RESEARCH ARTICLE

National Survey of Hospital Medication Safety Practice during Mass Gathering (Hajj-2016) in Makkah, Saudi Arabia: Drug Information

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Abstract

Objective: To explore the national survey of hospital medication safety during mass gathering (Hajj -2016) in Makkah, Saudi Arabia: Drug Information, the finding of ISMP (2011) self-assessment of medication safety at the hospitals. **Methods:** It is 15 days cross-sectional national survey of hospital medication safety at Makkah region. The survey modified from Institution of Safe Medication Practice (ISMP) self-assessment of hospital medication safety. It consisted of a demographic section and ten domains with 270 questions. The ten areas included patient information, drug information, communication of medication orders, drug preparation, medication distribution, medication devices, work environment, staff competency, patient education, quality process with risk management domain. The 5-points Likert response scale system used. The survey distributed to sixteen directors of hospital pharmacy during mass gathering Hajj-2016. The medications safety officer at Makkah region distributed the questionnaire and made follow up on a daily basis used physical visiting and through the telephone call. **Results:** The score of total score of all ISMP-self assessment of medication safety was 3.39 +/-0.51 (67.68 %) with CI (3.2-3.6) P< 0.05. The average of drug information domain at all hospital were 2.91+/- 0.54 (58 %) with CI (2.72-3.10), P< 0.05. The score of essential drug information was 2.84 (56.8%), and the core of the controlled formulary system was 3.09 (61.8%). The highest score of drug information key element was high-alert drugs used within the organization identified, error-reduction strategies established 4.18 (83.6%), and non-formulary products used only when therapeutically necessary and appropriate 3.55 (71%). The lowest score of essential drug information core was computerized physician order entry (CPOE) with explanation upon overriding a serious alert was 2 (40%), and standards of practice for the appropriate medication use of postoperative was 2.09 (41.8%). **Conclusion:** The drug information resources, protocol, guidelines missed at the hospital during mass gathering Hajj period. The updated CPOE with impeded updated drug information resources with alerting system highly recommended. The mandated drug information prevents any drug related problems and avoids unnecessary cost burden on health care system.

Key words: Medication Safety, Hajj, Drug, Information, Ministry of Health, Saudi Arabia.

INTRODUCTION

The ministry of health (MOH) released the new strategic planning 2010-2020 of health care in Saudi Arabia before seven years.[1] The strategic plan required a lot of changing in the MOH skeleton Administration and established new or expanded the old one. In addition to formulated several committees for all health care department including Pharmaceutical Care. The pharmacy and the therapeutic committee updated and implemented a new program that needs add a new medication to MOH formulary. The number of MOH formulary medications increased from around 500 line item to more than 1000 line items.[2] The tremendous incremental of medication therapy required several pharmacy programs to prevent medication adverse event and misadventure. The general administration of pharmaceutical Care established several pharmacy practices for that including medication safety program, pain management program, antimicrobial stewardship program, and anticoagulation program. Those programs used for all hospitals practice and primary care centers during regular days and mass Gathering hajj period. The consumption of medication increased several folds than regular days may lead high percentage of medication errors. Thus, there was the very demand of medicines safety program implementation. The program consisted of several elements including used of Institution of Safe Medication Practice; ISMP self-assessment of medication safety in the hospital. The tool is critical to scream the basic requirements of medication safety cultural with ten key element performance with emphasis on drug information. There was two studies of medication safety used ISMP self-assessment tools and conducted in the USA in 2000 and 2011 with significant improvement of most key elements. The overall score changed from 56 % to 71 %. The highest incremental changes were with communication with drug order 57.4%, patient education 41.7% and the patient information 41.2 % followed by patient information 39.5% and drug information 28.3 %.[3-5] A local study conducted in Saudi hospitals of medication safety. The authors found at 78 hospitals the drug information resources available at all patient care area was 61 %, and computerized drug information resources in the pharmacy were 43% of surveyed hospitals.[6] The study used selected items of medication safety and did not cover all ISMP key elements, and it selected from World Health Organization (WHO) medication safety tool. Also, the study did not use a scoring system for assessment; it did not conduct during mass gathering hajj period. The objective of our study to explore the national hospital medication safety practice during mass gathering hajj-2016 in Makkah region, Saudi Arabia, the finding of ISMP self-assessment medication safety at hospitals, with emphasis on drug information key element.

