National Adverse Drug Reaction Reporting System at the Ministry of Health, Saudi Arabia

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ABSTRACT

Objective: To illustrate the adverse drug reaction during the pharmacy strategic plan at the Ministry of Health of Health institutions in the Kingdom of Saudi Arabia. **Method:** It is description analysis of adverse drug reaction system at the Ministry of Health of Health institutions. It was analysis within the Pharmacy strategic plan 2012-2020. The modified pharmacy business model system and Project Management Procedure used in the report. **Results:** The adverse drug reaction established with a defined vision, mission and goals. The system human or economic and other resources described in the review. The risk management was discussed to assure the continuation of the system. Besides, the monitoring and controlling of the system as illustrated. The closing stage with convention to operation project demonstrated in the Analysis. **Conclusion:** The Adverse drug reaction system implemented and it is considered as part of the healthcare system and pharmacy regulations. The documentation of ADR is updating improving accordingly at all Ministry of Health institutions in the Kingdom of Saudi Arabia.

Key word: Adverse Drug Reaction, System, Pharmaceutical Care, Ministry of Health, Saudi Arabia.

INTRODUCTION

The documentation and reporting system of Adverse Drug Reaction (ADR)is one of the requirements mandated for international and national accreditation of healthcare institutions.[1,2] In addition, it is a part of the requirement from the registration agency in the Kingdom of Saudi Arabia (KSA). Regulations about the ADR reporting system have been released from various pharmaceutical societies and local and international registration agencies.[3] Till date, several investigations have focused on different perspectives of ADR such as ADR reporting system, knowledge on the ADR reporting system and perception of pharmacists/healthcare provider regarding the ADR reporting system.[4,5] However, to the best of our knowledge, there are no studies with regard to the description of the program in the Ministry of Health (MOH) and how it was established, the requirement of resources and the analysis of marketing with Strength, Weakness, Opportunity and Threats (SWOT). Therefore, in this review, we aim to explore the national ADR system at the MOH by using the Project Management tools in the KSA.

Method of Development of the Project

The task force committee consisted of expert people from the pharmacies of the MOH hospitals to set up a national ADR system for the pharmacies of hospitals, PHCs and dental centers. The first author of this article headed the medication safety committee; he conducted regular periodical meetings. The committee unitized and drove the pharmacy ADR of the General Administration of Pharmaceutical Care (GAPC) and from non-MOH hospitals system. Moreover, by the project written by using the international business model, pharmacy guidelines, project management institution guidelines for a new project.[6-9] The draft was sent to several reviewers of the RAPC. The selection was corrected and updated accordingly. Then, the second draft was submitted to the reviewers for their final comments and approval. This took around 4 months to complete the task. The GAPC at the MOH sent the final document to all the hospitals for implementation. The ADR documentation system consists of the following parts: initial phase, planning phase, execution phase, monitoring and controlling aspect.

Initial Phase

Assessment Needs

At any given time, pharmacy departments of any healthcare institution will have hundreds of medications stored for dispensing. All medications had ADRs documented through drug reference. In addition to causing an economic burden on the healthcare system, an ADR might cause serious problems to the patients which may even be fatal. The best method to prevent ADR is to report them whenever they occur. The prevention of ADR need the documentation of ADR and related information in the future.

Market Analysis

ADR documentation system was established in the early 2000s at the MOH's administration of

the pharmaceutical care unit. The first draft was updated during 2012–2015.[10] Several non-MOH institutions have their own system of ADR documentation, which could be either electronically or manually documented. Most private hospitals have manual ADR. Earlier there was a manual documentation system of ADR at the MOH institutions, which was then converted to an electronic form through the SurveyMonkey system.

