



Contributing factors to outpatient pharmacy near miss errors: a Malaysian prospective multi-center study

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Abstract

Background Detecting errors before medication dispensed or ‘near misses’ is a crucial step to combat the incidence of dispensing error. Despite this, no published evidence available in Malaysia relating to these issues. **Objective** To determine the incidence of medication labeling and filling errors, frequency of each type of the errors and frequency of the contributing factors at the final stage before dispensing. **Setting** Six Penang public funded hospitals outpatient pharmacies. **Methods** A prospective multicentre study, over 8 week’s period. Pharmacists identified and recorded the details of either medication labeling and/or filling error at the final stage of counter-checking before dispensing. Besides, the contributing factors for each error were determined and recorded in data collection form. Descriptive analysis was used to explain the study data. **Main outcome measure** The incidence of near misses. **Results** A total of 187 errors (near misses) detected, with 59.4% (n = 111) were medication filling errors and 40.6% (n = 76) were labeling errors. Wrong drug (n = 44, 39.6%) was identified as the highest type of filling errors while incorrect dose (n = 34, 44.7%) was identified as the highest type of labeling errors. Distracted and interrupted work environment was reported to lead the highest labeling and filling errors, followed by lack of knowledge and skills for filling errors and high workload for labeling errors. **Conclusion** The occurrence of near misses related to medication filling and labelling errors is substantial at outpatient pharmacy in Penang public funded hospitals. Further research is warranted to evaluate the intervention strategies needed to reduce the near misses.

Keywords Contributing factors · Filling · Labeling · Malaysia · Medication · Medication errors · Near misses

Impacts on practice

- Identifying the pattern and types of near miss errors helps to draw strategies to minimise actual error and improve patient safety.
- Reexamining the pharmacy work process and policies is warranted to reduce workload and improve the working environment that highly contributes to near miss errors.
- Extensive hands-on trainings on regular basis should be implemented to improve the pharmacy personnel’s competency in medication labelling and filling.

Introduction

A dispensing error at an outpatient pharmacy in a hospital setting is defined as the discrepancy between written prescription and the medicine that the pharmacist dispenses to the patient

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[1]. The prevalence of dispensing error reported was considerably high at hospital setting in the United States ranging from 0.06 to 18% and in the United Kingdom from 0.008 to 0.02% [2]. However, it is far lesser than reported near misses prevalence [2–5]. Near misses are errors detected up to and including the point at the final stage before the medicine is handed to patients [4]. Although near misses were considered less threatening, inefficient counter-checking could lead to real dispensing error and patient harm. Thus, a well-established mechanism to detect dispensing errors should be well incorporated in a pharmacy's work process.

So far, most of the available literatures in Malaysia have focused on other forms of medication errors like prescribing errors [6–9] and administration errors [10–12] but dispensing errors or near misses have been under-researched. The incidence of dispensing error is rather very small in percentage because majority of it was reported by patients. Therefore, it would require a long time to collect the data about the prevalence of these errors. However, the near misses are often detected at the counter-checking stage or by pharmacists during dispensing drugs. Therefore, the information derived from this study can be used to have an overview of the pattern and types of error. Better intervention at pharmacy level can be instituted to minimize or possibly eliminate dispensing errors. According to Malaysia National Quality Assurance Performances (QAP) 2013 report [13], medication labeling and filling errors were cited as the main cause of near misses occurrence at the outpatient pharmacy, accounting for 28.4% and 47.8% respectively. Unfortunately, there is no published data on the rate of near misses or its contributing factors, which are the first steps in the process of ensuring patient safety.

Aim of study

The present study aims to investigate the near miss at the outpatient pharmacy of six Malaysian public-funded hospitals and determine the contributing factors that lead to the near miss.

Ethics approval

The study was approved by Malaysia Research Ethics Committee (MREC) with Registration No. NMRR-15-2158-26650.