METHODS

It is a fifteen days cross-sectional national survey of medicines safety practice at Makkah region. The survey modified from Institution of Safe Medication Practice (ISMP) self-assessment of hospital medication safety. It consisted of a demographic section and ten domains with 270 questions. The ten areas included patient information, drug information, drug Labeling and Packaging and Nomenclature, drug standardization, storage and distribution, communication of drug orders and other drug information, medication devices acquisition, use, and monitoring. The environmental factors, workflow, and staffing, staff competency, patient education, quality processes and risk management domain. It contained a twenty core sections included essential patient information, essential drug information, a controlled drug formulary system, methods of communicating drug orders. Strategies to minimize the possibility of errors, clear labels that identify drugs are on all drug containers, standardized of IV solutions, drug concentrations, doses, and administration times. Medications provided to patient care units safely and securely, the unit stock, is restricted, hazardous chemicals safely sequestered, the potential for human errors, medications are prescribed, transcribed, prepared, dispensed, and administered within an efficient and safe workflow. The complement of qualified, well-rested practitioners matches the clinical workload without compromising patient safety. The practitioners receive sufficient orientation to medication use; the practitioners involved in medication use provided with ongoing education about medication error prevention and the safe use, patients, are included as active partners. A safety-supportive culture, practitioners are stimulated to detect and report adverse events, errors, hazards, and observed at risk behavior, and redundancies that support a system of independent double check at risk. The 5-points Likert response scale system used. The scoring key identified as number (1) equal to (A): No activity to implement, (2) equal to (B): Considered, but not implemented, (3) equal to (C): partially implemented in some or all areas. (4) Equal to (D): Fully implemented in some areas, and (5) equal to (E): Fully implemented throughout. The survey conducted at a permanent and temporary hospital located at Makkah and holy places. Most of the hospitals had outpatient, and emergency services, some of them had critical care section for adults, pediatrics, and internal medicine. The hospital provided

emergency and outpatient pharmacies, inpatient pharmacies. Some of the hospitals had intravenous admixture and total parenteral services and drug information services. Structural Clinical pharmacy services missed at most of the hospitals except critical care pharmacy and stewardship antimicrobial program at permanent hospitals, some essential Clinical pharmacy program; pain management, and anticoagulation program not existed at all hospital. The survey distributed to directors of hospital pharmacy during mass gathering Hajj-2016. The medications safety officer at Makkah region distributed the questionnaire and made follow up on a daily basis used physical visiting and through the telephone call. The study made as an electronic format, and it analyzed through survey monkey system and Microsoft Excel version ten. The authors suggested some solution to improve the scoring medication safety culture and the finding of ISMP self-assessment, the 5-points Likert scale system with high priority or opportunity to implement,[5] and low priority or opportunity to implement. [1] Those suggestions based on General Administration of Pharmaceutical strategic goals and Saudi Central Board of Accreditation for Health Care Institutions (CBAHI) standards in Saudi Arabia. The ten domains divided into for several parts for analysis, discussion, and solutions. Part one: patient information, part two: drug information, part three: medication preparation and dispensing (communication of drug orders and other drug information, drug Labeling and Packaging and Nomenclature). The part four: medication administration (drug standardization, storage and distribution, medication devices acquisition, use, and monitoring), part five: environmental factors, workflow, and staffing, staff competency, and part six: patient education, quality processes, and risk management. The study discussed the part two; it is a finding from ISMP (2011) medication safety at a hospital in Makkah.

RESULTS

The survey distributed to sixteen hospitals, the response rate, was eleven hospitals (68.75%). The number of permanent hospitals was six (54.45%) located at Makkah city while the temporary hospitals were five (45.45%) located at holy places. Of those four (36.4%) hospitals bed size was (100-199) and 3 (27.3%) bed size (200-299). The number of hospitals accredited by Saudi Central Board of Hospitals Accreditation (CIBAHI) was four (36.4%) while three hospitals (27.3%) accredited by USA International Joint Commission and CIBAHI. The total number of prescriptions was (120,598). Of those (72,627) were Ambulatory care prescriptions, while (43,242) were Emergency Prescriptions, and

