Descriptive analysis of medication errors reported to the Egyptian national online reporting system during six months

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ABSTRACT

Objectives This study analyzes reports to the Egyptian medication error (ME) reporting system from June to December 2014.

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).

Results Over the course of 6 months, 12,000 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.

Discussion There are common problems among different healthcare systems, so that sharing experiences on the national level is essential to enable learning from MEs. Internationally, there is a great need for standardizing ME terminology, to facilitate knowledge transfer. Underreporting, inaccurate reporting, and a lack of reporter diversity are some limitations of this study.

Egypt now has a national database of MEs that allows researchers and decision makers to assess the problem, identify its root causes, and develop preventive strategies.

Keywords: medication errors, incident reporting, patient safety, Egyptian Drug Authority (EDA), National Office for Handling and Reduction of Medication Errors (NO HARMe)

BACKGROUND AND SIGNIFICANCE

Medication errors (MEs) are a major problem in every healthcare system, worldwide. The risk presented by MEs was first brought to the attention of healthcare professionals and the public through an Institute of Medicine (IOM) report published in 1999, which estimated that 44,000–98,000 people die each year in United States hospitals from preventable medical errors and 7000 patients die from MEs.¹ Seven years later, another IOM report stated that, “At least 1.5 million MEs cause harm in the US each year.”² Other literature reports also provided statistics describing the impact. For example, data from the National Health Service in the United Kingdom reported that, in 6 years (from 2005–2010), there were about 86,000 cases of harm and 820 cases of death or severe harm caused by MEs, representing the second most commonly reported type of medical errors.³

Medication Error Definition and Categorization

The National Coordinating Council for Medication Error Reporting and Prevention (NCC-MERP) defines an ME 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.”⁴ According to NCC-MERP, ME outcomes are categorized into one of nine categories, ranging from Category A (circumstances that may lead to an error) and Category I (an error that lead to patient death).⁵

Methods for the Detection and Prevention of Medication Errors

The most important step in the prevention of MEs is detection. After detecting errors, their root causes can be analyzed, and proper preventive strategies can be implemented to avoid their recurrence. Voluntary reporting plays a crucial role in identifying MEs. Beyond internal reporting in individual organizations, MEs should also be reported to a national reporting system, so that the shared experiences of different organizations can contribute to the development of valuable educational programs.⁶ Several countries have national systems for reporting MEs, such as the Institute of Safe Medication Practice (ISMP) in the US, the Canadian Medication Incident Reporting and Prevention System (CMIRPS) in Canada, the National Reporting and Learning System (NRLS) in the UK, and the Central Medication Incidents Registration (CMIR) in the Netherlands. France, Spain, Australia, Ireland, Denmark, Sweden, Japan, and Norway also have similar systems.⁷,⁸

Medication Errors in Egypt

Data on MEs in Egypt are limited. One systematic review of MEs in Middle Eastern countries reported that only three studies addressed...
this problem in Egypt.9–12 Each of these studies only focused on errors occurring in one hospital department during a certain time period. The lack of data in Egypt is not only a result of a lack of research in this field, but also due to the absence of voluntary reporting systems, except in very few hospitals. Despite this information gap, there is no doubt that MEs still represent a major concern around the globe, even in developed countries. Due to limited resources in developing countries such as Egypt, there are more risk areas that may result in higher rates of MEs. Although such problems are not present in all health organizations, some have already overcome them, and others are still in the process of addressing them.

Regarding pharmacy practice, the effective contribution of clinical pharmacists in ward rounds is not yet applied in most hospitals. Hospital and community pharmacists have very high work loads with minimal availability of pharmacy technicians. In addition, 24/7 pharmacist support and unit dose dispensing systems are often unavailable.

