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CASE STUDY ON THE MANAGEMENT OF MEDICATION ERRORS AND NEAR MISSES: MALAYSIA PERSPECTIVE

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Abstract: Hospital A is a private hospital in Malaysia and this hospital monitored both medication errors and near misses. For 2015 a total of 141,309 prescriptions were issued from January to August 2015 and 146,361 issued for the same period in 2016.This hospital monitors medication errors and near misses based on the prescribing, dispensing and administration errors for 2015 and 2016 for a period of January to August. A trending was done to compare all data collected in 2015 again data collected in 2016. Data was analysed to find out reason for medication errors, near misses and prescription intervention. In 2015 one case of dispensing error was reported but there was no case reported in 2016. 12 cases of administration errors were reported in 2015 which had reduced to only 1 case in 2016. In term of near misses the number of cases reduced from 4 cases in 2015 to only one case in 2016 followed by 3 cases of dispensing near misses in 2015 to 2 cases in 2016. For wrong drug, there were 7 cases reported in 2015 but reduce to 3 cases in 2016. Wrong time/frequency recorded 5 cases in 2015 but only 1 case reported in 2016. In term of wrong dose, for 2015 there were 2 cases reported but no case recorded in 2016. There was 1 case each for wrong quantity and wrong labelling in 2015 but no case recorded in 2016. In term of dispensing error only one case reported in 2015 but no case reported for 2016. Two cases of near miss- dispensing of wrong drug and 1 case of near miss-dispensing with wrong label were reported in 2015 followed by 2 cases of near miss-dispensing of wrong drug in 2016. Through prescription interventions 2 cases of wrong drug and 2 cases of wrong strength were detected in 2015 and this figure had reduced to only one case of wrong drug in 2016.

Keywords:medication errors, near misses, prescribing, dispensing and administration errors, prescription interventions.

1. INTRODUCTION

The goal of drug therapy is to achieve defined therapeutic outcomes that will improve a patient's quality of life and minimizing patient risk (Hepler CD, 1990). The therapeutic use of drugs (prescription and non-prescription) and drug administration devices are associated with inherent risks, both known and unknown. The incidents or hazards that result from such risk have been defined as drug misadventure, which includes both adverse drug reactions (ADRs) and medication errors (Manasse HR, 1989).

Medication error is any preventable event that may cause or lead to inappropriate medication use or patient harm while the medication is in the control of the healthcare professional, patient or consumer (FDA) Near-miss (or potential errors) is when there is error but the medication is yet to be supplied to the patients.

Medication errors are the most common medical errors in all countries, particularly in developing countries(Kohn LT,2000;Osborne J,1999;McLeod MC,2013). Medication errors may account up to one-third of all medical errors in hospital, and it can lead to adverse outcomes such as increased mortality rates, increased length of hospital stay, and high medical expenses (Caglar S, 2011, Keers RN, 2013).

The National Patient Safety Agency revealed that medication errors in all care settings in the UK occurred in each stage of the medication treatment process, with 16% in prescribing, 18% in dispensing, and 50% in administration of drugs(NPSA,2006)

In the health-care system, medication errors compromise patient confidence and increase health-care costs. The problems and sources of medication errors are multidisciplinary and multifactorial due to lack of knowledge, sub-standard performance and mental lapses, or defects or failures in systems (Davis NM, 1981; Zellmer WA, 1990)

Experienced and inexperienced staff, including pharmacists, physicians, nurses, supportive personnel (e.g., pharmacy technicians), students, clerical staff (e.g., ward clerks), administrators, pharmaceutical manufacturers, patients and their caregivers, and others may commit medication errors. Valid comparisons of different studies on medication errors are extremely difficult because of differences in variables, measurements, populations, and methods making the incidence of medication errors indeterminate (Zellmer WA, 1990).

The pharmacist should lead collaborative, multidisciplinary efforts to prevent, detect, and resolve drug-related problems that can result in patient harm through a system – oriented approach (Davis NM, 1981).