Methods

Study design and setting

This is a prospective cross-sectional study which involved detection of any medication labeling and filling errors

before dispensing (near misses) at the outpatient pharmacy of six public-funded hospitals in Penang of the north-west of Malaysia. The hospitals were Hospital Pulau Pinang, Hospital Seberang Jaya, Hospital Bukit Mertajam, Hospital Sungai Bakap, Hospital Kepala Batas and Hospital Balik Pulau. Data were collected during office hours from September to October 2015. The study was conducted in two steps:

Step 1 The incidence of near misses detected with either medication labeling or filling error or both in the final stage of counter-checking at the dispensary counter were included. Pharmacist reporting the error was not informed regarding the study to minimize bias in reporting. The error reporting was incorporated into the existing workflow, and the pharmacist needs to fill up a data collection form at the dispensary counter upon detecting an error. The data collection form includes the categorization of the near misses (medication labeling or filling errors), classification of labeling or filling error and personnel involved. Table 1 shows the classification of the labeling and filling errors.

Step 2 A trained personnel not involved in the study was assigned as the data collector at each study setting. The data collector was responsible for collecting the data collection form, verifying the information noted by the pharmacist and interviewing the staff committed the error using a validated questionnaire on the same day or the next day of error during office hours to determine the possible contributing factors to the near misses. Further information on the personal demographics (age and education background) and work-related factors (designation and work experience) were also obtained.

Validation

The definition and classification of medication labeling and filling errors used for this study were adapted from a previously published study [1] and merged with few definition and classification that occur at the local settings during series of group discussions involving the investigators. Both the data collection and list were distributed to all the chief pharmacists of Penang public funded health facilities and a few experienced independent pharmacists for content and face validation. The feedback was used to make minor amendments accordingly.

Further, the classification and contributing factors determined by the data collectors were cross-evaluated by study investigators. Discussion was instituted by them on the data and results, and third-party involvement took place if the consensus was not reached.

Table 1 Classification of labeling and filling errors. Adapted from Beso et al. [1]

Labeling errors	
<i>Omission patient details</i>	Omission of the patient's data on the prescription
<i>Incorrect drug name</i>	The drug name on the label deviate from that specified by prescribers
<i>Incorrect drug strength</i>	Where more than one strength available, the strength labeled deviate from that specified by the doctors
<i>Incorrect dosage form</i>	The dosage form on the label deviate from that specified by the prescribers
<i>Incorrect of administration method</i>	Omission or deviation of specific administration instruction
Filling errors	
<i>Unfilled drug</i>	Omission of the drug that specified by prescribers during the filling process
<i>Wrong drug</i>	Deviation of drug filled from that specified by prescribers
<i>Wrong strength</i>	Where more than one strength available, the strength filled deviate from that specified by the doctors
<i>Wrong quantity</i>	Different quantity filled deviate from that specified by prescribers
<i>Wrong dosage form</i>	Different dosage form filled deviate from that specified by prescribers

Data analysis

Data was analyzed using predictive analytics software (PASW) version 18.0. Descriptive statistics were used to determine the near misses, medication labeling and filling errors in frequency (percentage). The contributing factors were analyzed according to medication labeling and filling errors with the profession category consisting of pharmacists, pharmacist trainees, dispensers (pharmacy technicians) and dispenser trainees.

Results

During the 2 months study period, approximately 220,000 prescriptions with 720,000 items were received at the outpatient pharmacy of the hospitals. Out of the total, 78 prescriptions had 187 near misses, of which filling errors were 59.4% (n = 111), and labeling errors were 40.6% (n = 76). Therefore, the prevalence of near misses that can be generated from this data was 0.0003% which means there were 3 near misses with every 10,000 items dispensed. Of those near misses, the leading type of filling errors recorded were wrong drugs (39.6%, n = 44), wrong quantities (29.7%, n = 33) and wrong strengths (18.0%, n = 20). Meanwhile, the medication labeling errors mostly were drug dose (44.7%, n = 34) followed by drug strength (19.7%, n = 15) and drug name (14.5%, n = 11).

The personnel's contributed to the filling errors were the dispensers (40.5%, n = 45) followed by dispenser trainees (27.9%, n = 31). Dispensers were most frequently involved in supplying the wrong drugs (38.6%, n = 17) and wrong strength of the medications (65.0%, n = 13). Whereas dispenser trainees were most frequently involved in supplying wrong drugs (34.1%, n = 15) and wrong quantities (30.3%, n = 10). Pharmacists were found to commit the most labeling errors (44.7%, n = 34), followed by dispensers (38.2%, n = 29). They were frequently found to label the dose of the medication incorrectly. Tables 2 and 3 summarize the details of the frequency and type of filling and labeling errors according to the professional categories.