Other factors are related to the lack of automation, such as computerized physician order entry, electronic profiles, barcode machines, and pharmacy software. Poor documentation, ie, missing prescribing instructions, verbal orders, transcribing errors, and incomplete nursing sheets, is another factor. Information on patients’ past medical history and allergies may not be available. In addition, there is a lack of drug information centers, updated formularies, and practice guidelines in many hospitals in Egypt. Patients’ low educational levels and the fact that most of the dispensed medications are paid for out-of-pocket may further compromise proper medication use.

Characteristics of the National Office for Handling and Reduction of Medication Errors (NO HARMe) in Comparison to Other National Systems

The National Office for the Handling and Reduction of Medication Errors (NO HARMe) was recently established within the Hospital Pharmacy Administration in the Central Administration of Pharmaceutical Affairs. In June 2014, NO HARMe launched a national online system for reporting MEs.13 The primary objective of this system is to reduce MEs and improve medication safety in Egypt by gathering ME data, sharing and learning from the experiences of multiple organizations, and developing recommendations to avoid the recurrence of MEs. Four other national reporting systems described in the literature can be compared with the Egyptian system: ISMP in the US, CMIRPS in Canada, NRLS in the UK, and CMR in the Netherlands.

The NO HARMe system is voluntary and nonpunitive. Reports to the system are used only for learning, not for punishing individuals or organizations, similar to the other four systems discussed herein.14 Another important feature of NO HARMe is the optional anonymity and confidentiality it offers. The user can either identify himself or report to the system anonymously. In all cases, the reporter’s personal information is kept confidential, in any reports or publications. CMIRPS is similar.14 ISMP mandates that the reporter at least provide an email address,15 and reporting to NRLS is totally anonymous.14

The scope of NO HARMe covers both actual and potential medication incidents. The scope of the other systems is the same, except for NRLS, which also allows reporting of all other patient safety incidents. An online website is our main reporting route. Reporting via telephone, email, and paper forms is also available, but these routes have not yet been implemented in Egypt and are not part of the NRLS system, although they already used in the other three systems.7

Currently, our system is available for individual professionals in any clinical setting. However, the initial dissemination of the system has only targeted hospital pharmacists as its first users. Up until now, there has been no channel for patients as well as healthcare organizations to report MEs. In the other systems, patients can report MEs to the system, except CMR.7,14 Receiving reports from a healthcare organization’s internal system is available in NRLS and CMR.7,14

The reporting form contains sections for identifying the medication, incident type, stage, outcome, causes, recommendations, setting, and reporter. The form includes multiple-choice items as well as free text entry. Classifications are mainly based on the NCC–MERP taxonomy. Most of the other systems use a similarly structured form, except for ISMP, which uses a form that only allows for a narrative description of the incident.13–17

Aim of the Study

This study was conducted to analyze all ME reports received by the NO HARMe system from June to December 2014. Our preliminary analysis can give insight into national trends of MEs occurring in Egypt. This article highlights the most common types and causes of errors, the medications involved, and patient outcomes.

METHODS

Pharmacists Training

A nonrandom sample of 50 junior clinical pharmacists from seven different hospitals was selected, and the pharmacists were trained on the process of reporting of any MEs that arose during their work, including near misses. All the pharmacists that were part of the study were residents in a clinical pharmacy program. Most of them had no previous clinical experience. Less than 40% had a clinical pharmacy diploma, and only three had advanced credentials such as a board certification or a Pharm.D. All the pharmacists included in the study were working in tertiary care teaching hospitals. One of the hospitals is specialized in mental health and one in diabetes. And almost all acute specialties were represented in the other hospitals.

Review of the Received Reports

Any received reports were periodically reviewed. The narrative description of the event was read to verify that all items in the report were complete and consistent with the description. If there were any discrepancies or the report was incomplete, the reporter was contacted to clarify their report or fill in any missing data. Reports based on clinical data such as drug interactions, contraindications, and dose selection were checked against credible drug information references, such as Lexicomp Online to verify their accuracy in light of the specific patient information.

