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National Survey of Hospital Medication Safety Practice during Mass Gathering (Hajj-2016) in Makkah, Saudi Arabia: Patient Education, Quality Process, and Risk Management

Yousef Ahmed Alomi^{1*}, Nezar Adnan Yahya Khayat², Mustafa Jamil Baljoon², Yasir Abdulraheem Bamaga³, Hani Mohammed Ali Jumah³

¹*The Past General Manager of General Administration of Pharmaceutical Care and Head, National Clinical pharmacy, pharmacy practice and Pharmacy R & D Administration, Ministry of Health, Riyadh, KSA*

²*General Director, Makkah Health Affairs Region, Makha, KSA*

³*Pharmaceutical Care Administration, Makkah Medical Affairs Region, Makha, KSA*

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*Correspondence to:

Dr. Yousef Ahmed Alomi,

*The Past General Manager of General Administration of Pharmaceutical Care, Head, Saudi Clinical Pharmacy Forum, and Pharmacy R & D Administration, Ministry of Health, Riyadh 11392, Kingdom of Saudi Arabia (KSA)
Email: yalomi@gmail.com.*

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Abstract

Purpose: To explore the national survey of hospital medication safety practice during mass gathering (Hajj -2016) in Saudi Arabia, finding from ISMP (2011) self-assessment of medication safety at the hospital with emphasis on Patient education, quality process, and Risk Management. **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 survey distributed to sixteen hospitals, the response rate, was eleven hospitals (68.75%). 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. The average rating of Patient Education domain at all hospital were 3.75 (63.6 %) while the mean score Quality Processes and risk management domain at all hospital were 3.18 (67.8%). The highest score of both domains was a Drug selection, preparation, and labeling errors identified during routine checking processes reported and collected 4.1 (82%). The lowest score of both domains was the Machine-readable coding used to verify all based solutions and additives 2 (40%). **Conclusion:** The patient education and quality process and risk management related to medication safety were acceptable at the hospital during mass gathering Hajj period. May be the correction of computerized physician order entry and using of new technology will minimize the patient risk and improve hospital pharmacy management of medication safety during a mass gathering in Makkah, Saudi Arabia. **Key words:** Medication Safety, Hajj, Patient education, Quality Process, Risk Management, Ministry of Health, Saudi Arabia.

INTRODUCTION

The pharmacy strategic plan at Ministry of Health (MOH) consisted of six general strategic goals and more than eighty projects including patient education and pharmacy total quality management.^[1] The both key elements required for pharmacy accreditation of Saudi Central Board for Accreditation of Health Care Institutions and joint international commission for hospital accreditation. The pharmacy quality management standards to be taken by all pharmacist and pharmacy technician to prevent, document, and monitor medication errors and adverse drug reaction with regular improve the pharmacy system for that, and it highly recommended during mass gathering hajj period.^[2,3] Also, those fundamental elements are essential to prevent adverse drug events and medication related problem. The poor information about medication may lead hospital admission or critical care admission or death. There is inferior patient knowledge of medicines with the terrible perception of drug therapy in Saudi Arabia. The authors and his colleagues did survey about medication knowledge with more 600 patients; they found that is (54.8%) and (56.8%) of responders do not know or weak information about the generic name of Medicines, and drug indication respectively.^[4] Another study by the author and research team about drug related problems knowledge and perception the authors found they had poor information drug interaction (37.5%) and drug poisoning (44.5%). The most drug-related problems occurred was drug noncompliance (71.4%), indications without medication (50%), and adverse medication events (40%)(4). For this reason, some hospitals during mass gathering started comprehensive patient medication education with more five languages.^[5] The Institution of Safe Medication Practice (ISMP) formulated self-assessment tool for medication safety at hospitals, patient education, and pharmacy quality were key elements among them.^[6] Those tools handy to measure the medication safety culture related both elements. The both elements investigated in two studies in 2000 and 2011 and the author found patient education improved from 48% to 68%, and the quality process and risk management from 51% to 72%.^[7,8,9] The authors are not familiar with local study, Gulf, or Middle East countries investigations about used ISMP key elements. The goal of the survey to explore the national survey of medication safety practice during mass gathering (Hajj -2016) in Makkah hospitals, Saudi Arabia, finding from ISMP (2011) self-assessment of medication safety at hospital with emphasis on patient education, quality