Overall, work environment (n = 44), workload (n = 32), lack of knowledge and skills (n = 30) and stressors (n = 20) were concluded as the primary contributing factors for their near misses. As for the work environment, distraction accounted for 54.6% (n = 24) and interruption 29.5% (n = 13) and most frequently cited by the dispensers (47.8%, n = 21). The circumstances most often associated with workload were busyness during peak hours (15.6%, n = 5) and time constraint (to reduce patient's waiting time) (71.9%, n = 23). Furthermore, pharmacy staffs' physical conditions (95%, n = 19) such as illness and sleep deprivation were reported as the most contributing factors for stressors. The contributing factors according to the professional categories and subcategories of contributing factors to near misses are demonstrated in Tables 4 and 5.

Table 2 Type and frequency of filling errors based on profession categories

Profession category, errors (n, %)	Type and frequency of filling errors, n (%)				
	Unfilled drug	Wrong drug	Wrong strength	Wrong quantity	Wrong dosage form
Pharmacists (16, 14.4)	1 (8.3)	5 (11.4)	4 (20.0)	6 (18.2)	0 (0.0)
Pharmacist trainees (19, 17.1)	5 (41.7)	7 (15.9)	1 (5.0)	6 (18.2)	0 (0.0)
Dispensers (45, 40.5)	3 (25.0)	17 (38.6)	13 (65.0)	11 (33.3)	1 (50.0)
Dispenser trainees (31, 27.9)	3 (25.0)	15 (34.1)	2 (10.0)	10 (30.3)	1 (50.0)
Total filling errors (111, 59.4)	12 (10.8)	44 (39.6)	20 (18.0)	33 (29.7)	2 (1.8)

Table 3 Type and frequency of labeling errors based on profession categories

Profession category, errors (n, %)	Type and frequency of labeling errors, n (%)					
	Patient details	Drug name	Drug strength	Administration method	Dose	Frequency
Pharmacists (34, 44.7)	2 (66.7)	5 (45.5)	7 (46.7)	2 (66.7)	12 (35.3)	5 (50.0)
Pharmacist trainees (13, 17.1)	0 (0.0)	1 (9.1)	1 (6.7)	1 (33.3)	7 (20.6)	3 (30.0)
Dispenser (29, 38.2)	1 (33.3)	5 (45.5)	7 (46.7)	0 (0.0)	15 (44.1)	2 (20.0)
Dispenser trainees (0, 0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Total labeling errors (76, 40.6)	3 (3.9)	11 (14.5)	15 (19.7)	3 (3.9)	34 (44.7)	10 (13.2)

Discussion

Identifying types of medication filling, labeling errors and their contributing factors are crucial steps to draw strategies, in order to curb the reoccurrence of near misses and to improve patient safety. Analyzing near misses can reduce the risk of potential dispensing errors.

From our study, we found wrongly filled drug and strength were highest among dispensers. Given the fact that most of the medication filling at hospital settings in Malaysia carried out by dispensers, this finding was alarming. The undetected error of wrongly filled drug or drug strength reaching patients might be linked with serious adverse events [14–16]. However, to our greatest relief, the errors were captured at the counter-checking stage. Numerous studies have established the importance of quality control or counter-checking of the medications labeled and filled before dispensing to patients [1, 16–18]. Although counter-checking is proposed as a reliable step to ensure the right dose, administration and frequency of medication delivered to right patients, some major barriers need to be addressed to promote its effectiveness. Firstly, with the high workload in Malaysian public-funded hospitals handling, an additional/selective counter-checking serves as an alternative option for busy settings. However, the inconsistency of the counter-checking practice and considerable variability of the practice at each setting affect its ability to detect errors. Thus, a standard and validated process in conducting counter-checking with emphasis on pharmacy staff training is essential. In Cancer Institute of East Melbourne, implementation of Dispensing Accurately and Near Miss Program (DANMP) has successfully reduced dispensing errors. This program aimed to provide extensive training based on dispensing module assessment checklist, besides to minimize reliance on staffs' memory on protocols and procedures [19].