Figure 1: Percentages of errors occurred at each stage of the medication use process.
Data Analysis

All the reports received by the system were automatically gathered into a spreadsheet. Reports from June to December 2014 were analyzed. Data were quantitatively analyzed and results were expressed as frequencies and percentages. The primary pieces of information analyzed were patient age, gender, clinical setting, stage, error type, medication class, patient harm, possible cause(s), and recommendation(s). Further parameters also analyzed included the top errors associated with each stage, the classification of stages and medication classes according to the resulting outcome category, and common errors reported with each medication class. A listing of all errors related to sound-alike and look-alike medications is presented as an example of the reported errors.

Ethical Considerations

According to the system disclaimer, the reports do not include any patient, health professional, or organization identifying information. In addition, reporter details (name, phone, or email) are masked in any publication, for the protection of reporters’ confidentiality.

RESULTS

During the 6-month study period, 12,000 reports were validated and included in this analysis (with an average rate of 200 reports per month). There were 42 identifiable reporters, all of whom were pharmacists working in governmental and university hospitals, and only 25 reports were submitted anonymously. The patients involved in reports were

Table 1: Common Error Types Associated with Each Stage of the Medication Use Process

<table>
<thead>
<tr>
<th>Stage</th>
<th>Administration (n = 192)</th>
<th>Dispensing (n = 36)</th>
<th>Prescribing (n = 648)</th>
<th>Monitoring (n = 300)</th>
<th>Transcribing (n = 24)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Common Types</td>
<td>%</td>
<td>%</td>
<td>%</td>
<td>%</td>
<td>%</td>
</tr>
<tr>
<td>Extra dose</td>
<td>16.5%</td>
<td></td>
<td>32.5%</td>
<td>52%</td>
<td>37%</td>
</tr>
<tr>
<td>Dose omitted</td>
<td>15%</td>
<td>13.5%</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Medication omitted</td>
<td>10.5%</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Incorrect dosage form/route</td>
<td>7.5%</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Incorrect drug</td>
<td>7%</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Figure 2: Classification of errors according to error type (represented in absolute numbers).
predominantly male (44%); 35% were females, and, in 21% of the reports, gender was not specified. The patients were mainly adults (49%), with a smaller percentage of children (34%), elderly patients (14%), and those whose age was not specified (3%). The majority of reports (66%) came from inpatient settings, 23% came from intensive care units (ICUs), and 11% came from outpatient clinics and pharmacies.

Stage and Type of Error
The medication use process is divided into five stages (Figure 1). Most reported errors were prescribing errors (54%), followed by monitoring and administration errors. MEs are classified into 23 types; the top five types were: incorrect dose, drug interactions, incorrect frequency, incorrect drug, and lack of monitoring (Figure 2). The most common types of MEs associated with each stage of the medication use process are also detailed in Table 1. For the administration stage, extra dose, dose omission, and medication omission were the most reported types of MEs, while incorrect dose, frequency, interactions, rate, and untreated indications were the most common prescribing errors.

Patient Outcome
The degree of harm from the ME event is classified into one of nine categories according to the NCC-MERP category index.5 Category A (potential errors) made up 25% of all the reports, while 11% of reported MEs were prevented (Category B). Actual MEs that did not lead to harm (Categories C and D) made up 24% and 27% of the reports, respectively. All MEs that lead to patient harm (Categories E–I) made up 13% of the reports (Figure 3). The data presented in Supplementary Appendix 1 further classifies each stage according to the outcome category. For example, potential MEs represent a major part of transcribing and prescribing errors (50% and 36%, respectively). Preventable MEs are higher in dispensing and transcribing stages (41.5% and 25%, respectively).

Possible Causes and Reporters’ Recommendations
In the possible causes and reporters’ recommendations section of the report, there is a predetermined list of possible causes of the ME and recommendations, and the reporter must select one or more options and can enter free text as well. The total number of causes selected in the reports we analyzed was 1674, and the most common causes selected were lack of knowledge and experience, environmental factors (eg, work load and distractions), lack of drug information sources, and incomplete prescribing instructions (Figure 4). The causes selected for Category A are separately analyzed in Figure 5. Potential errors were mainly due to a lack of prescribing or transcribing instructions, a lack of nurse documentation, illegible handwriting, and a lack of patient information. In the recommendations section, 2074 recommendations were selected. The most common were staff education and training, establishing of local ME reporting systems, and improving work environment (Figure 6).