process and risk Management

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, communication of drug orders and other drug information, environmental factors, workflow, and staffing, staff competency, patient education, drug labeling and packaging and nomenclature, drug standardization, storage, and distribution. The medication devices acquisition, use, and monitoring, 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. The clear labels that identify drugs are on all drug containers, standardized of intravenous 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. 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 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. 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 carried out 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 hospital 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 5-points Likert response scale system used. 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 for Accreditation of 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 explored the part number six; it is a finding from ISMP (2011) medication safety at hospitals 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 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 score of Patient Education domain at all hospital were 3.75 ± 0.35 (63.6 %) with CI (3.48-4.02), $P < 0.05$ and range (3.00 – 4.20). The average score Quality Processes and risk management domain at all hospital were 3.18 ± 0.51 (67.8%) with CI (3.062 – 3.29), $P < 0.05$ and range (2.75 – 3.93) as explored in Table 2. The highest score of the Patient Education was Patients are educated routinely upon admission to assist healthcare professionals with proper identification 4.00(80 %) while the lowest score was the organization develops and conducts at least one annual community education program or another proactive public health effort 3.00 (60 %) as explored in Table 3. The highest score of quality processes and risk management key element was No disciplinary action taken against a practitioner for making a human error 4.00 (80%). The lowest score was the Standards in the USP General Chapter <797> Pharmaceutical Compounding—Sterile Preparations followed in all areas where IV admixture occurs 2.70 (54%) and all detail results with all cores explored in Table 4.

DISCUSSION

The pharmacy strategic planning of Ministry of health consisted of six overall goals and more than eighty projects.^[1] One of the major projects was patient medication educations and pharmacy total quality Management.^[10] The central committee of pharmacy TQM formulated at MOH with expert pharmacists from several regions. The committee had planned for next five years and educational session to all pharmacists working in Saudi board of healthcare organizations accreditation at hospital pharmacies. Also, the committee had several consultations to a different hospital to prepare for pharmacy accreditation. Another essential central medication safety committee established to oversee all medication safety issues. For

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 key elements of ISMP medication safety hospitals in Makkah.

Core #	Core Characteristic	Mean score	SD	Range	Percent	SD %	Range %	USA, 2000 Scores %	USA, 2011 Scores %
IX	Patient Education	3.75	0.35	3.00 – 4.20	75.00	7.00	60.00 – 84.00	48.00	68.00
16	Patients included as active partners increase through education	3.75	0.35	3.00 – 4.20	75.00	7.00	60.00 – 84.00	48.00	68.00
X	Quality Processes and risk management	3.18	0.47	2.00 – 4.10	63.60	9.40	40.00 – 82.00	51.00	72.00
17	Safety-supportive Just Culture & increase accountability model	3.37	0.26	2.73 – 4.00	67.40	5.20	54.60 – 80.00	46.00	71.00
18	Practitioners detect and report adverse increase events, errors, and hazards, and teams analyze the reports	3.38	0.34	2.90 – 4.10	67.60	6.80	58.00 – 82.00	55.00	73.00
19	Redundancies that support a system of increase independent double checks or automated process used	2.69	0.50	2.00 – 3.91	53.80	10.00	40.00 – 78.20	41.00	68.00
20	Proven infection control practices increase followed	3.31	0.347	2.70 – 3.64	66.20	6.94	54.00 – 82.80	83.00	87.00
	Average self-assessment	3.39	0.51	2.75 – 3.93	67.68	10.20	55.00 – 78.60	56.00	71.00

instant report and analysis of medication error events, report and analysis all adviser drug reaction and drug quality, giving a lecture of basic medication course to all healthcare providers. Formulating hospital and primary care center medication safety committee and follow up them, and make an annual survey of ISMP self-assessment tools including all types of survey.^[11,12] Also, the central committee of public education responsible for patient counseling program and relates issues.^[10] One

of the tools can integrate the total quality management and medication safety in one face coin in addition to the integration of patient counseling, and medication safety was the ISMP tools. Another the authors assess this tool at hospitals during mass gathering hajj 2016. The results of patient education were better than the study by Vaida, AJ *et al.* in 2000 and lower than the study by Vaida, AJ *et al.* in 2011 and 2011, because the pharmacy administration formulated patient program through

Table 3: The highest and lowest scores items of domain Patient Education.