The data from this study indicated labeling errors are more prevalent among pharmacists with mostly involving drug name, strength, and frequency. In line, a review paper on preventable and unpreventable dispensing errors reported that wrong drug and wrong strength/dose on label, accounts for the majority of labeling errors but without

any specification on pharmacist errors [2]. Pharmacists in Malaysia, especially in the outpatient pharmacy are commonly multi-tasked. Most of them play a wide range of roles including dispensing medications, patient counseling, management of the outpatient pharmacy and helping out at the counter to label and fill at peak hours. Notably, the pharmacists surveyed mentioned that workload as their main reason for the near misses. Consistently, a cross-sectional study conducted among 209 registered pharmacists in Tasmania reported workload as a significant contributing factor to dispensing errors. The authors suggested that a mechanism of work schedules need to be implemented with input from all parties involved without compromising patient safety and quality of service provided [20]. Besides, an observational study mentioned that lunchtime is an ideal situation for error to occur with fewer staffs but higher patient loads [21]. Although our current study fails to investigate this correlation, such condition is highly anticipated in our setting.

The work environment is another strong contributing factor to labeling and filling errors. Further sub categorization found distraction and interruption as a major part of this factor. Elizabeth and colleague [21] reported dispensing error rate for prescription with one or more interruption and distraction was 6.65% with both significantly associated with the errors. Thus as in our study settings, an overall approach should be undertaken to minimize this condition. One of the strategies is job specification to avoid any form of distraction and interruption. Many times personnels especially pharmacists need to answer or make calls to verify prescription while they are labeling or filling medications. Designated pharmacists should be appointed to perform this task, hence reducing the involvement of staffs that are labeling or filling. Besides if there is any call to be attended urgently, the ongoing labeling or filling job should be handed over to another staff with clear instructions. Another strategy highlighted in a study is the use of fax or answering machine that may be able to reduce distraction from phone calls [22].

Near misses due to lack of knowledge and skills especially among pharmacist trainees and dispenser trainees should not be overlooked. Extensive trainings and teaching sessions emphasizing hands-on activities are necessary to

Table 4 The contributing factors according to the profession category, n (%)

Contributing factors Profession category	Work environment			Workload			Knowledge and skills			Stressors			Drug design			Communication																
	Filling	Labeling	Total	Filling	Labeling	Total	Filling	Labeling	Total	Filling	Labeling	Total	Filling	Labeling	Total	Filling	Labeling	Total														
	(n)	(%)	(n, %)	(n)	(%)	(n, %)	(n)	(%)	(n, %)	(n)	(%)	(n, %)	(n)	(%)	(n, %)	(n)	(%)	(n, %)														
Pharmacists	5	(11.4)	11 (25.0)	3	(9.4)	8 (25.0)	11	(34.4)	0	(0)	2	(6.7)	2	(10.0)	3	(15.0)	3	(37.5)	1	(12.5)	4	(50)	0	(0)	0	(0)	3	(50.0)	3	(50.0)		
Pharmacist trainees	2	(4.5)	6 (13.6)	1	(3.1)	1 (3.1)	2	(6.2)	4	(13.3)	2	(6.7)	6	(20.0)	3	(15.0)	3	(15.0)	1	(12.5)	2	(25.0)	2	(25.0)	0	(0)	0	(0)	0	(0)		
Dispenser	13	(29.6)	21 (47.8)	10	(31.2)	7 (21.9)	17	(53.1)	1	(3.3)	0	(0)	1	(3.3)	4	(20.0)	7	(35.0)	11	(55.0)	1	(12.5)	1	(12.5)	2	(25.0)	0	(0)	1	(16.7)		
Dispenser trainees	6	(13.6)	6 (13.6)	2	(6.3)	0	(0)	2	(6.3)	21	(70.0)	0	(0)	21	(70)	0	(0)	0	(0)	0	(0)	0	(0)	0	(0)	0	(0)	2	(33.3)	2	(33.3)	
Total	26	(59.1)	44 (100.0)	16	(50.0)	16	(50.0)	32 (100.0)	26	(86.6)	4	(13.4)	30	(100.0)	8	(40.0)	12	(60.0)	20	(100.0)	5	(62.5)	3	(37.5)	8	(100.0)	2	(33.3)	4	(66.7)	6	(100.0)

