursing, pharmacy and medical staff, 5) develop an online ETP for MUS in collaboration with HIT, 6) conduct MUS

sessions to new and old healthcare providers, 7) MSU will deliver a safe MUS session for all new general practitioners, 8) patient with discharged medications should be counseled regarding its use, side-effects, adherence and regular follow-up if needed together with instructions to family members to help patient in proper medication use.

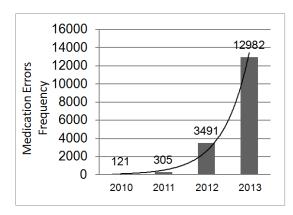


Fig. 4. Distribution of reported MEs by year

3.2.5 KSMC newsletter development

MSU staff should follow; 1) create a team to develop a quarterly Pharmacy and DPIC services Newsletter, 2) the specific sections in the newsletter should relate to epidemiology, causes, prevention and intervention strategies for MEs, D-DIs, and NMs and food-drug interactions (FDIs). 3) In addition, these sections should address good lessons learned from reported MEs, ADEs, ADRs, and NMs. 4) the newsletter should have encouraging messages and strategies for the staff for reporting MEs, ADEs, ADRs, and NM. 5) The newsletter should also include a note on regular basis about BLAME FREE / JUST CULTURE and its impact on ME reporting, and PATIENTS' RIGHTS-right treatment with respect, understanding and compassion, supportive care, and transparency and basics of medical professionalism, and 6) the Newsletter should contain a list of LASA. prohibited abbreviations and HAMs.

3.2.6 Development of drug protocols and standard order form / steps

MSU should do; 1) to form a team to develop, monitor and follow drug protocols and standard order forms, which will guide the safe use of medications, 2) develop guidelines for standard order sets, 3) standardize the currently used drug protocols and standard order forms.

3.2.7 Independent double check systems / steps

MSU concerned staff should do; 1) develop policy and protocol for independent double-check of HAMs, 2) two clinicians (or nurses or pharmacists) independently check and then compare results for each component of prescribing, dispensing, and verifying the HAMs before administering to the patient, 3) implement the HIT solutions such as the CPOE and bar code system (BCS), 4) implement the manual redundancies such as double checks, 5) develop checklists for independent double checks of HAMs.

3.2.8 Rules, policies, and guidelines

Multidisciplinary team should do; 1) implement and follow the International Patient Safety Goals: identify patients correctly (IPSG.1), improve effective communication (IPSG.2), and 3) improve the safety of HAMs (IPSG.3), 2) review and revise the current policies specific to the process or stage of medication use system (procurement and supply, purchase, delivery, distribution, storage, prescribing / ordering, transcribing and entry, preparation, dispensing and delivery - unit dose system (UDS), administration, monitoring and evaluation). 3) develop other policies that are not available currently. Elements are: patient information, drug information, communication of drug information, drug labeling, packaging and nomenclature, drug storage, stock, standardization, and distribution, drug device acquisition, use, and monitoring, proper handling of expired medications, HAMs use guidelines, observation / monitoring of patient after medication use, use of radioactive drugs or contrast media drugs, implantable prosthesis, environmental factors, staff education and competency development, patient education, quality processes and risk management, interdisciplinary team approach, prescribing privilege of medications, review and update the manuals for pharmacy services (PSs) and Safe medication use system (MUS), 4) provide each hospital and patient care area with the updated manuals, and 5) review and update the hospital formulary list and 6) Five Rights of Medication Administration was changed to 6 Rights, as follows: Right to a complete and clear order. Right to have the correct drug, route (form), and dose dispensed, Right to have access to information, Right to have policies to guide safe medication administration, Right to administer medications safely and to identify system problems, and Right to stop, think, and be vigilant when administering medications.

3.2.9 Automation and computerization

MSU staff should do; 1) encourage and justify to the Board of Directors and Senior Management to continuously implement / update HITs such as CPOE, bar-coding, smart pumps, computerized MEs and ADEs / ADRs reporting and monitoring, 2) coordinate with HIT department to embed the online computerized drug information systems, direct physician order entry, which provide drug information and warnings during order input in the pharmacy system, 3) coordinate with the Clinical Engineering Department to procure / purchase smart IV infusion pumps with safe design mechanisms to prevent free-flow, and automatic dispensing machines such as Pyxis, and Repackaging devices, 4) update upgrade EPS and its integration with Clinical Decision Support system, alert system, and availability of complete information including clinical information on admission and discharge of patients to pharmacy units.