Classes of Medications Involved and Their Relation to the Outcome Category and Error Type
The form allows for entry of one or two medications for each event, although some reports are not specific to any specific medication. The overall number of medications involved in the reports we analyzed was 1247. The top three drug classes of those medications were antibiotics, drugs acting on the central nervous system, and drugs acting on the cardiovascular system (19.4%, 17.3%, and 11.6%, respectively) (Table 2). For MEs that resulted in patient harm (Categories E–I), 54 medications were identified in the reports we analyzed (Table 3). Medication classes were also classified according to outcome category (Table 4). The potential for errors was high when chemotherapeutic agents were involved. The percentage of MEs that caused patient harm (Categories E–I) was high when insulin, potassium chloride, and drugs acting on the cardiovascular system were involved. Finally, it was noted that each medication class was associated with certain types of errors. The major error types associated with each medication class are detailed in Supplementary Appendix 2.

Sound-Alike and Look-Alike Errors
As an example of reported MEs, sound-alike and look-alike errors were responsible for 11 events. A complete list of those errors, medications, stage of the medication use process, and patient outcome is included in Supplementary Appendix 3.

Drug Information Sources
When discussing prescribing errors due to incorrect dose, contraindication, or interaction, the source of correct drug information is important to note. Analysis of this field of the form revealed that the most common references used were Medscape, Lexicomp Online, Global RPh, and Drugs.com, representing 38%, 32%, 8%, and 7.5% of all
DISCUSSION
This study is the first pioneer study that describes the ME problem on the national level in Egypt. All reporters were governmental hospital pharmacists. Most reports (66%) came from inpatient settings, 23% from ICUs, and 11% from outpatient settings. These numbers reflect the type of health professionals who have received training on the system. Therefore, the reader should be cautious when interpreting this data, because it represents errors detected by pharmacists and does not include some clinical settings (i.e., private hospitals or community pharmacies). However, patient demographics included both genders and all age groups.

Current System Users
Most reports were received from pharmacists who were trained in using the reporting system. The number of trained users was limited in this early phase to test the system’s stability and suitability before opening the reporting system to the entire nation. The pharmacists were trained both to detect errors and conduct proper investigations into those errors. The fact that few pharmacists have previous clinical education may raise doubts regarding their ability to review medication

Figure 4: Possible causes of errors, as selected by the reporters.

Figure 5: Causes of Category A errors (potential errors).
orders. However, this reflects the reality of any voluntarily reported data – accuracy cannot be verified and it is necessary to rely on the reporter’s judgment. To minimize this problem, we ask the reporter to provide the source of the drug information they reference in their report, and we communicate with the reporters to gather any missing data (specifically in cases in which MEs resulted in severe patient harm). Finally, we excluded any subjective reports that were contradictory or depended on the clinical situation or the physician’s experience.

Stage of the Event
In our results, the prescribing stage was the most common stage involved in MEs, followed by the monitoring and administration stages. National data from the US, the UK, and the Netherlands also revealed high rates of prescribing and administration errors, though there were some differences in the exact ranking and percentages of these types of errors in other countries. This emphasizes the fact that those two stages of the medication use process are critical and more prone to errors than other stages. For example, prescribing errors were the second most common type of ME recorded in CMR data,\textsuperscript{7} the NRLS,\textsuperscript{3} and a study of a New York State reporting system,\textsuperscript{19} and the fourth most common in MEDMARX data.\textsuperscript{18} According to our analysis and the literature, we concluded that there are three reasons for the higher percentage of prescribing errors in our results.