Of 187 detected near-miss errors, only 140 contributing factors included. 47 Near-misses excluded due to more than one contributing factors (32 near-misses), not be stated any contributing factors (3 near-misses), factors stated not in the list (12 near-misses)

Table 5 Subcategories of contributing factors to near misses (n = 140)

Category of contributing factors	Subcategories of contributing factors	n (%)
Work environment	Distraction	24 (54.6)
	Interruption	13 (29.5)
	Working conditions	1 (2.3)
	Drug arrangement	6 (13.6)
Workload	Time constraint	23 (71.9)
	Busy	5 (15.6)
	Short staffed	4 (12.5)
Skills and knowledge	Unfamiliarity with the tasks	26 (86.7)
	Inadequate knowledge	4 (13.3)
Stressors	Physical conditions	19 (95.0)
	Low motivation	1 (5.0)
Drug designs	Look alike	6 (75.0)
	Sound alike	2 (25.0)
Communication	Illegible writing/incomplete prescription	5 (83.3)
	Ambiguous abbreviations	1 (16.7)

provide enhanced skills that are beneficial for their daily work at outpatient pharmacy. Indeed, some of pharmacists and dispensers also have stated that lack of knowledge and skills as contributing factors to their near misses. These could be explained by a high turnover staff rate, appointment of new staffs and frequent switching of the work stations at the outpatient pharmacy.

Although look-alike and sound-alike (LASA) medication still seem to contribute to the near misses in the current study, but they are only in a smaller percentage. Credits go to the tremendous on-going efforts by the Pharmaceutical Service Division, Malaysian Ministry of Health with the introduction of an established national guideline [23]. Some of the measurements in the guideline were the use of Tall Man lettering to emphasize differences in medications with sound-alike names, additional warning labels for look-alike medications and different storages of the medications that sounds and looks alike. However, the implementation of the guidelines needs to be strengthened to reach all staffs. Besides prescribers' illegible writing, use of non-standard abbreviation, confusing brand names, and incomplete prescription, serve as barriers to good communication between prescribers and pharmacists, which may cause dispensing errors if not solved. This practice will become habitual if not prevented early. In a study conducted in Saudi Arabia, an education intervention, consisted of lecturers, hospital staffs and educational tools (including flash cards and printed list on high-risk abbreviation) had significantly reduced the incidences of the abbreviation usage [24]. Similarly, Pharmaceutical Services Division, Penang State Health Department had launched a guideline titled Penang State Health Department Good Prescribing Guideline [25] in 2016, which was aimed to create and promote awareness among healthcare providers on the good prescribing pattern with a restriction on abbreviation and brand names. It also

served as a training module to improve prescribing practices, thus reducing the risk of dispensing errors. Since the guideline is still in its infancy stage, no obvious outcome yet to be seen, nevertheless the great attempt should be encouraged.

This is perhaps the first study in Malaysia setting particularly public-funded hospitals, which assessed the type and frequency of medication labeling and filling errors and the contributing factors that cause the near misses. Furthermore, the prospective nature of the study gives the opportunity to include all the incidents of near misses occurred in the routine flow of outpatient pharmacy, and thus reduces the missing data. Another strength of the current study is the involvement of two independent personnel that are pharmacists with vast experience in the outpatient settings to cross-evaluate the categorization and contributing factors, in order to strengthen the reliability and reduce the risk of bias.

The study was not without any limitation. Firstly, the error detected and reported by the pharmacists at the counter-checking stage or before dispensing to patients, can be under-reported. Therefore, the data presented in our study is more of an estimation of the near miss incidences and probably a direct observation is warranted for more accurate data. Secondly, the interviewer involved may introduce social desirability bias. However, it was minimized with the involvement of independent pharmacists from other pharmacy units. Thirdly, the presentability and reproducibility of the study findings could be limited because the near miss errors were reported only from one state in Malaysia.

Conclusions

The occurrence of near misses in the outpatient pharmacy setting is 0.0003% and these errors are considered harmful if drugs are dispensed to patients. A concerted effort is needed to curb the near misses; this includes system changes, continuous education, monitoring of implementation, and policy changes. Computerizing the medication process system in these settings could help to reduce the errors (especially the labeling errors). However, future investigation is warranted to evaluate the intervention strategies needed to reduce the near misses.

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