SWOT Analysis

To meet the project goals, we performed a SWOT analysis. The "strengths" of the project were accompanied by the documentation of pharmacy workload for the prevention of medication errors, the calculated cost of avoidance of medication errors and the calculated cost of correction of medication errors. The "weaknesses" in this project were accompanied by increased pharmacy workload and misuse of documentation through the evaluation of the performance of pharmacy staff. The "opportunities" examined in this review included the implementation of national and international standards of healthcare institutions, implementation of New Saudi Vision 2030 and the calculated cost of medication errors.[11] Among the "threats," changes in the pharmacy administration and the accreditation standards were analyzed.

Planning Phase

The Scope of the Project

The ADR documentation collects demographic data of the patient, severity and causality of the ADR, the person identifying the ADR, reasons of ADR, the medications involved, the analysis of ADR and the reporting of ADR to the Saudi Food and Drug Authority (SFDA).

Vision, Missions and Goals

The vision of this project is to define the best system of ADR documentation and related information and prevention of medication errors at the MOH institutions. The mission is to provide the ADR documentation and prevention system at MOH institutions so that there is a reduction in morbidity, mortality and economic burden on the healthcare system due to ADR in the KSA. Goals of this project were to facilitate ADR documentation at MOH institutions, analyze the ADR, prevent ADR complications and document the cost avoidance related to the prevention of ADR.

Description of the Project

The identified ADRs are based on the SFDA, World Health Organization (WHO and definition of the American Society of Hospital Pharmacy (ASHP).[12-15]

All pharmacies and healthcare centers should follow the following policies.

1. If any caregiver in the MOHs/PHC centers notices that a patient experiences an ADR, then he/she must assess the patient, including his/her vital signs.
2. The caregiver should record the assessment in the patient's medical record.
3. The caregiver should notify the patient's attending physician for any immediate action that might be needed. The physician may need to change the therapy and/or provide necessary treatment.
4. The caregiver should notify the nursing shift manager. A clear label/note on the medical record should be affixed in order to indicate that the patient has an allergy from such medication.
5. The caregiver should utilize the ADR Report form (appendix 1) and complete the following information:
   - ✓ Patient demographics;
   - ✓ Suspected drug information;
   - ✓ Concomitant drugs;
   - ✓ Adverse drug reaction description;
   - ✓ Outcome data;
   - ✓ Classification of adverse drug reaction according to:
   - ✓ The Naranjo causality scale for an adverse drug reaction, (See the Naranjo table and scoring in the attached ADR Form page 3);
   - ✓ Adverse drug reaction severity (mild, moderate, or severe);
   - ✓ Cost avoidance impact;
   - ✓ Name, profession, address, phone and fax.
6. The caregiver, who notifies the ADR, should sign the ADR Report Form and write the date.
7. The caregiver should send the completed ADR Report Form to the Medication Safety Officer in the Pharmacy Department.
8. If the caregiver, while documenting, needs clarification regarding any item that should be completed, then he/she may ask the Medication Safety Officer to assist him in how to fill the required information.
9. The Medication Safety Officer is responsible for sending the com¬pleted form (And enter the data in the electronic form in the MOH website) to the GAPC, National Drug Information Center, Medi¬cation Safety Department.
10. The Medication Safety Officer is responsible for keeping all the original completed ADR Forms confidentially.
11. The Medication Safety Officer is accountable to aggregate the data of all the ADRs reported and formulate a Monthly ADR Summary Report.
12. The Director of Pharmacy or designee shall review all Monthly ADR Summary Report.
13. The Medication Safety Officer is responsible for submitting the Monthly ADR Summary Report to:
    - ✓ Quality Department;
    - ✓ PTC Committee;
    - ✓ Patient Safety Committee;
    - ✓ Medication Safety Committee.
14. In addition, the Medication Safety Officer is responsible for submitting the Report of the Independent Case (Considered as sentinel event) to them.
15. An investigation of the ADRs, especially preventable ADRs, causes and contributing factors should be performed and documented by the Medication Safety Officer in coordination with the affected department(s)/ assigned team, or RCA investigation if the case is considered as a sentinel event.
16. All necessary action(s) should be taken with necessary follow-up actions to prevent ADRs, especially preventable ADRs.