Monitoring of patients and medications associated with increased risk for serious errors can be improved by understanding the risk factors associated with medication errors and should enable the development of organizational systems designed to minimize risk(Lesar RS,1990).

Educating patients is very important to reduce medication errors. The patient has much to contribute to these processes. Some responsibility has to be taken by them for their own medicines management and ideas are given within the document to try to develop this aspect of patient care. Good communication, as in all areas of safe health care, is important and to be encouraged by all. Again, agreed and prioritised goals should be set and monitored, using patient groups as appropriate.

National patient safety agency in United Kingdom had made the following recommendations to reduce medication errors (Department of Health, 2004b)

1. All serious prescribing errors and "near misses" should be reported to the NPSA
2. Prescriptions should always carry patient directions and never be issued with the instruction "as directed"
3. Particular attention should be paid to checking the accuracy of complex dose calculations
4. The patient's medical record should always be checked before a new prescription is written
5. The treatment plan, including how the response to drug therapy is to be monitored, should be clearly documented in the patient's clinical record
6. Prescribers should be trained and assessed as competent before being required to prescribe

Medication errors are always avoidable.Some adverse reactions to medicines are unpredictable and therefore cannot be avoided. Similarly side effects that are known and are part of the accepted risks of treatment can, by careful prescribing, be minimised or even avoided. Emphasis has to be placed on, and energy directed towards, what are described asmedication errors, i.e. "mistakes, slips or lapses made when medicines are prescribed, dispensed or used", as these are "always avoidable". Medication errors include prescribing errors, dispensing errors, medication administration errors, and patient compliance errors (Jane Cowan,2004).

Types of medication can be categorised as per the following table:

Type	Definition
Prescribing error	Incorrect drug selection,dose, dosage form, quantity,route, concentration, rate of administration, illegible prescriptions or medication orders that lead to errors that reach the patient
Omission error	The failure to administer an ordered dose to a patient before the next scheduled dose if any
Wrong time error	Administration of medication outside a predefined time interval from its scheduled administration time
Unauthorized drug error	Administration to the patient of medication not authorized by a legitimate prescriber for the patient
Improper dose error	Administration to the patient of a dose that is greater than or less than the amount ordered by the prescriber
Wrong dosage-form error	Administration to the patient of a drug product in a different dosage form than ordered by the prescriber
Wrong drug-preparation error	Drug product incorrectly formulated or manipulated before administration

In order to minimize error, organizational systems for ordering, dispensing, and administering medications should be designed. It may involve process breakdowns in more than one aspect of a system. Organizational policies and procedures should be established to prevent medication errors. Development of the policies and procedures should involve multiple departments, including pharmacy, medicine, nursing, risk management, legal counsel, and organizational administration. The following recommendations are offered for organizational management and clinical staff (Davis NM, 1981;ASHP,1980)

Ongoing quality improvement programs for monitoring medication errors are needed. The difficulty in detecting errors has long been recognized as one of the barriers to studying the problem effectively(Baker KN, 1962). Medication errors should be identified and documented and their causes studied in order to develop systems that minimize recurrence (Davis NM,1981; Zellmar WA, 1990). Several error monitoring techniques exist (e.g., anonymous self-reports, incident reports, critical incident technique, and disguised observation technique) and may be applied as appropriate to determine the rates of errors (Allan EL, 1990; Allan EL,1990). There are differences in the validity of data obtained by the various error monitoring techniques or combined techniques. Program managers should determine the best method for use in their organizations in consideration of utility, feasibility, and cost. Monitoring programs for medication errors should consider the following risk factors(ASHP,1991; McClure ML,1985)

For patients today, pharmacotherapy remains the primary mode of treatment . For year 2008 , in the Ministry of Health Malaysia alone, a total of 33.6 million prescriptions were dispensed at the outpatient pharmacy while 7.9 million prescriptions were filled for inpatients compared to 32 million and 6.9 million prescriptions respectively the previous year. This shows a significant increase in the numberof prescriptions filled and dispensed by pharmacy and the growing trend is verylikely to continue in the years ahead.The primary objective of medication error reporting is to obtain information onthe occurrence of medication errors, maintain a database of medication errors,analyse reports, propose remedial actions and monitor the situations in an effortto minimise the reoccurrence of such errors and, ultimately, to improve patientsafety.(MOH, 2009).

