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Ain Shams University
Faculty of Pharmacy

Establishment of a National Reporting Form for Detection of Medication Errors within Pharmaceutical Vigilance System

A Thesis submitted for the fulfillment of Master Degree
In Pharmaceutical Sciences
(Clinical Pharmacy)

By

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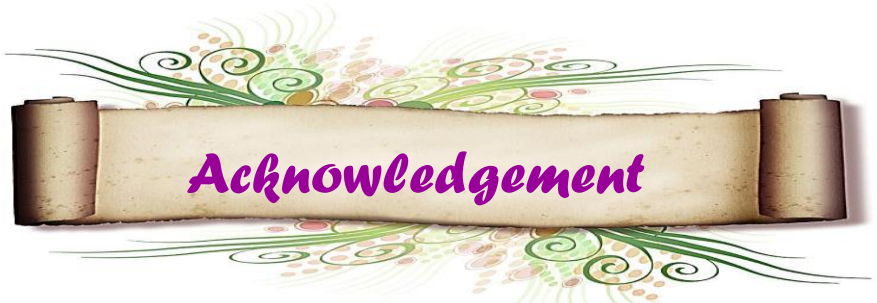

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Rowan Wahid

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List of Abbreviations

ADE	Adverse drug event
ADR	Adverse drug reaction
AE	Adverse event
ASHP	American Society of Health-System Pharmacists
CDC	Centers for Disease Control
DHPC(s)	Direct Healthcare Professional Communication(s)
EDA	Egyptian Drug Authority
EMA	European Medicines Agency
EPVC	Egyptian Pharmaceutical Vigilance Center
EPVC-ALEX	Alexandria Regional Center of the Egyptian Pharmaceutical Vigilance Center
ER	Emergency room
EU	European Union
FDA	Food and Drug Administration
HCP(s)	Health-care practitioners/ healthcare professional(s)
HRIG	Human rabies immunoglobulin
ICSR(s)	Individual Case safety report(s)
ICU	Intensive care unit
IM	Intramuscular
IMSN	International Medication Safety Network
IOM	The Institute of Medicine
ISMP	Institute of Safe Medication Practice (USA)
IV	Intravenous
LLT	Lowest Level Terms
MAE	Medicine administration error
ME(s)	Medication error(s)
MedDRA	Medical Dictionary for Regulatory Activities
MHRA	Medicines and Healthcare Products Regulatory Agency
MM	The Monitoring Medicines project
NCC MERP	National Coordinating Council for Medication Error Reporting and Prevention
NHS England	National Health Service
NIH	National Institutes of Health
NO HARMe	National Office for Handling and Reduction of Medication errors
NPSA	National Patient Safety Agency (England)
NRLS	National Reporting and Learning System
PCC	Poison control centre
PEP	Postexposure Prophylaxis

List of Abbreviations *(Cont ..)*

PS	Patient Safety
PSA	Patient Safety Alert
PSO	Patient safety organization
PV	Pharmacovigilance
PVCs	Pharmacovigilance centres
RCA	Root cause analysis
Smpc/ Spc	Summary of product characteristics
SOCs	System Organ Classes
UMC	Uppsala Monitoring Centre
VAERS	Vaccine Adverse Event Reporting System
WHO	World Health Organization
YC	Yellow Card

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Abstract

Introduction: Health care professionals (HCPs) may still think of pharmacovigilance (PV) strictly in terms of identifying and reporting adverse drug reactions (ADRs), however, the scope of national pharmacovigilance centres (PVCs) has expanded to identify, analyse and prevent medication errors (MEs) through collection of reports of MEs.

Aim: To detect MEs which were inadvertently collected as ADRs by Alexandria Regional Center of the Egyptian Pharmaceutical Vigilance Center (EPVC-ALEX) and to establish a valid national medication error reporting form within pharmaceutical vigilance system to strengthen the capacity of EPVC to detect MEs.

Methods: The study is an ambispective study, conducted on 3 phases: Pre-interventional phase: Retrospective analysis of PV database operated by EPVC was applied on reports received from the primary care units dated from March to November 2013 and additional fatal ME reports dated in 2014. Interventional phase: The proposal of a National Reporting Form for detection of medication errors within pharmaceutical vigilance system. Post-interventional phase: Prospective study was conducted in 2019 to validate the newly developed reporting form by conducting two rounds of Delphi technique on experts in clinical pharmacy practice by using Likert scale questionnaire. Pharmacists successfully reported MEs by using the developed form.

Results: The current study revealed that the Egyptian PV database was a rich source of MEs, many of which were found to originate in the hospital setting and reported as ADRs (66%) from March to November 2013. 91% of the detected ME cases were not encoded as ME $p< 0.001$ and 61% of errors were encountered in Direct Healthcare Professional Communication ($p< 0.05$). Characteristics of the yellow card (YC) revealed that male patients exposed to MEs were more than females, most of them were 18 years and older, the weight was not mentioned by the reporters in the majority of the reports. The most commonly used route was intravenous IV. Most of the suspected drugs reported were antibiotics, antithrombotic agents, systemic antihistamines and rabies vaccine. Most reporters were pharmacists who used the YC English version more than the Arabic one. Case fu was done mostly by phone.

The current study showed the limitations and invalidity of the existing ADR reporting form within EPVC (YC) to report MEs. Although 4% of the yellow cards were considered invalid, this percentage is underestimating the real rate due to the inability of the items on the yellow card to capture near misses, potential or prevented errors because the reaction is missing. Seriousness of the suspected reactions was inaccurately judged by both EPVC assessors and reporters in most cases. Moreover, reporters were significantly confused in rating reactions severity and confused between what should be reported as "reaction" versus the "outcome" in 22% of the cases as in case of death, which was reported as a "reaction" although it is an "outcome", the analysts got confused as well in 17 % of the cases $p< 0.001$.

The causality criteria of the YC didn't apply on 75% of ME cases $p<0.001$. Assessors assigned "Possible" causation between the suspected drug and the reaction in 42% of the cases; which confirms that ADR has no certain pharmacological relation to