Planning Cost Management

This program needs financial assistance for the education and training of the pharmacy staff, the electronic system for ADR conversion for instant Survey Monkey system and for several other factors related to the pharmacy and the engagement of ADR reporting and documentation purposes.

Execution Phase

Management Team

The management team responsible for the follow-up of the ADR reporting and documentation was the Medications Safety Committee. The

Central Committee is designed through GAPC at the MOH; The committee consists of representatives from each region specialized in medications safety. A Regional Committee established for each area includes representatives from each hospital and group primary care center. Each hospital or group primary care center creates a Local Medications Safety Committee. The local committee consists of medications safety pharmacists, physicians and nurses and members of quality management and risk management, as well as an invited member. All committees have a monthly meeting to discuss ADR reporting and documentation, ADR analysis and ADR prevention.[10]

Education and Training

The central committee of medications safety or in the region or peripheral hospital or primary care centers should conduct the several education and training sessions for all stake holders, management team's members and healthcare staff.

Risk Management

There are six types of risks: budget, scope, personal, schedule, technical and quality risks. Most of the risks experienced might be due to budget or personal and quality risks. A budget risk is related to the unavailability of enough funds for the education and training of the project and for the conversion of the ADR manual documentation to the electronic documentation system. A project might experience personal risks that are related to a shortage of human resources with a high workload of documentation ADR system. In addition, the pharmacy staff might not have received education or training about the project. The project might be exposed to quality risks due to nonqualified pharmacists and due to poor training in the quality pharmacy tools. The project might be exposed to other technical risks such as the nonavailability of an electronic system of ADR documentation with friendly use.

Monitoring and Controlling Phase

Project Quality Management

The following Key Performance Indicators (KPIs) of ADR documentation system was established to monitor the system implementation at MOH institutions: the adherence documentation of ADR, the cost avoidance analysis of ADR, the ADR analysis with detailed information, the reporting rate of ADR and the number of reporting to SFDA.[16,17]

The Closing of the Project

The ADR documentation system at MOH institutions is a critical tool to prevent drug-related problems in the KSA. The system should continue with the corporate committee and other related committees. The annual report of ADR should be done. Education and training courses for healthcare providers should be conducted regularly. Further project expanded to include the cost avoidance of prevention ADR in the future is required and the annual celebration with the project members.

ACKNOWLEDGMENT

None.

CONFLICT OF INTEREST

None.

ABBREVIATIONS

MOH: Ministry of Health; **KSA:** Kingdom of Saudi Arabia; **ADR:** Adverse drug reaction; **RCA:** Root cause analysis; **SWOT:** Strengths, Weaknesses, Opportunities and Threats; **WHO:** World Health Organization; **SFDA:** Saudi Food and Drug Authority; **ASHP:** American Society of Hospital Pharmacy; **PHC:** Primary healthcare center; **PTC:** Pharmacy and Therapeutic Committee; **RAPC:** Regional Administration of Pharmaceutical Care; **GAPC:** General Administration of Pharmaceutical Care.

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وزارة الصحة
Ministry of Health

Appendix (1)_____Hospital
Pharmaceutical Care Department
_____Region
ADVERSE DRUG REACTION FORM
ANONYMOUS
(Please fill all applicable information and forward the form to the Pharmacy Department within 24 hrs)
تقرير آثار جانبية لدواء

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

PATIENT DEMOGRAPHICS معلومات المريض

Patient Name (Optional) _____ اسم المريض

الطول:_____ الوزن:_____ الجنس:_____العمر:_____ رقم الملف:_____

File Number _____ **Age** _____ **Sex** _____ **Weight (kg):** _____ **Height (cm):**_____