In Malaysia, medication error reporting is at the moment on a voluntary basis.Under the Malaysian Medication Error Reporting System, it is proposed that a Medication Safety Centre (MedSC) be established. The MedSC will solicit and encourage reporting of medication errors and will maintain strict confidentiality with regards to the identity of patients and the healthcare providers involved. The primary objective of medication error reporting is to obtain information on the occurrence of medication errors, maintain a database of medication errors,analyse reports, propose remedial actions and monitor the situations in an effort to minimise the reoccurrence of such errors and, ultimately, to improve patient safety.

Classification of Medication Error severity

Category A (no error)	Potential error, circumstances/events that have the potential to cause incident
Category B (error, no harm)	An error occurred but the error did not reach the patient (an error of omission' does reach the patient).
Category C (error, no harm)	An error occurred that reached the patient but did not cause patient harm.
Category D (error, no harm)	An error occurred that reached the patient and required monitoring to confirm that it resulted in no harm to the patient and/or required intervention to preclude harm
Category E (error, harm)	An error occurred that may have contributed to or resulted in temporary harm to the patient and required intervention
Category F (error, harm)	An error occurred that may have contributed to or resulted in temporary harm to the patient and required initial hospitalisation.
Category G (error, harm)	An error occurred that may have contributed to or resulted in permanent patient harm.
Category H (error, harm)	An error occurred that required intervention necessary to sustain life.
Category I (error, death)	An error occurred that may have contributed to or resulted in the patient's death

(MOH, 2009)

11. OBJECTIVES

i. To compare number of medication errors and near misses reported from January to August 2015 versus January to August 2016.

ii. To analyse medication errors and near misses recorded from January to August 2015 and

2016
iii. To analyse medication errors and near misses by types for both period of 2015 and 2016
iv. To analyse medication errors in dispensing and administration for both period of 2015 and 2016
v. To analyse near misses in dispensing and prescription intervention for both period of 2015 and 2016

III. METHODOLOGY

Retrospective study was conducted for a period of two years from January to August 2015 and January to August 2016. Data were collected based on number of medication errors and near misses. Data were also collected for types of medication errors and near misses, medication errors in dispensing, administration and prescription intervention. A trending will be done to compare all data collected in 2015 again data collected in 2016. Data will be analysed to find out reason for medication errors,near misses and prescription intervention. Analysis will also be done for each data.

