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National Drug Quality Reporting System at Ministry of Health in Saudi Arabia

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Abstract

National Quality Reporting System at Ministry of Health (MOH) in Kingdom of Saudi Arabia is a unique system existed. It is part of National Medication Program. The system is the only tool to detect and follow up the quality of medications products in hospital pharmacies or primary care center pharmacies. It looks alike of post-marketing surveillance in registration agencies national and international wise. The system prevents any risk of drug-related problems before occurs, promote the effective medications, prevents fake drugs, and stop bad quality medicines. The system started before ten years in Saudi Arabia with small scale then expanded and became National System through General Administration of Pharmaceutical Care at MOH. The system updated with using an electronic form of documentation. The system is very demandable for implementation locally and nationally. It improves the quality of medication, and it is an excellent system and apart of pharmacy indicator of successful pharmacy strategic plan at MOH in Saudi Arabia.

Keywords: Drug; Quality; System; Pharmaceutical cares; Ministry of health; Saudi Arabia

Introduction

General Administration of Pharmaceutical Care of Ministry of Health (GAPD-MOH) in Saudi Arabia started National Medication Safety Program (NMSP) in 2013 [1]. NMSP is consisting of several elements for instance but not limited to the following; formulating of medication safety program central committees, updating of medication errors system, upgrade of adverse drug reaction system, updating of the medicine quality reporting system. Also; necessary medication safety education course, medication safety training Center self-assessment, medication safety officer in hospitals, human resources of medication safety program, awareness material of drugs Safety program, and drug information resources for medication safety [2].

Food and Drug Administration (FDA) in the United state of America described Drug Quality Reporting System as "voluntarily report observed or suspected defects or quality problems with marketed drug products" [3]. That is excluding any problem related to Adverse Drug Reaction and Medication Errors. The Drug Quality Reporting System had founded in the United States of America in 1971s by FDA, then updated in 1988 and 1993 through Med Watch system with online submitting information [4-6]. In 2007, The Executive Board of the Health Ministers for the Arab Gulf Cooperation Countries (EBHM-GCC) by Central Drug Registration Department had launched Post Marketing Surveillance including Drug Quality Reporting System and requested from all Gulf countries to report on any quality problem of any registered or purchased medication through the particular form [7]. Then Oman started Drug Quality Reporting System with excellent update form to submit through dMedical Supply Directorate at MOH [8]. In Jordan Electronic Drug Quality Reporting had begun [9].

Benefit of Drug Quality Reporting System in Saudi Arabia

The pharmaceutical market in Saudi Arabia estimated around 3.5 billion US dollars in 2012, with excepted grow to 5.6 billion US dollar in 2030. King of Saudi Arabia registered 147 patents the largest numbers among Arabic countries [10]. The counterfeit medications estimated around 14% annually. One report from US Pharmacopeia as organization Promoting the Quality of Medicines (PQM) program about media reports of medicine quality stated that; the fake drug less than 0.5% of medicine while Saudi Food and Drug Authority (SFDA) seized more than 1000 counterfeit brought by pilgrims during Hajj period [10,11]. There are very studies investigated drug qualities reporting of medication in Saudi Arabia. There is a study examined the quality of Amoxicillin product at four Arabic countries included Saudi Arabia, Jordan, Lebanon and Egypt. The authors founded 66% Amoxicillin capsules not compliance United State Pharmacopeia (USP) requirements. The 59% of the sample lower than what label claimed while 8% of suspension out of USP limits [12]. Another study purchased Amoxicillin from nine community pharmacies (4 chains and five independent) community pharmacies. It used Lot Quality Assurance Sampling (LQAS) technique with a predefined threshold. The authors found all the samples rejected as unacceptable [13].The authors not familiar with any publications discussed the National Drug Quality Reporting System in Gulf countries or Middle East countries. Those potential reports lead to necessary applying this program to prevent the risk of counterfeit medication, and not appropriated diseases management.