Diagnosis:_____ التشخيص

Past Medical History:_____ التاريخ المرضي

_____

Allergies: _____ تفاعلات الحساسية

SUSPECTED DRUG INFORMATION معلومات الدواء المسبب للآثار الجانبية

Drug Name (Brand & Generic)_____ اسم الدواء " التجاري" والعلمي"

Dose / Route / Frequency_____ الجرعة/ عن طريق/ عدد المرات

Manufacturer & Batch Number_____ الشركة الصانعة ورقم التشغيلة

Manufacture & Expire Date_____ تاريخ الانتاج وتاريخ الانتهاء

Drug, started & stopped date_____ تاريخ بداية إعطاء الدواء وتاريخ ايقافه

Indication of use _____ سبب وصف الدواء

CONCOMITANT DRUGS الأدوية الأخرى

Drug الدواء	Dose/ Frequency الجرعة وعدد المرات	Route عن طريق	Date Started بداية استخدام الدواء	Date Stopped نهاية استخدام الدواء

Relevant Laboratory Data, Diagnostic Imaging and/ or Biopsy Results(if applicable): **الاختبارات المخبرية , نتائج التصوير الاشعاعي, فحص الانسجة(إن وجدت)**

ADVERSE DRUG REACTION DESCRIPTION وصف الآثار الجانبية للدواء

Adverse Drug Reaction (s) (ADR): الآثار الجانبية:

1. _____-1

2._____-2

3._____-3

4._____-4

(ADR) Started & stopped date:_____ تاريخ بداية ظهور الآثار الجانبية وتاريخ وتوقفها

Did the adverse event(s) appear after the suspected drug was administered? ◯YES◯NO◯NA هل ظهر الأثر الجانبي بعد تعاطي الدواء المشتبه به ؟ ☐نعم ☐لا ☐لاتوجد معلومات

Did the reaction(s) stop after stopping drug? ◯YES◯NO◯NA هل اختفى الأثر الجانبي بعد يقاف الدواء المشتبه به ؟ ☐ نعم ☐ لا ☐ لاتوجد معلومات

Did the reaction(s) reappear after restarting drug? ◯YES◯NO◯NA هل عاد ظهور الأثر الجانبي بعد إعادة استعمال الدواء المشتبه به؟ ☐ نعم ☐ لا ☐لاتوجد معلومات

Are there alternative causes(other than the drug)**that could on their own have caused the reaction?** ◯ YE◯ N◯ NA هل هناك سبب آخر غير الدواء يحتمل أنه تسبب☐نعم ☐لا☐لاتوجد معلومات في حدوث الأثر الجانبي؟

If Yes, specify:_____ إذا كانت الاجابة بنعم فما هي الأسباب

_____

_____

OUTCOME DATA: نتيجة الأثر الجانبي النهائية

Symptoms الأعراض المصاحبة	Changes to therapy التغير في الخطة ا لعلاجية	Treatments علاج الأثر الجانبي	Action Taken الإجراء المتخذ
☐ أعراض الجهاز العصبي ☐ **CNS symptoms**	☐ تم إيقاف الدواء ☐ **Drug Discontinued**	☐ لا يتطلب معالجة ☐ **No treatment Required**	☐ تم توثيقها في السجل الطبي ☐ **Medical record documentation**
☐ أعراض الجهاز التنفسي ☐ **Respiratory symptoms**	☐ تم تخفيف الجرعة ☐ **Drug Dosage decreased**	☐ يتطلب تدخل لتفادي الأضرار ☐ **Required intervention to prevent Impairment**	☐ تم نصح المريض ☐ **Patient counseled**
☐ أعراض الجهاز الهضمي ☐ **GI symptoms**	☐ تم تخفيف عدد مرات الاستعمال ☐ **Drug frequency decreased**	☐ يتطلب تدخل دوائي ☐ **Required treatment with Prescribed medication**	☐ تم اشعار الطبيب بذلك ☐ **Prescribed notification**
☐ أعراض الجهاز القلبي ☐ **Cardiovascular symptoms**	☐ تم تخفيف معدل تسريب الدواء عن طريق الوريد ☐ **Infusion rate decreased**	☐ صعوبة ا لتشخيص ☐ **Significantly complicated Diagnosis**	
☐ أعراض الجهاز البولي ☐ **Urinary symptoms**	☐ تم تعديل الخطة العلاجية **Therapy changed**	☐ يتطلب معالجة داعمة ☐ **Significant treatment necessitated**	
☐ أعراض الغدد الصماء ☐ **Endocrine symptoms**	☐ تم إيقاف المعالجة **Therapy held**		
☐ أعراض الجهاز العضلي الحركي ☐ **Musculoskeletal symptoms**	☐ لا يوجد تعديل **No change**		