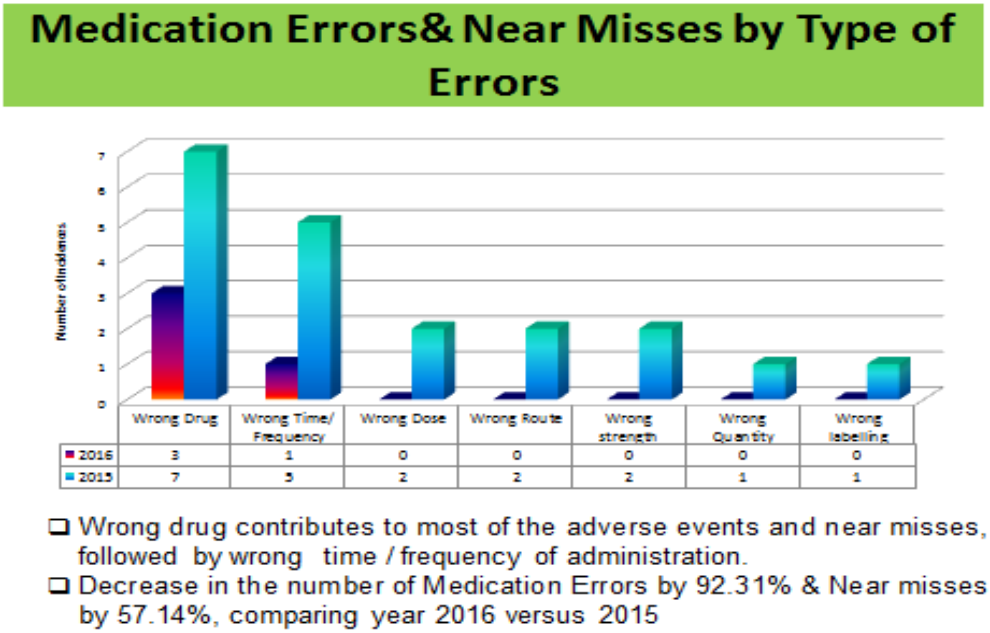
IV. RESULTS

TABLE 1

MEDICATION ERRORS AND NEAR MISSES

Incidences	As at 31st August 2016		As at 31st August 2015		Variance (%)
Medication Error		Per 1000 Rx		Per 1000 Rx	
Number of Rx	146,361		141,309		+3.58%
Prescribing Error	0	0	0	0	Nil
Dispensing Error	0	0	1	0.007	(100%)
Administration Errors	1	0.0068	12	0.085	(91.67%)
Sub Total	**1**	**0.0068**	**13**	**0.092**	**(92.31%)**
Near Miss		Per 1000 Rx		Per 1000 Rx	
Prescribing Error	1	0.0068	4	0.028	(75%)
Dispensing Error	2	0.014	3	0.021	(33.33%)
Administration Errors	0	0	0	0	Nil
Sub Total	**3**	**0.020**	**7**	**0.049**	**(57.14)**
Total	**4**	**0.027**	**20**	**0.142**	**(80%)**

TABLE 2



- Wrong drug contributes to most of the adverse events and near misses, followed by wrong time / frequency of administration.
- Decrease in the number of Medication Errors by 92.31% & Near misses by 57.14%, comparing year 2016 versus 2015

TABLE 3

Medication Error– Dispensing

Near Miss – Rx Interventions	As at 31st August 2016		As at 31st August 2015		Variance (%)
Prescribing Errors	*No*	*Per 1000 Rx*	*No*	*Per 1000 Rx*	
Number of Prescriptions	146,361		141,309		+3.58%
Wrong Quantity	0	0	1	0.0086	(100%)
Total	0	**0**	**1**	**0.0086**	**(100%)**

- Wrong quantity of antibiotic suspension– stability issue (should have supplied one reconstituted bottle plus one un-reconstituted bottle, but both reconstituted)
  - A freshly prepared bottle of suspension was managed to deliver to patient without interrupting the antibiotic course.
- Improvement Plan:
  - A table of stability data for antibiotic suspension was being compiled and displayed on reconstitution corner. This is to provide immediate reference to all staff diluting the syrup.

TABLE 4

Medication Error– Administration

Medication Error	As at 31st August 2016		As at 31st August 2015		Variance (%)
Administration	*No*	*Per 1000 Rx*	*No*	*Per 1000 Rx*	
Number of Prescriptions	146,361		141,309		+3.58%
Wrong Time/ Frequency	1	0.0068	5	0.043	(80%)
Wrong Drug	0	0	3	0.026	(100%)
Wrong Dose	0	0	2	0.017	(100%)
Wrong Route	0	0	2	0.017	(100%)
Total	1	**0.0068**	**12**	**0.103**	(91.67)

- Once daily dosing given twice daily
  - However it does not exceed the maximum dose and patient has not presented with any undesired adverse effects
- Main contributing factors :staff competency level (66.67%)
- Improvement plan:
  - Refresher training on reading prescription in full, proper verification of frequency of drug dosing, annual competency assessment, bedside monitoring, National Nursing Audit by unit managers
  - Education of Proper Drug Administration to be conducted every two-monthly