In 1990; General Directorate of Medical and Pharmaceutical Licensing of Ministry of Health in Saudi Arabia had established Drug Quality Reporting System (DQRS) with the unique form. In 2007 the form was updating the form as part of recommendations after Gulf Symposium of Post Marketing Surveillance [7]; then in 2013 General

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GAPD-MOH updated the form based on FDA, EBHM-GCC, Oman. Jordan and current literature at that time [14]. Recently in 2015; Saudi Food and Drug Authority (SFDA) updated system of DQRS and changed their name to Pharmaceutical Products Quality Reporting Form with an electronic version [15,16]. Also, General Administration of Pharmaceutical Care has finished e-form through monkey survey system; it launched on September 5th, 2015 [17]. All manual submission stopped by the end of the year 2015 and replaced of e-form.

International and National Drug Quality Reporting System

The authors compared MOH the DQRS the old and new system with currently available in SFDA, Oman, GCC, Jordan, and FDA system. It compared the updated system based on several things; the purpose of the form, definition, description of the product, type of the product, type of Quality problem, the severity of the problem, description of the problem, The action to solve the problem. Also, type of report, type of reporter, report to the manufacture, time to report the incident, summary of reporting, responsible for collecting reports in hospital pharmacy, role of Pharmacy and Therapeutic Committee, E-Form of data gathering, responsible, and time to follow up the problems as explored in Table 1.

The Purposes and Definitions of the program of most the countries mentioned and they were the same, to maintain medication safety of the product and report drug-related quality problems respectively. All the systems published the description of the product including the name of the product, product date, expiry date and lot number of the product. In the type of the product sector, it is NOT available at MOH; either new or old system, GCC and FDA. While SFDA, Oman, Jordan, and not presented, because MOH and GCC are not using herbal products at their hospitals and vaccines which included in the form while others registered a common product, herbal or food supplement, and they have another form of vaccines.

The element of the type of quality problem presented at all except MOH old shape and GCC; they are old forms; it is very useful information to be available. The severity of the problem, it was presented in MOH new shape and FDA. Otherwise, all was not presented; this information is necessary to measure the action plan for each report. The description of the problem, it was introduced in all except MOH new form and FDA, may be the quality issue is enough instead of this items. The action to solve the problem, the type of report, type of reporter, report to the manufacture, time to report the incident, the summary of reporting, responsible for collecting reports in hospital Pharmacy. Also, the role of Pharmacy and Therapeutic Committee, responsible, and time to follow up the problems, all those items are presented in MOH new form only, they are related to converting the report to action plan and follow up and more practical. E-Form of data collecting offered at all of them except GCC this form need to be updated; in Table 1 with the very clear comparison between all of them.

National Drug Quality Reporting System in Saudi Arabia

If any health care provider found any problem related to the medications, he or she can report the problem; by filling the form either manual or electronically. Then it should be sent to Medication Safety officer at hospital or primary care center. All those reports should discuss through Medication Safety Committee and Pharmacy and Therapeutic Committee. The full report should send to Regional Medication Safety Committee. Thus; the committee should review all reports came from all hospitals and primary care centers. All reports with detail report should send to Medication Safety Officer and coordinator of the medication safety program at General Administration of Pharmaceutical Care. The central committee of medication safety discuss all reports came from all regions in Saudi Arabia, and action take place with follow-up procedure until the problem finished. The authors listed the policies for drug quality reporting system at MOH as follows:

