The Impact of Newly Introduced Online Medication Error Reporting System on The Reporting Behavior of Pharmacists for Medication Errors

Thesis

Submitted for the fulfillment of the Master Degree
in Pharmaceutical Sciences
(Clinical Pharmacy)

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2016

Acknowledgement

I would like to express my sincere gratitude to my supervisors **Prof. Dr. Nagwa Ali Sabri** and **Prof. Dr. Ahmed Abdelsalam Elmelegy** for their continuous support, motivation, useful comments and engagement through the learning process of this master thesis.

Furthermore I would like to thank Dr. Mahmoud Diaa Elmahdawy for introducing me to the topic as well for the support on the way. Also, I like to thank the participants in my survey, who have willingly shared their precious time during the process of interviewing.

I would like to thank my loved ones, who have supported me throughout entire process, both by keeping me harmonious and helping me putting pieces together.

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List of Abbreviations

AAQTE	Association pour l'Assurance Qualité en Thérapeutique et l'Evaluation
ADR	Adverse Drug Reaction
AE	Adverse Event
AEM	Agencia Española de Medicamentos (Spanish Medicine Agency)
AIDS	Acquired Immune Deficiency Syndrome
AIMS	Australian Incident Monitoring System
AIMSTM	Advanced Incident Management System
APSF	Australian Patient Safety Foundation
ASHP	American society of Hospital Pharmacist
BGL	Blood Glucose Level
BNF,	British National Formulary
BP	Blood Pressure
CDER	Center for Drug Evaluation and Research
CDSS.	Clinical Decision Support Systems
CHF	Congestive Heart Failure
CIHI	Canadian Institute for Health Information
CMIRPS	Canadian Medication Incident Reporting and Prevention System
CMR	Central Medication Incidents Registration
CNS	Central Nervous System
CPOE	Computerized Physician Order Entry
CPSI	Canadian Patient Safety Institute
CQI	Continuous Quality Improvement
CrCl	Creatinine Clearance
CVS	Cardiovascular System
CYP	Cytochrome P450
D5W	5% Dextrose in Water
DM	Diabetes Miletus
DMEPA	Division of Medication Error Prevention and Analysis
ECG	Electrocardiography
ECHO	Echocardiogram
EPVC	Egyptian Pharmacovigilance Center
FDA	Food and Drug Administration
GIT	Gastrointestinal Tract
ICU	Intensive Care Units
IM	Intramuscular
IMSN	International Medication Safety Network

List of Abbreviations

INR	International normalized ratio
IOM	Institute of Medicine
ISMP	Institute of Safe Medication Practice
IT	Information Technology
ITH	Intrathecal
IV	Intravenous
KCl	Potassium Chloride
KSA	Kingdom of Saudi Arabia
MEDAP	Medication Error Detection, Amelioration and Prevention Study
MERP	Medication Error Reporting Program
MEs	Medication Errors
NCC-MERP	National Coordinating Council for Medication Error Reporting and Prevention
NGT	Nasogastric Tube
NHS,	National Health Service
NO HARMe	National Office for Handling and Reduction of Medication errors
NPH	Neutral Protamine Hagedorn
NPSA	National Patient Safety Agency
NRLS	national reporting and learning system
NS	Normal Saline
NZPhvC	New Zealand Pharmacovigilance Centre
OTC	Over-The-Counter
PO/PR	Per oral/ per rectal
PRN	Pro Re Nata, or as needed.
PSO	Patient Safety Organization
RBCs	Red Blood Cells
RCA	Root Cause Analysis
RDA	Recommended Daily Allowance
REEM	Réseau Épidémiologique de l'Erreur Médicamenteuse (French Epidemiologic network for medication errors reporting)
SC	Subcutaneous
SOP	Standard Operating Procedures
SWI	Sterile Water Injection
TID.	Ter In Die or three times daily
UAE,	Unites Arab Emirates
UK	United Kingdom
US	United States
USP	United States Pharmacopeia
UTI	Urinary Tract Infection

Background: Medication safety is a worldwide concern and voluntary reporting is one of the most important detection methods used to avoid medication error recurrence. Medication errors should be reported to a national monitoring program so that the shared experiences can facilitate learning and enhance error prevention strategies. In June 2014, we established the National Office for the Handling and Reduction of Medication Errors (NO HARMe) and its national online system for medication error reporting. The primary objective of this system is to improve medication safety in Egypt by learning from errors and sharing such experiences among health care organizations.

Purpose: This study analyzes reports to the Egyptian medication error (ME) reporting system from June to December 2014. The study also evaluates MEs reporting barriers from the pharmacists' perspective, before and after using the NO HARMe reporting system and to what extent this new system was effective, satisfactory and suitable for their use.