IX: Patient Education									
ISMP No.	Key elements	A 1	B 2	C 3	D 4	E 5	Rating Average	Percent	Response Count
	Core # 16: Patients included as active partners increase through education								
	The highest scores items								
195	Patients are educated upon admission to assist healthcare professionals with proper identification	1	0	1	4	4	4.00	80.00	10
197	During each drug administration, nurses routinely provide patients and/or families with the name of the drug, the general purpose of the drug, and the prescribed dose, and during initial drug administration, nurses also provide information on significant side effects	1	0	2	2	5	4.00	80.00	10
	The lowest scores items								
198	Patients provided with up-to-date, written information at primary language about drugs that prescribed at discharge	3	0	1	1	5	3.50	70.00	10
207	The organization develops and conducts at least one annual community educational program or other proactive public health effort designed to improve the safe use of medications in the community.	4	0	2	2	3	3.00	60.00	11
	<i>answered question</i>								11
	<i>skipped question</i>								0

Table 4: The highest and lowest scores items of domain Quality Processes and risk management.

X: Quality Processes and risk management									
ISMP No.	Key elements	A 1	B 2	C 3	D 4	E 5	Rating Average	Percent	Response Count
	Core # 17 Safety-supportive Just Culture and increase shared accountability model								
	The highest scores items								
209	No disciplinary action taken against a practitioner for making a HUMAN ERROR.	1	0	2	3	5	4.00	80.00	11
227	Patient safety articulated in the organization's mission and/or vision statements.	2	0	2	1	5	3.70	74.00	11
	The lowest scores items								
224	The Board of Trustees/Directors actively demonstrates its commitment to patient safety	4	0	2	1	4	3.09	61.80	11
221	Practitioners and other staff involved in serious errors that cause patient harm emotionally supported by leadership and their colleagues.	4	0	2	1	4	3.09	61.80	11
217	Error rates are not determined or calculated from practitioner error reports and not used for internal (unit-to-unit) and/or external (hospital-to hospital) comparison.	5	0	2	1	3	2.73	54.6	11
	Core # 18: Practitioners detect and report adverse increase events, errors, and hazards, and teams analyze the reports								
	The highest scores items								
242	Drug selection, preparation, and labeling errors identified during routine checking processes reported and collected to identify system design issues and to develop error prevention strategies.	2	0	0	1	7	4.10	82	10
238	When an event involves human error, an investigation is undertaken to uncover any pre-existing performance shaping factors	2	0	2	1	5	3.70	74	10
	The lowest scores items								
247	An efficient way of measuring medication safety	4	1	1	0	5	3.09	61.80	10
248	Hospital leadership actively engages in dialogue about the untoward consequences of intimidation and deals effectively with reported and observed disruptive behaviors	4	1	0	2	4	3.09	61.80	11
245	A convened interdisciplinary team routinely evaluates the literature for new technologies and successful evidence-based practices that have been effective in reducing error	3	1	2	1	3	3.00	60.00	11
	Core # 19: Redundancies that support a system of increase independent double checks or automated process used								
	The highest scores items								
250	Prescribers' orders include the patient specific dose to calculate dose for all chemotherapy drug orders.	2	1	0	1	7	3.91	78.20	11

257	When selected high-alert drugs removed from unit stock (including ADCs), both the drug and the dose are INDEPENDENTLY DOUBLE CHECKED by another practitioner	3	0	0	3	4	3.50	70.00	10
	The lowest scores items								
252	A pharmacist verifies that the dosing method used to calculate the patient specific dose listed with a chemotherapy order is correct according to the protocol or treatment plan	7	1	0	1	2	2.09	41.8	11
262a	In hospitals WITH automated compounders: Machine-readable coding used to verify all based solutions and additives attached to automated IV admixture compounders.	7	1	0	2	1	2.00	40.00	11
	Core # 20: Proven infection control practices increase								
	The highest scores items								
268	Containers of eye or eardrops not used for more than one patient.	3	0	1	1	6	3.64	72.80	11
	The lowest scores items								
265	Standards in the USP General Chapter <797> Pharmaceutical Compounding—Sterile Preparations followed in all areas where IV admixture occurs.	5	0	0	3	2	2.70	54.00	10
	answered question								11
	skipped question								0

Table 5: Recommendation to improve the items of domain Patient education, Quality processes, and Risk management during mass gathering Hajj period.