1. If any Medical, Pharmacy, Nursing and other staff notes any quality related problem while receiving, using, or dispensing any drug product (Over The Counter or prescription), he/she should report that using the official Drug Quality Report Form as showed in Figure 1.
2. The one noting quality related problem may contact their pharmacists first if they have drug quality concerns or complaints. Pharmacists can provide essential information about the product and the product labeling.
3. The one noting quality related problem should fill the Drug Quality Report Form out completely as possible about suspect product information and contact details. If the one is noting quality related problem while documenting need clarification of any item that should complete, he/she may ask the Medication Safety Officer to assist him in how to fill out documentation of all the required information.
4. The completed Drug Quality Report Form should deliver to the Medication Safety Officer in the Pharmacy Department within 24 h.
5. If a product defect is suspected to be a widespread problem which may be detrimental to patients, the Medication Safety Officer notifies the Pharmacy Director for further action to be taken. Pharmacy inventory and purchasing staff are also informed to implement measures such as a recall, if necessary.
6. The Medication Safety Officer is responsible for sending the completed form (and enter the data in the electronic form in MOH website) to the General Administration of Pharmaceutical Care. The National Drug Information Center, Medication Safety Department using the Fax No. 0096614056848 or e-mail: phacare-NCDI@moh.gov.sa, if Medication Safety Officer needs to contact the authorized pharmacist he/she should contact through telephone no. 0096614015555 Ext. 1686.
7. The Medication Safety Officer is responsible for keeping all the original completed Drug Quality Report Form in confidential and secure manner. The Medication Safety Officer must not respond to any request from any employee asking for photocopying any Drug Quality Report Form.
8. The Medication Safety Officer is responsible for aggregating the data of all as a Monthly Drug Quality Summary Report.
9. The Director of Pharmacy or designee shall review all Monthly Drug Quality Summary Report.
10. The Medication Safety Officer is responsible for submitting the Monthly Drug Quality Summary Report to Pharmacy and Therapeutic Committee, Medication Safety Committee.
11. An investigation of the drug product quality related problem should be performed and documented by the Medication Safety Officer. Necessary action(s) should take with follow-up as appropriate.

No	Items	New method of MOH	Old method of MOH	SFDA	FDA	MOH	GCC	FDA (USA)
	Country	**Saudi Arabia**	**Saudi Arabia**	**Saudi Arabia**	**Jordan**	**Oman**	**GCC**	**USA**
1	Founded	1990	1990	2010	Non	2008	2007	1971
2	Updated	2013	2013	Non	Non	Non	Non	1988 – 1993-2007
3	Purpose	Yes	Yes	Yes	Yes	Yes	Yes	Yes
4	Definition	Yes any drug related problems not include ADR or Medication errors	Yes	Yes	Yes	Yes	Yes	Yes
5	Description of the product	None	Yes	Yes	Yes	Yes	Yes	None
6	Type of the product	None	None	Yes	Yes	Yes	None	None
7	Type of Quality Problem	1-Not effective: 3-Difficulty in use: 5-package insert:	None	5-Stability: 6-Counterfeit products Defective components	5-Stability: 6-Counterfeit products Defective components	Yes	None	All
8	Severity of the problem:	Three levels of proprietary resemble FDA	None	None	None	Yes	None	Yes
9	Description of the problem	None	Yes	Yes	Yes	None	Yes	None
10	The action to solve the problem	Drug recalls Repackaging or reformulation of products Drug safety alerts Product label change Others	None	None	None	None	None	None
11	Type of report	Either a problem founded or as part of drug safety surveillance or any new method of data collecting	None	None	None	None	None	Yes
12	Type of reporter	Medical, Pharmacy, Nursing	Medical, Pharmacy, Nursing	All health care professional	All health care professional	Yes	Yes	All health care professional and public
13	Report to the manufacture	None	None	Yes	Yes	None	None	None
14	Time to report the incident	With 24 hours	None	None	None	None	None	None
15	Summary of reporting	Monthly	None	None	None	None	None	None
16	Responsible for collecting reports in hospital pharmacy	Medication Safety Officer in Hospital Pharmacy	None	None	None	None	None	None
17	Pharmacy and therapeutic committee	Should be revised	None	None	None	None	None	None
18	E-form of data collecting	Yes through monkey survey system	None	None	None	None	None	Yes
20	Responsible	The Medication Safety Officer is responsible for communicating the completed Drug Quality Reports to General Administration of Pharmaceutical Care,	Yes	National Pharmacovigilance and Drug Safety Center	National Pharmacovigilance and Drug Safety Center	None	None	Yes
21	Time to follow up the problems	None	None	None	None	None	None	None Initial Working 5 days

Table 1: Comparison of drug quality reporting system over international and Arabic countries.