The first reason is that we analyze all MEs, including potential, prevented, and harmless MEs. According to Supplementary Appendix 1, 36.5% of the prescribing errors were potential MEs (Category A). Examples of the causes of these MEs include illegible handwriting and missing prescribing instructions. In contrast, in MEDMARX, potential errors by stage are not included.\textsuperscript{19} In a study of a New York State ME reporting system, only those errors that resulted in severe harm were collected; accordingly, the authors of the study explained that there are many checkpoints that intercept prescribing errors but no system can intercept administration errors.\textsuperscript{19}

Secondly, inappropriate drug therapy, ie, wrong dose or contraindications, were a subset of the prescribing MEs reported. In MEDMARX, inappropriate drug therapy was rarely reported, because that information is documented in other software systems by clinical pharmacists as a clinical intervention.\textsuperscript{18}

Finally, in Egypt, the administration process is poorly documented, so detecting such errors is difficult. In MEDMARX, more administration errors are reported because they are more well documented and easier to catch.\textsuperscript{18} Moreover, clinical pharmacists generally give more attention to reviewing prescriptions than to other aspects of the medication use process.

Error Type
The top reported ME types were incorrect dose, incorrect frequency, incorrect drug, and drug interactions. This highlights areas of the health system that need a great deal of improvement and raises the importance of the clinical pharmacist in adjusting medication doses and frequencies as well as avoiding drug interactions. The wrong dose, drug, and frequency were also highly ranked MEs in other published national data.\textsuperscript{3,18,19} The present study is the first that identifies common ME types associated with each stage of the medication use process (Table 1). Such classification gives more insight into important problems in each of these stages that should considered priority issues.

Patient Outcome
A large proportion of ME reports were potential errors (25%), prevented errors (11%), or errors that did not lead to any harm (51%). Harm to the patient (of any degree) occurred in 13% of all ME cases. Although MEs that resulted in patient harm represent a small percentage of the data we collected, it is essential to report all errors, including near misses and harmless errors, because these are a good source for learning and for preventing possible harm in other situations. This fact is also reported in other systems, in which the
percentage of patient harm range from 3%–16%.\textsuperscript{3,7,18} However, different systems use different classification methods. While MEDMARX uses the same classification method as NO HARMe, CMR of the Netherlands does not include a category for potential errors and NRLS of the UK does not have categories for either potential or prevented errors. Moreover, what is classified as a potential error also varies between systems. Interindividual variability in assessing patient risk is another common problem, one which was studied in the NRLS system.\textsuperscript{20} Data describing patient outcome in our study may be under- or overestimated, because, in most cases, pharmacists were unable to follow up on all the cases over time. Therefore, actual harm to patients may have occurred but may not have been detected. However, in some cases (eg, in cases of severe harm or death) it is not easy to assess causality between the ME and the patient outcome.

Recommendations

The top recommendations for addressing MEs were addressing professional education, work environment, prescribing instructions, drug information sources, and local ME reporting systems. These recommendations reflect the reporter’s opinion on ways to avoid future errors. However, a root cause analysis and developing more targeted recommendations by a panel of experts could produce a specific action plan to educate health professionals and improve the medical system.

Medications and Medication Classes

This study analyzed all medications commonly involved in MEs, the relationship between medication classes and clinical outcome, medications that caused harm to patients, and common MEs associated with certain medications. This analysis can help researchers and policy makers organize their priorities for developing educational plans, drug policies, and clinical practice guidelines. For example, 60% of MEs involving central nervous system drugs were related to drug interactions, which emphasizes the need for interaction checkers, a formulary spread, and clinical pharmacists in psychiatric departments that prescribes a great number of such medications.