(4,729) were inpatient orders. The total number of the pharmacist was (180) while pharmacy technician (83) and some clinical pharmacists not reported as explored in Table 1. The total score of all ISMP-self assessment of medication safety was 3.39 +/-0.51 (67.68 %) with CI (3.2-3.6) P< 0.05 and range (2.75 – 3.93). The average of drug information domain at all hospital were 2.91+/- 0.54 (58 %) with CI (2.72-3.10), P< 0.05 and range (2.00 – 4.18). The score of essential drug information was 2.84 +/- 0.57 (56.8%) with range (2.00 – 4.18), and the core of the controlled formulary system was 3.09 +/- 0.42 (61.8%) with range (2.20 – 3.55) as explored in Table 2. The highest score of drug information key element at essential drug information core was high-alert drugs used within the organization identified and error-reduction strategies established 4.18 (83.6%), while at controlled drug formulary system core was non-formulary products used only when therapeutically necessary and appropriate 3.55 (71%) as explored in Table 3. The lowest score of essential drug information core was computerized physician order entry (CPOE) with explanation upon overriding a serious alert was 2 (40%). The standards of practice for the appropriate medication use of postoperative was 2.09 (41.8%), and Updates of drug information for information technology systems utilized in the hospital was 2.11 (42.2%). Also, at the controlled drug formulary core was computer order entry system tested after adding a new drug to the formulary 2.20 (44%) as explored in Table 4.

DISCUSSION

The ministry of health in the kingdom in Saudi Arabia provides health care to all pilgrims through hospitals and primary care centers. The services primary, secondary and tertiary care to acute and chronic diseases over permanent and temporary medical institution. The majority of health care services provided through an emergency care, acute care or critical care, and Ambulatory care services.[1-7] Most of the pilgrims had cardiovascular diseases, Infection diseases, and Endocrinology diseases, Obstetrics and gynecology diseases. The number of pilgrims increased annually visited emergency services within fifteen days was Ambulatory care and hospital admission.[7] The huge number of patient with different diseases need high numbers of medication quantity with different pharmacological classification. Also, many pilgrims brought their medication from various their countries had different brand names and different dosage forms and strength. All those factors had a very risky to committing medication errors, and it needs an electronic database of drug information. The drug information

Table 1: Type of hospital services and pharmaceutical care section of surveyed hospitals in Makkah

No and Hospitals	Location	Hospital Type	No of Beds	Accreditations	No of Pharmacy Technician	No of Pharmacist	No of Clinical Pharmacist	No of OPD Prescriptions		No of Emergency Prescriptions		No of Inpatient Prescriptions		Total No of Prescriptions
								Pilgrims	Non-Pilgrims	Pilgrims	Non-Pilgrims	Pilgrims	Non-Pilgrims	
1.Mena-1	Mena	Temporary	100-199	Non	9	1	NR	6,180	500	992	67	179	6	
2. Mena-2	Mena	Temporary	100-199	Non	18	1	NR	15,203	330	1,661	113	612	17	
3. Mena-3	Mena	Temporary	200-299	Non	19	2	NR	12,286	1,016	1,281	99	350	22	
4. Arafat-1	Arafat	Temporary	200-299	Non	10	1	NR	527	73	272	22	129	6	
5. Arafat-2	Arafat	Temporary	100-199	Non	8	1	NR	4,073	155	328	13	192	6	
6. M-1	Makkah	Permanent	300-399	CIBAHI	12	9	NR	22	650	244	6,135	31	664	
7. M-2	Makkah	Permanent	200-299	CIBAHI - JCI	23	10	NR	34	3,208	185	9,408	46	728	
8. M-3	Makkah	Permanent	400-599	CIBAHI - JCI	60	24	NR	6,706	15,222	4,033	4,026	428	490	
9. M-4	Makkah	Permanent	50-99	JCI	7	2	NR	0	0	1,754	1,159	55	11	
10. M-5	Makkah	Permanent	100-199	CIBAHI	4	2	NR	1,037	NR	3,353	NR	29	NR	
11. M-6	Makkah	Permanent	300-399	CIBAHI	10	30	NR	2,640	2,765	2,988	5,109	411	317	
Total					180	83		48,708	23,919	17,091	26,151	2,462	2,267	120,598

No.: Number, NR: Not reported

Table 2: The scores of key elements of ISMP medication safety hospitals in Makkah.