وزارة الصحة
Ministry of Health
الإدارة العامة للرعاية الصيدلية
General Administration of Pharmaceutical Care

_____Hospital
Pharmaceutical Care Department
_____Region

DRUG QUALITY REPORT

(Please fill all applicable information and forward the form to the Pharmacy Department within 24 h)

FILE NO. ☐☐☐☐☐☐☐☐
NAME: _____
AGE: ☐☐ SEX: ☐ M ☐ F
NATIONALITY: _____
CONSULTANT IN-CHARGE:_____

DRUG INFORMATION معلومات الدواء

Product Name(Brand & Generic)		اسم المستحضر (العلمي والتجاري)
Dosage Form		الشكل الصيدلاني
Strength and Package Size		التركيز وحجم العبوة
Batch No.		رقم التشغيلة
Mfg and Exp. Date		تاريخ انتهاء الصلاحية
Storage Condition		ظروف الحفظ
Manufacturer/Country of origin		الشركة الصانعة / البلد المصنعة
Agent		الوكيل
MOH Item Code		الرقم الكودي للوزارة

TYPE OF QUALITY PROBLEM نوع ملاحظة الجودة

(You can choose more than one)

1) Not effective: ( ) Patient complaint ( ) Clinical evaluation

Specify ……

2) Non compliance with specifications: ( ) Chemical ( ) Physical ( ) Microbial

Specify ……

3) Difficulty in use: ( ) Taste ( ) Odor ( ) Size ( ) Opening ( ) Closure ( ) Storage ( ) Others

Specify ……

4) Packaging error: ( ) Look-alike ( ) Inner pack ( ) Cartons ( ) Poor quality

( ) Capsule leakage ( ) Label mix-up/mislabel ( ) Quantity ( ) Outer pack

( ) Product mix-ups ( ) Broken, cracked, or chipped syringes

( ) Packaging that is torn or punctured

Specify ……

5) package insert: ( ) Required information not available ( ) Misleading information ( ) Others

Specify ……

❖ **Severity of the problem:**
( ) Priority 1 … Imminent or serious health hazard
( ) Priority 2 … potentially significant manufacturing problem
( ) Priority 3 … Routine follow-up

❖ **The action:**
( ) Drug recalls ( ) Repackaging or reformulation of products
( ) Drug safety alerts ( ) Product label change ( ) Others

- **Type of report:** ( ) Finding a problem ( ) Drug safety surveillance ( ) Others

- **Please fill all applicable information and forward the form to medication safety officer in the Pharmacy Department within 24 h.**
- **Please send completed form to the MSO in the pharmacy department within 24 h.**
- **General Administration of Pharmaceutical Care, National Drug Information Center, Medication Safety Department.**
- **How to report : ( ) Online ( ) Email..** phacare-NCDI@moh.gov.sa **( ) Phone... 0114015555 ( ) Fax.. 014056848**

REPORTER DETAILS بيانات كاتب التقرير

Name			الاســـم
Occupation			الوظيفة
Adders			العنوان
Phone			هاتـــف
Fax			فاكـــس
Date			التاريخ
Sig			التوقيـــع

Figure 1: Drug quality report.

Conclusion

National Drug Quality Reporting System is an emotional tool to follow up the implementation of National Medication Safety Program at all hospital pharmacies and primary care center pharmacies. It is part of the strategic planning of General Administration of Pharmaceutical Care in Saudi Arabia. Applying this system is potential at MOH organizations; the system prevents drug-related quality problems including the look a like sound like errors, maintaining safety products and meet quality standards need to pharmacy practice. Expanding the system to all pharmacy organizations and institutions improve pharmaceutical care quality services patients, prevent of an additional unnecessary medicine and health care cost.

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