3.2.10 Medication safety program

MSU 1) created interdisciplinary teams for the following medication safety program: a) prevent harm from HAM, 2) prevent ME and ADE from Medication Reconciliation and Verbal and Telephone orders, 3) control and monitor of Concentrated Electrolytes, 4) prevent errors from LASA medication, 5) develop guidelines or implementation toolkits for each program, 6) develop mechanism for clarification and variation of orders.

3.2.11 Failure mode and effects analysis (FMEA) tool

MSU created an interdisciplinary team to conduct FMEA for all the high risk procedures and HAMs such as anticoagulants and concentrated electrolyte.

3.2.12 Forcing functions and constraints

MSU should do; 1) remove potassium chloride injection and other concentrate electrolytes from all critical care areas, 2) minimize floor stock medications in the ward and critical care areas and 3) avoid nursing access to the floor stock in the night shift. Floor stock medication guidelines and list are available here [136,137].

3.2.13 Drug hospital formulary

MSU staff should do; 1) update DHF in collaboration with pharmacy and therapeutic committee (PTC) and distribution to all healthcare providers and 2) DHP should contain all drug monograph information.

3.2.14 Staffing plan

Each department should do; 1) should develop and create staffing plan and scope of services according to their needs and activities because shortage of medical staff leads to MEs and overload on existing staff and 2) Job description should be formulated for each medical staff.

3.2.15 Medication safety committee [MSC]

As part of MSU, MSC was formed in June 2012. A number of policies for organizing consultative meetings of this committee were developed [available upon request from IAAZ]. The MSC is comprised of 16 members and reports to Pharmacy and Therapeutics Committee [P&TC] of KSMC. The primary function of MSC is to help implement medication safety programs [MSPs] in KSMC. Other relevant activities of the committee are; to oversee reporting of MEs / NMs and ADEs; to find suitable solutions for preventing their occurrence; to review and implement the approved medication safety programs; to tailor educational material for the training of medical and allied staff including students of Clinical Pharmacy Program; to review and analyze the MEs and ADEs reporting documents and suggest recommendations to DIPC for improving the scenario; to develop MSPs with a view to continuingly update them; to review and discuss quarterly reports on MEs in coordination with P&TC and Quality & Patient Safety Improvement Committee; and finally write a draft of annual report that shows the impact of MSU programs both on the safe medication management and patient safety in KSMC. Letters of approval of Medication Safety Unit Annual Plan were drafted by the MSC. These letters were reviewed by Chairman of pharmaceutical Care and TQM Deputy Director and Director and were approved and signed by Chairpersons of P&TC, KSMC Medical Council / Asst. CEO for Therapeutic Affairs and KSMC Quality Council / CEO.

4. DISCUSSION

Medication safety unit is a powerful tool for safe medication management and use in a hospital

setting. In addition, medication safety committee in collaboration with related committees in hospitals of KSMC tend to tailor a number of medication safety programs, policies, procedures and guidelines to seamlessly manage medication cross all stages of medication use with a focus on patient safety and satisfaction. Furthermore, medication safety unit develops annually medication safety plan with concrete steps to be taken by healthcare providers, users and administrators, which is a dynamic process and needs modifications based on a number of reports of medication safety unit of pharmacy and other related departments including quality, patient safety and poisoning and information center in KSMC. Notably, all these MSU programs, tasks and tactical steps are done in alignment with evidence based data available at various scientific biomedical journal websites across the world. Though the limitation of this study is a descriptive design, the strength is that the programs are effectively applied and actions related to annual medication safety plan were taken by concerned staff in order to streamline the medication management and use with a focus on patient safety in hospitals of KSMC. This is evident from increased reporting of MEs and counseling of patients and decreased MEs occurrence in KSMC [47,114]. This study met one of the recommendations of a survey, which reported that many hospitals lack MSU programs in Saudi Arabia [113]. Arguably, the MSU programs need to be monitored and evaluated [24] to further substantiate their usefulness and possible modifications in future. This work led by medication safety team is already in progress in KSMC.

5. CONCLUSION

In summary, MSU a useful tool to manage safe medication use, encourages reporting of MEs, decreases MEs that in turn increase patient safety. Beside establishing MSU in all hospitals, this study calls for a randomized controlled study in future that identify potential human and system related factors that impact safe medication management and use associated with patient safety culture in Saudi Arabia and possibly other Arabian Gulf countries.

ACKNOWLEDGEMENTS

We acknowledge the technical support of key leaders, heads of related departments and members of various committees of King Saud Medical City.

CONSENT

It is not applicable.

ETHICAL APPROVAL

This study was approved by the Academic Department of KSMC.

COMPETING INTERESTS

Authors have declared that no competing interests exist.

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