TABLE 5

Near Miss– Dispensing

Near Miss – Rx Interventions	As at 31st August 2016		As at 31st August 2015		Variance (%)
Prescribing Errors	*No*	*Per 1000 Rx*	*No*	*Per 1000 Rx*	
Number of Prescriptions	146,361		141,309		+3.58%
Wrong Drug	2	0.0137	2	0.0141	Nil
Wrong Labelling	0	0	1	0.0071	(100%)
Total	2	**0.0137**	3	**0.0212**	**(33.33%)**

- Main contributing factors include:
- Task factor : staff compliance to policy and procedures, fail to double check or improper checking.
- Individual factors : competency / knowledge of staff and personal factors such as lack of focus due to personal problems
- Staff involved in the incidences were found to be a mixture of experienced and less experienced staff (less than one year).
- Improvement plan: Permanent checker, Medication Audits, Staggered hours Duty, Medication Safety Awareness Programme

TABLE 6

Near Miss – Prescription Interventions

Near Miss – Rx Interventions	As at 31st August 2016		As at 31st August 2015		Variance (%)
Prescribing Errors	*No*	*Per 1000 Rx*	*No*	*Per 1000 Rx*	
Number of Prescriptions	146,361		141,309		+3.58%
Wrong Drug	1	0.0068	2	0.0141	(50%)
Wrong Strength	0	0	2	0.0141	(100%)
Total	1	0.0068	4	0.0282	(75%)

- Three (3) near misses detected in year 2015 while one in year 2016
- Prescribers involved have been noted about the near-misses and emphasized on the appropriate prescribing as to avoid prescribing error.
- Prescribers were also encouraged to educate patients more on indications of medicines prescribed- to help to capture any errors
- Data was presented to hospital's Pharmacy and Therapeutic Committee

NB: Statistics were extracted from Pharmacy Prescription Interventions and excluding Incompleteness of Prescriptions statistics

V. DISCUSSION

Total prescription from January to August 2015 was 141,309 and for the same period for 2016were 146,361. There was no medication error as at August 2015 and as August 2016. One case of dispensing error was reported in 2015 but there was no case reported in 2016. Administration errors had reduced from 12 cases in 2015 to only 1 case in 2016. In term of near misses the number of cases reduced from 4 cases in 2015 to only one case in 2016 followed by 3 cases of dispensing near misses in 2015 to 2 cases in 2016. For both years there was no reported case of near misses for administration of medication. Compared to the total number of

prescription for both years the number of medication errors and near misses are very low compared to other centres. According to the National Patient Safety Agency revealed that medication errors in all care settings in the UK occurred in each stage of the medication treatment process, with 16% in prescribing, 18% in dispensing, and 50% in administration of drugs(NPSA,2006). The number of cases for both medication errors and near misses had reduced in 2016 compared to 2015 because of continuous teaching conducted for both pharmacy and nursing staff.

Medication errors and near misses for both years are further subdivided into wrong drug; wrong time/frequency; wrong dose; wrong strength; wrong quantity and wrong labelling. For wrong drug, there was 7 cases reported in 2015 but reduce to 3 cases in 2016. Wrong time/frequency recorded 5 cases in 2015 but only 1 case reported in 2016. In term of wrong dose, for 2015 there was 2 cases reported but no case recorded in 2016. There was 1 case each for wrong quantity and wrong labelling in 2015 but no case recorded in 2016. The reduction in number of cases reported in 2016 was due to the continues effort taken to improve the quality of care as stated by (Baker KN, 1962) where ongoing quality improvement programs for monitoring medication errors are needed. The difficulty in detecting errors has long been recognized as one of the barriers to studying the problem effectively. Medication errors should be identified and documented and their causes studied in order to develop systems that minimize recurrence (Davis NM,1981; Zellmar WA, 1990).