CLASSIFICATION OF ADVERSE DRUG REACTION SEVERITY تصنيف شدة الأثر الجانبي للدواء

NARANJO CAUSALITY SCALE FOR ADVERSE DRUG REACTIONS

☐ **> 9 = definite adverse drug reaction** ☐ **5-8 = probable ADR** ☐ **1-4 = possible ADR** ☐ **0 = doubtful ADR**

Minor: A reaction that does not require treatment or prolongatio خفيف الخطورة: الأثر الجانبي لا يتطلب معالة أو إطالة بالمستشفى وقد

Of hospital stay. It can cause the following; يسبب مايلي:

☐ **Reduction in dosage** ☐ **discontinuation of medication** ☐ تخفيف الجرعة ☐ إيقاف الدواء

☐ **No intervention other than monitoring report** ☐ **No permanent effect** ☐ لاحاجة للتدخل عدا مراقبة المريض ☐ بدون أثر دائم

Moderate: A reaction that requires treatment and/or prolongs متوسط الخطورة: الاثر الجانبي يتطلب معالجة أو إقامة بالمستشفى

Hospitalization by at least one day. It can cause the following; لمدة يوم واحد وقد يسبب مايلي

☐ **Change in physiological status** ☐ **Some intervention necessary** ☐ تغير في الحالة الفسيولوجية للمريض ☐ يحتاج المريض بعض التدخلات العلاجية

☐ **No permanent effect** ☐ بدون أثر دائم

Severe: A reaction that cause the following problems; شديد الخطورة : الاثر الجانبي الذي يتسبب في مايلي :

Hospitalization ☐	☐ **دخول المستشفى**
Temporary disability ☐	☐ **عجز مؤقت**
Permanent disability ☐	☐ **عجز دائم**
Congenital malformation	☐ **تشوه خلقي**
Life – threatening ☐	☐ **تعرض حياة المريض للخطر**
Prolonged healthcare facility stay ☐	☐ **زيادة استخدام وسائل الرعاية الصحية**
Prolonged hospitalization <24 hour ☐	☐ **البقاء في المستشفى أقل من 24 ساعة**
Prolonged hospitalization >24 hour ☐	☐ **البقاء في المستشفى أكثر من 24 ساعة**
Required ER visit ☐	☐ **الحاجة لزيارة قسم الطوارئ**
Symptoms continued ☐	☐ **إستمرار ظهور الآثار الجانبية**
Symptoms resolved <24 hour ☐	☐ **زوال الآثار الجانبي في أقل من 24ساعة**
Symptoms resolved >24 hour ☐	☐ **زوال الاثر الجانبي في أكثر من 24 ساعة**
The patient died ☐	**وفاة المريض** ☐

Name:_____ الاسم_____

Profession:_____ المهنة_____

Address:_____ الجهة المرسلة:_____

Phone:_____**Fax:**_____ هاتف:_____ فاكس:_____

Signature:_____ **Date:**_____ التوقيع:_____ التاريخ:_____

Please send completed form to:

General Administration of Pharmaceutical Care
National Drug Information Center
Medication Safety Department
Telephone No. 014015555 Ext. 1686
Fax No. 014056848
Email : **phacare-NCDI@moh.gov.sa**