No	Key elements	Mean score	SD	CL (95%)	Range	Percent	SD %	CL (95%)	Range %	USA, 2000 Scores %	USA, 2011 Scores %
I	Patient information	2.75	0.57	0.23	1.73 – 3.91	55.00	11.46	4.63	34.60 – 78.20	43.00	60.00
II	Drug Information	2.91	0.54	0.19	2.00 – 4.18	58.00	10.80	3.80	40.00 – 83.60	53.00	68.00
III	Communication of drug orders and other drug information	3.53	0.65	0.347	2.55 – 4.50	70.60	13.00	6.94	51.00 – 90.00	47.00	74.00
IV	Drug Labeling and Packaging and Nomenclature	3.57	0.68	0.238	2.10 – 4.90	71.4	13.60	4.76	42.00 – 98.00	61.00	74.00
V	Drug Standardization, Storage and Distribution	3.54	0.50	0.17	2.73 – 4.80	70.80	10.00	3.40	54.60 – 96.00	73.00	81.00
VI	Medication Devices acquisition, Use, and Monitoring	2.97	0.45	0.21	2.33 – 3.78	59.40	9.00	4.20	46.60 – 75.60	69.00	70.00
VII	Environmental Factors, Workflow, and Staffing	3.93	0.44	0.20	3.36 – 4.70	78.60	8.80	4.00	67.20 – 94.00	70.00	77.00
VIII	Staff competency and education	3.69	0.445	0.18	2.91 – 4.40	73.80	8.90	3.60	58.20 – 88.00	53.00	64.00
IX	Patient Education	3.75	0.35	0.27	3.00 – 4.20	75.00	7.00	5.40	60.00 – 84.00	48.00	68.00
X	Quality Processes and risk management	3.18	0.47	0.118	2.00 – 4.10	63.60	9.40	2.36	40.00 – 82.00	51.00	72.00
	Average self-Assessment	3.39	0.51	0.215	2.75 – 3.93	67.68	10.20	4.30	55.00 – 78.60	56.00	71.00

CL: Confidence Level

database should impede in the computerized Physician order enter. CPOE should contain altering system and clinical design support system to prevent all stages of drug therapy including procurement, preparation, dispensing, administration, and monitoring medication. Several reports stated that is using altering system prevent medication errors and adverse drug reaction.[8-9] ISMP had excellent tools for self-assessment to check medication safety at hospitals. The author surveyed that, and they found the general score same as what done in 2000, and less than what reported in started

Table 3: The highest scores items of core domain essential drug information of ISMP medication safety hospitals in Makkah.

ISMP No	Key elements	E 1	D 2	C 3	B 4	A 5	Rating Average	Percent	Response Count
	Drug Information								
	Core # 2 Essential drug information								
34	High-alert drugs used within the organization identified, high-leverage error-reduction strategies established for these drugs	0	0	4	1	6	4.18	83.60	11
35	Current Protocols, guidelines, dosing scales, and/or checklists for high-alert drugs readily accessible to prescribers, pharmacists, and nurses	2	0	1	2	6	3.91	78.20	11
49	Pharmacists regularly (e.g., at least one 8-hour shift per 24 hours) work directly in inpatient care units performing clinical activities such as reviewing	2	2	1	2	4	3.36	67.20	11
	Core # 3 A controlled drug formulary system								
60	Non-formulary products used only when therapeutically necessary and appropriate	3	1	0	1	6	3.55	71.00	11
51	The hospital formulary contains a minimal duplication of therapeutically equivalent products.	3	1	1	0	6	3.45	69.00	11
52	Before a decision is made to add a drug to the formulary, the potential for error with that drug investigated	3	1	0	2	5	3.45	69.00	11
	Answered question =11 and skipped question= 0								

Table 4: The lowest scores items of core domain essential drug information of ISMP medication safety hospitals in Makkah.

ISMP No	Key elements	E 1	D 2	C 3	B 4	A 5	Rating Average	Percent	Response Count
	Drug Information								
	Core # 2 Essential drug information								
43	COES require practitioners to enter an explanation upon overriding a serious alert	5	3	0	1	1	2.00	40	10
37	Standards of practice established and followed for the appropriate use of postoperative IV solutions	7	0	2	0	2	2.09	41.8	11
46	Drug information updates for information technology systems used in the hospital	5	2	0	0	2	2.11	42.2	9
	Core # 3 A controlled drug formulary system								
56	COES tested after adding a new drug to the formulary to verify that necessary clinical warning are functional	6	1	0	1	2	2.20	44	10
57	A designated practitioner or team is assigned responsibility to search the literature to identify published reports of errors and adverse drug events	4	2	1	1	3	2.73	54.6	11
55	Ongoing hospital-wide surveillance for at least six months initiated immediately after adding a drug to the formulary that identified.	4	1	1	3	2	2.82	56.4	11
	Answered question =11 and skipped question= 0								

by Vaida AJ *et al*. in 2011 with same assessment tools.[3] Using of computerized drug information database as part of Computerized Physician order entry existed almost in Saudi Arabia hospitals but less than the percentage of USA hospitals.[10,11] The number of hospitals uses an electronic perception during mass Gathering hajj 2016 were very few.[12] The authors reviewed all detail self-assessment of cores drug information suggested several recommendations to overcome this problem for instance; the implement Full online drug information and regularly updated for a new medication, non-formulary drug, and non-registered medication admitted during mass gathering hajj period. Implement of therapeutic interchange system of drug information and updated regularly, and implement online drug information medical library and update regularly. All complete suggestion for recommendation as explored in Table 5.