In 2015, 141,309 prescriptions have been dispensed which increase to 1465,361 in 2016. Only one case of dispensing error reported in 2015 but no case reported for 2016. For the dispensing error reported in 2015 two bottles of antibiotic were reconstituted instead of one bottle causing shortage of supply to cover the whole cause of the treatment. As a remedial measure the pharmacy service had issued another bottle of un-reconstituted antibiotic by sending the drug to patient's house so that the patient can have sufficient stock to complete the treatment. For improvement plan a table of stability data for antibiotic suspension was compiled and displayed on reconstitution corner to provide immediate reference to all staff doing the dilution.

Five cases of wrong time/frequency, 3 cases of wrong drug, 2 cases of wrong dose and 2 cases of wrong route were reported in 2015. However only 1 case of wrong time/frequency reported in 2016 with no reported cases for wrong drug, wrong dose and wrong route. In total 12 cases reported in 2015 but only one case reported in 2016. Therefore there was a big reduction in term of cases reported in 2016. Out of 1000 prescription administered in 2015, the percentage of wrong time/frequency was 0.043, wrong drug 0.026, wrong dose 0.017 and wrong route 0.017 which are relatively low. However for 2016 only 0.0068 percent of wrong time/frequency for wrong time/frequency with no reported cases for wrong drug, wrong dose and wrong route. The main contributing factor of administration error is lower competency level of staff (66.67%). Therefore in order to reduce number of administration error refresher training on reading prescription in full, proper verification of frequency of drug dosing, annual competency assessment, beside monitoring and nursing audit by unit managers were conducted. On top of that education on proper drug administration were also conducted every two monthly.According to (Zellmar WA, 1990), valid comparisons of different studies on medication errors are extremely difficult because of differences in variables, measurements, populations, and methods making the incidence of medication errors indeterminate. However experienced and inexperienced staff, including pharmacists, physicians, nurses, supportive personnel (e.g., pharmacy technicians), students, clerical staff (e.g., ward clerks), administrators, pharmaceutical manufacturers, patients and their caregivers, and others may commit medication errors.

For 2015, 2 cases of near miss- dispensing of wrong drug and 1 case of near miss-dispensing with wrong label were reported. However for 2016 the number of near miss-dispensing of wrong drug reported remain the same as 2015 with no near miss- dispensing with wrong label. In term of percentage per 1000 prescription, the percentage for wrong drug near miss- dispensing for 2015 and 2016 were 0.0141 followed by 0.0071 for near miss-dispensing with wrong label for 2015 with no reported case in 2016.

Near misses were also detected through prescription interventions. Two cases of wrong drug and 2 cases of wrong strength were detected in 2015 and this figure had reduced to only one case of wrong drug in 2016. The percentage in term of per 1000 prescription was very low which is 0.0282% in 2015 and much lower in 2016 with only 0.0068%.

V. CONCLUSION

141,309 total prescriptions were issued from January to August 2015 and 146,361 issued for the same period for 2016 where there was no medication error as at August 2015 and 2016. In 2015 one case of dispensing error was reported but there was no case reported in 2016. 12 cases of administration errors were reported in 2015 which had reduced to only 1 case in 2016. In term of near misses the number of cases reduced from 4 cases in 2015 to only one case in 2016 followed by 3 cases of dispensing near misses in 2015 to 2 cases in 2016.For wrong drug, there were 7 cases reported in 2015 but reduce to 3 cases in 2016. Wrong

time/frequency recorded 5 cases in 2015 but only 1 case reported in 2016. In term of wrong dose, for 2015 there were 2 cases reported but no case recorded in 2016. There was 1 case each for wrong quantity and wrong labelling in 2015 but no case recorded in 2016. In term of dispensing error only one case reported in 2015 but no case reported for 2016. Two cases of near miss- dispensing of wrong drug and 1 case of near miss-dispensing with wrong label were reported in 2015 followed by 2 cases of near miss-dispensing of wrong drug in 2016. Through prescription interventions 2 cases of wrong drug and 2 cases of wrong strength were detected in 2015 and this figure had reduced to only one case of wrong drug in 2016.

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