S.No	Strategic Goals	CIBAHI standards	Suggestion for improvement during mass gathering Hajj	Propriety scores	Opportunity scores
1	Pharmacy computerization				
1.1	Strategic Goal 3	MM.31 MM.32	Implement electronic pharmacy TQM indicators	4	3
2	Pharmacy automation				
2.1	Strategic Goal 3	MM.31 MM.32	Use bar coding for preparation and administration medication	4	3
2.2			Use automated dispensing cabinet used from drug distribution	4	3
3	Pharmacy human resources				
3.1	Strategic goal 2	MM.2 MM.3	Increase number of trained qualified pharmacist	5	3
3.2			Increase number of qualified, trained nurses	5	3
3.3			Implement education courses for pharmacist and nurses of new technology system	5	5
3.4			Hospital leaders training for MOH clinical and TQ program	5	5
4	Pharmacy innovation and empowering culture				
4.1	Strategic Goal 4	MM.26 MM.28 MM.35	Apply 797 and 800 standards for preparation medication regular and chemotherapy respectively	5	4
4.2			Expand the patient education transportation languages	4	4
4.3			Open position counseling clinic with emphasis to diabetes asthma epilepsy	3	3
5	Guidelines and protocols				
5.1	Strategic Goal 1	MM.5 MM.19 MM.20 MM.22	Implement pharmacy pain management program indicators at all permanent and temporary hospital during mass gathering hajj period	5	4
5.2			Implement Antimicrobial stewardship program at all permanent and temporary hospital during mass gathering hajj period	5	4
5.3			Implement pharmacy anticoagulation program at all permanent and temporary hospital during mass gathering hajj period	5	4
6	Pharmacy risk management				
6.1	Strategic goal 1	MM.30 MM.39	Implement the pharmacy risk management program	5	4
6.2			Implement pharmacy infection control	5	5
7	Pharmacy clinical audit				
7.1	Strategic Goal 5	MM.35 MM.40 MM.41	Annual report of Implement all pharmacy key performance indicators	5	4
7.2			Annual survey of ISMP with emphasis on patient counseling and Pharmacy TQM indicators	5	4
7.3			Implement of patient education indicators	4	4
7.4			Annual report of medication errors prevented or not prevented	5	5
7.5			Annual report of drug quality report	5	5
7.6			Annual report of ADR	5	5

public education committee. The program consisted of patient counseling through ambulatory care clinic operated by a pharmacist, patient counseling during discharge, and at outpatient pharmacy. The pharmacist covered common disease needed patient education for instant diabetes, Asthma, and Epilepsy. The pharmacy public education committee had real experiences of patient counseling during hajj period. Recently the program implemented with several languages last year 2016.^[7-13] The results of the quality process and risk management more than a study by Vaida, AJ, *et al.* in 2000 and lower than the study by Vaida, AJ *et al.* in 2011. It was a normal finding as the pharmacy total quality management program just recently started before several years ago then it needs a couple of time for much improvement.^[7-10] The authors suggested some recommendation to improve pharmacy TQM and patient medication counseling for instance; implement 797 and 800 standards for preparation medication regular and chemotherapy respectively, implement pharmacy infection control, and annual report of Implement all pharmacy key performance indicators, for more detail recommendations as explored in Table 5.

CONCLUSION

Patient education and Pharmacy TQM has an acceptable score as a comparison with high development countries. The continuous with level and higher highly recommended. The ISMP self-assessment of medication safety as an excellent tool to measure the relationship between medication safety and pharmacy TQM. In addition to measuring the relationships of patient counseling and medication safety.

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CONFLICT OF INTEREST

None

ABBREVIATION USED

GAPC: General administration of Pharmaceutical Care, CBAHI: Saudi Central Board for Accreditation of Health Care Institutions, MOH: Ministry of Health, ISMP: Institution Safe Medication Practice.

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