CONCLUSION

The drug information system is critical issues in the treatment of pilgrims during mass gathering hajj period. The annual survey of assessment tools of medication at hospitals through ISMP system is required. Also, the Implementation of Computerized Physician Order entry is highly recommended to avoid any drug-related problems and prevent the high economic burden on health care system in Saudi Arabia.

No.	Strategic Goals	CBAHI standards	Suggestion for improvement during mass gathering Hajj	Propriety scores	Opportunity scores
Table 5: The recommendations to improve the items of domain essential drug information during mass gathering Hajj period.					
1	Pharmacy computerization				
1.1	Strategic Goal 3	MM.7 MM.8 MM.9 MM.20	Implement Full online drug information and regularly updated for outside and inside health care professionals	5	4
1.2			Implement comprehensive online drug information and regularly updated for public for inside and outside Pilgrim with different languages	4	4
1.3			Implement of CPOE at inpatient and output pharmacy linked with full drug information and updated regularly	5	4
1.4			Use alerting system in CPOE linked with comprehensive drug information and updated regularly	5	3
1.5			Implement Full online drug information and regularly updated with link to clinical decision support system	4	4
1.6			Implement Full online drug information and regularly updated for new medication, non-formulary drug, and non-registered medication admitted during mass gathering hajj period	5	5
1.7			Implement of therapeutic interchange system of drug information and updated regularly	5	5
1.8			Implement online drug information medical library and update regularly	5	4
2	Pharmacy automation				
2.1	Strategic Goal 3	MM.7 MM.8 MM.9	Implement full drug information and regularly updated link to automated dispensing cabinet from inpatient drug distribution	5	4
2.2			Implement comprehensive drug information and regularly updated link to repackages unit dose for inpatient drug distribution	5	4
2.3			Implement Full online drug information and regularly updated for new medication, non-formulary drug, and non-registered medication admitted during mass gathering Hajj period and link with all pharmacy automation	5	4
2.4			Implement of therapeutic interchange system of drug information and updated regularly and link with all pharmacy automation	5	4
3	Pharmacy human resources				
3.1	Strategic Goal 2	MM.2 MM.3	Increase drug information center workforce during mass gathering hajj period	5	5
3.2			Increase all specialties of drug information clinical pharmacist workforce during mass gathering hajj period	5	4
4	Pharmacy innovation and empowering culture				
4.1	Strategic Goal 4	MM.7 MM.8 MM.9	Implement full online drug information linked to managed care pharmacies to dispense medication for pilgrim	4	3
4.2			Implement Full online drug information and regularly updated for new medication, non-formulary drug, and non-registered medication admitted during mass gathering Hajj period and link with all managed care pharmacies	4	3
4.3			Implement of therapeutic interchange system of drug information and updated regularly and link with all managed care pharmacies	4	3
4.4			Implement online drug information medical library and update regularly and link with all managed care pharmacies	4	4
5	Guidelines and protocols				
5.1	Strategic Goal 1	MM.5 MM.20 MM.22	Full drug information and regularly updated of pain management medication	5	5
5.2			Comprehensive drug information and regularly updated of anticoagulation medication	5	5
5.3			Complete drug information and regularly updated of antimicrobial steamship medication	5	5
5.4			Implement online drug information medical library and update regularly and link with all guidelines and protocols	5	4
6	Pharmacy risk management				
6.1	Strategic goal 1	MM.30 MM.39	Implement medication preparation indicators	5	5
6.2			Implement medication dispensing indicators	5	5
7	Pharmacy clinical audit				
7.1	Strategic Goal 5	MM.5 MM.22 MM.39 MM.40 MM.41	Annual survey of ISMP self-assessment of medication safety for all mass gathering hajj hospitals	5	5
7.2			Antibiotics consumption and uses report	4	5
7.3			High alert medication consumption and usage report	5	5
7.4			Drug related problems electronic surveillance regularly	4	3
7.5			Full reporting of new medication, non-formulary drug, and non-registered medication admitted during mass gathering hajj period	4	4
7.6			Full reporting of therapeutic interchange medication system	4	4
7.7			Full reporting of all Guidelines and protocol medications	5	4

ACKNOWLEDGEMENT

CONFLICT OF INTEREST

None

ABBREVIATION USED

WHO: World Health Organization, CPOE: Computerized physician order entry, MOH: Ministry of Health, USA: United States of America, ISMP: Institution Safe Medication Practice

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