Reporting Rate

The reporting rate is a useful metric for comparing the reporting culture between different countries and in the same country over several years, to study the degree of awareness of and confidence in the reporting system. However, reporting rates cannot be used to measure ME incidence or the quality of the health system. Studies have shown that voluntary reporting only captures a small percentage of the actual errors, the “tip of the iceberg.”\textsuperscript{21} The NCC-MERP considers that the value of reporting is to identify system weaknesses while using error rates to compare systems is useless.\textsuperscript{21}

In our study, the reporting system received an average of 200 reports per month. This reporting rate can be used in the future to study the growth of the reporting culture in Egypt over time. At this moment, we have not related this number to the population, the number beds, or the number of hospitals days per stay as a benchmark for comparisons with other countries, because, up until now, we have not achieved a real nationwide spread of the system. The cumulative number of reports per 1 000 000 inhabitants during the fifth year of the use of national systems in the US, Canada, the UK, and the Netherlands were 23, 509, 6301, and 1495, respectively.\textsuperscript{7}

The Value of National ME Data

There is no doubt that each individual medical institute has its own specific system defects, and it is essential to analyze MEs internally to address such problems. However, different health systems have many
similarities as well as common problems; therefore, sharing experiences on the national level is essential to enhance learning about MEs among different institutions. Some MEs are product-related, such as in problems with the medication name, package, or insert. Such errors could not be detected in internal systems and must be addressed and managed on the national level. In addition, national systems act as a model for all organizations to develop their own reporting systems and can help coordinate efforts for standardizing the methodology and taxonomy of ME analysis. Likewise, on the international level, a study from the Netherlands described how relevant lessons could be learned from national systems in other countries.22

**Future Plans**

To achieve the maximum benefit from the ME data we collected, we conducted a meeting with a panel of experts to discuss our results. We are now planning to publish the recommendations of this panel in a newsletter, to educate healthcare professionals. In this study, we are presenting the NO HARMe data set in its early phases of development. Only a pilot group of clinical pharmacists has been trained to use the system. In the next phases, more pharmacists, physicians, and nurses from all clinical settings will be trained and encouraged to report any errors. The system should be continuously updated to add any other types or classifications that can enable better analysis of all MEs. The system’s reliability should be tested so that different individuals can describe and report the same error in the same way. Our database should be connected with hospitals’ internal systems, so that the automatic transfer of reports is allowed, to help with better incident investigation on the local level and to eliminate the time needed for duplicate reporting to both systems. Researchers in the field of medication safety can use this preliminary analysis to generate new hypotheses and conduct further controlled studies for the assessment of certain error types or problems with specific medications. On the international level, there is a great demand for better collaboration between countries for standardization of ME terminology. Such unified taxonomy can help with knowledge transfer between national systems and can help facilitate the interpretation of publications from different countries.

**Study Limitations**

Although our reporting form was designed to collect the best available details on each ME event, like any other voluntarily reported data, the information in this observational uncontrolled study may be subject to bias. Sources of bias include underreporting, inaccurate reporting, and personal selection of which errors warrant reporting. Interindividual differences in the assessment of patient outcomes and the inability of pharmacists to follow up on cases may result in under- or
overestimation of the percentages of outcomes in each category. Moreover, the limited diversity of reporters’ demographics may affect the generalizability of the results. Reports from different health professional groups in other clinical settings may provide more accurate results. In general, voluntarily reported data cannot be used to calculate actual ME rates in the community; however, it is very useful for drawing trends and exploring areas that need improvement.

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. Despite the general limitations of voluntarily reported data, our analysis of this database has provided useful background for researchers and decision makers in Egyptian health systems that can be used to assess the ME problem, identify the root causes of MEs, and develop new preventive strategies and educational programs to address MEs. Continuous learning from our errors on internal, national, and international levels is the best way to improve patient safety standards in Egypt.

CONTRIBUTORS
N.A.S. and A.A.E. worked on study implementation and evaluated the whole project. Zahraa H. Shehata helped in study design, data analysis, and drafted the manuscript. All authors assisted in editing and providing guidance on the manuscript. All authors reviewed and approved the final submission.

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COMPETING INTERESTS
None.

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SUPPLEMENTARY MATERIAL
Supplementary material is available online at http://jamia.oxfordjournals.org/.

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