Methods: Fifty hospital pharmacists received training on ME reporting using the national reporting system. All received reports were reviewed and analyzed. The pieces of data analyzed were patient age, gender, clinical setting, stage, type, medication(s), outcome, cause(s), and recommendation(s).

After six months of using the new system, we used a paper based questionnaire with participants to describe: Barriers of reporting they were facing during reporting of errors (before receiving the training), any

remaining barriers they still have while using the new system and their feedback on the national form.

Results: Over the course of 6 months, 12, 00 valid reports were gathered and included in this analysis. The majority (66%) came from inpatient settings, while 23% came from intensive care units, and 11% came from outpatient departments. Prescribing errors were the most common type of MEs (54%), followed by monitoring (25%) and administration errors (16%). The most frequent error was incorrect dose (20%) followed by drug interactions, incorrect drug, and incorrect frequency. Most reports were potential (25%), prevented (11%), or harmless (51%) errors; only 13% of reported errors lead to patient harm. The top three medication classes involved in reported MEs were antibiotics, drugs acting on the central nervous system, and drugs acting on the cardiovascular system. Causes of MEs were mostly lack of knowledge, environmental factors, lack of drug information sources, and incomplete prescribing. Recommendations for addressing MEs were mainly staff training, local ME reporting, and improving work environment.

From the questionnaire analysis; four reasons represented the major reporting barriers for pharmacists before training on the new system. Those barriers were, lack of knowledge that MEs should be reported, lack of knowledge on how to report them, unavailability of specific reporting form and inability to know the details of the medication incident or event. The main barrier that stills prevent some participants from reporting, is their inability to be directly involved in the medication use process. Generally all barriers reduced after training and availability of the national form. According to their feedback two criteria can be considered successful with the mode of selection being *(**excellent**)*.

Those criteria are; ease of access to the online form and feeling safe because their information is confidential and secured. On the other hand, five other items identify possible areas for system improvement with the mode of selected evaluation was (***good***).

Conclusion: For the first time, Egypt has a national database of MEs gathered through an online reporting system – NO HARMe, within the Egyptian Drug Authority. Although there are general limitations of voluntarily reported data, our analysis of this database has provided useful background for researchers and decision makers that can be used to assess the problem, identify the root causes of errors, and develop new preventive strategies. Despite the positive impact of the newly established national reporting system in changing the reporting behaviors, this culture is still growing up in Egypt.

Keywords: Medication errors, Medication safety, voluntary reporting, reporting barriers.

Review of Literature

1-Definition of medication errors

The National Coordinating Council for Medication Error Reporting and Prevention (NCC-MERP) defines a medication error as "any preventable event that may cause or lead to inappropriate medication use or patient harm while the medication is in the control of the health care professional, patient, or consumer. Such events may be related to professional practice, health care products, procedures, and systems, including prescribing; order communication; product labeling, packaging, and nomenclature; compounding; dispensing; distribution; administration; education; monitoring; and use. **(FDA 2015)**

It can also be defined as 'a failure in the treatment process that leads to, or has the potential to lead to, harm of the patient'. **(Aronson 2009)**

Medication errors can occur while:

- Drug selection—irrational, inappropriate, under-prescribing and overprescribing.
- Prescribing errors—problems with writing the prescription, including illegible handwriting.
- Manufacturing the formulation to be used—wrong strength, contaminants or adulterants, wrong or misleading packaging.
- Dispensing the medication—wrong drug, wrong strength, wrong dosage form, incorrect labeling.
- Administering or taking the drug—wrong dose, wrong route of administration, wrong frequency, wrong duration.
- Monitoring therapy: inability to change the regimen when needed, change to inappropriate drug.

The word 'failure' in the definition means that there are certain standards, and failure can be judged against them. All health professionals in the medical field should establish or at least understands such standards. They should use specific measures to make sure that no failure in meeting the standards not or unlikely to occur. **(Aronson 2009)**

An adverse event is 'any abnormal sign, symptom or laboratory test result, or any syndromic combination of such symptoms, any unexpected or unplanned occurrence (e.g. an accident or unplanned pregnancy), or any unexpected progression in a concurrent illness. If an adverse event happened while a person is using a drug it may be an adverse drug reaction. If an adverse event is not caused by the drug it remains an adverse event; if it can be attributable to a drug it will be a suspected **adverse drug reaction**. An ADR is 'an actually harmful or undesired reaction, resulting from the use of a medicinal product'. Sometimes medication errors result in ADRs but many do not.(Aronson 2009) The relationship between adverse events, ADRs, and medication errors is illustrated **in the Venn diagram in Figure 1.**

Figure 1. A Venn diagram showing the relation among adverse events, ADRs and medication errors **(Aronson 2009)**