Simulated Medication Errors: A Means of Evaluating Healthcare Professionals' Knowledge and Understanding of Medication Safety

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Abstract

OBJECTIVE: To determine multi-disciplinary perceptions of the clinical significance of medication errors (MEs), the responsible health professional(s), the contributing factors and potential preventive strategies.

METHODS: The five simulated ME cases represented errors from five wards at a children's hospital in Australia. Pre-determined answers for each case were developed through consensus among the researchers. The root cause analysis (RCA) was undertaken via a questionnaire disseminated to physicians, nurses and pharmacists at the study hospital to seek their opinions on the ME cases. Agreement model between the participants and pre-determined responses regarding the contributing factors was conducted using general estimating equation (GEE) analysis.

RESULTS: Of the 111 RCA questionnaires distributed, 25 questionnaires were returned. The majority (93%) of respondents rated the significance of the MEs as either 'moderate' or 'life-threatening'. Furthermore, they correctly identified two contributing factors relevant to all cases: dismissal of policies/procedures or guidelines (90%) and human resources issues (87%). GEE analysis revealed varied agreement patterns across the contributing factors. Suggested prevention strategies focused on policy and procedures, staffing and supervision, and communication.

CONCLUSION: Simulated case studies had potential use to seek front-line healthcare professionals' understanding of the clinical significance and contributing factors to MEs, along with preventive measures.

Keywords: Medication error, root cause analysis, paediatrics.

1. Introduction

Health service provision occurs in a complex and high-risk environment. Errors usually suggest organisational system failure [1, 2]. Root cause analysis (RCA) is a form of system analysis that may be used to investigate incident reports, as well as a tool for academic research or training. RCA encompasses methods for retrospective, structured investigation of adverse incidents, near misses and sentinel events [3]. There is broad consensus that RCA can be completed via different approaches instead of a single method. One commonality between these approaches is the organisation of the RCA in sequential steps [4].

When applied to health systems, RCA can be used to investigate all subsets of medication misadventure, e.g. adverse drug events, adverse drug reactions and medication errors (MEs) [5]. In Australia, medication misadventure places a significant burden on the health system, accounting for 2.4-3.6% of all hospital admissions in general patients, with up to 69% of these misadventures being potentially preventable [6]. In the United States of America (USA), MEs account for a significant proportion of errors during healthcare delivery [7]. In the United Kingdom, a 2007 National Patient Safety Agency report cited over 86,000 incidents relating to ME in that year [8].

Some patient groups are particularly vulnerable to ME and their consequences. Studies of ME in paediatric inpatients have reported incidence rates of 6% [9, 10] to 13% [11]. However, further research is required to identify the medications of most concern and the children at greatest risk [12, 13].

Effective system improvement ascertains the underlying causes of ME through well-structured investigations utilising RCA [5]. MEs are preventable and independent of the patient's physiology and pathology, and hence are particularly suitable for RCA to prevent recurrence. Research suggests that multiple health professionals, particularly those at the patient care interface, are commonly implicated in the occurrence of MEs [7, 14]. However, research into the contribution of frontline health professionals in preventing MEs, particularly in high-risk areas such as paediatrics, is lacking.

RCA in healthcare settings such as surgery, emergency and pharmacy has been conducted using authentic cases reviewed by medication safety teams [15-17]. Learning opportunities using this approach are limited by the confidentiality of authentic cases. Use of simulated cases in RCA has demonstrated improvements in terms of confidence and technical skills of staff, and ME reduction [18]. RCA involving simulated cases may promote awareness and understanding of medication safety issues including MEs without the fear of legal ramifications [18, 19].

This study aimed to apply RCA using a sample of simulated cases to determine multi-disciplinary perceptions of the clinical significance of MEs and the responsible health professional(s). Additionally, it aimed to investigate participants' views on the contributing factors for the MEs and strategies to reduce error recurrence.

2. Methods

2.1 Development of Simulated Clinical Case Studies and the Survey Instrument

The principal researcher developed five simulated cases depicting paediatric patients, as described in the Results section. The cases were based on the most common types of MEs observed in a major children's teaching hospital in Western Australia [20]. Each case demonstrated one of the following errors: prescribing error (setting = General Medical Ward for Infants), dispensing error (General Medical Ward for Young Children), administration error (General Medical Ward for Adolescents), transcribing error (Hematology-Oncology Ward) and monitoring error (General Surgical Ward). The cases were constructed such that any nurse, physician or pharmacist could reflect on the scenario, regardless of their specialty. Each case was reviewed by two experienced academic pharmacists for accuracy of clinical information and representativeness of practice at the study hospital. For each case, four or five contributing factors were pre-determined by the academic pharmacists and principal researcher to allow comparison with the participants' responses. Three contributing factors were common to all cases: dismissal of policies/procedures or guidelines, human resources, and miscommunication (Table 1). Content and face validity of the questionnaire were reviewed by the academic pharmacists.

The questionnaire (available on request) was designed for self-completion by health professionals, and comprised two sections. Section 1 documented participants' demographic characteristics (age, gender, health profession, position, and years of experience as a health professional overall and in paediatrics). Section 2 presented the five cases, followed by questions related to the ME and RCA. ME-related questions required rating of the clinical significance of the error, as per methods reported by the National Coordinating Council for Medication Error Reporting and Prevention/NCCMERP [21] and identification of the health professional(s) perceived to have significantly contributed to the error. RCA questions were adapted from the *Clinical Incident Management Toolkit* [22], whereby participants identified the contributing factor(s) from six categories: specific patient issues, dismissal of policies/procedures/guidelines, human resources-related issues, communication-related issues, physical environment of the health service, and control/provision of medication. 'Unsure' and 'other' options were also provided. Participants were also asked to suggest strategies to prevent recurrence of the error. Questionnaires were produced in hard copy and code-numbered, only allowing identification of respondents by health professional group (accompanying consent forms were collected separately).

2.2 Participants and Questionnaire Administration

One hundred and eleven questionnaires were distributed during study period (July-October 2014). Potential participants included all pharmacists in the hospital (n=37) and a convenience sample (20%) of physicians (n=31; 5-6 physicians/ward) and nurses (n=43; 8-9 nurses/ward) from the five study wards, with the intention to generate comparable numbers of responses that could be compared descriptively. There is little published guidance for sampling in RCA studies; our intention was exploratory analysis to compare patterns of agreement with the predetermined answers.

The principal researcher handed the questionnaires directly to all 37 pharmacists. To introduce the study to physicians and nurses, questionnaires were distributed by the ward pharmacists or the principal researcher under supervision of a ward pharmacist, using convenience sampling, to reach the predefined number of potential participants per ward. Two reminders were emailed to all pharmacists in August and September, while prompts to physicians and nurses were provided by the ward

pharmacists via email and/or ward meetings. Participants were asked to return the questionnaires and the consent form by the predefined time in the envelope provided. The survey period was limited by upcoming hospital accreditation.

2.3 Data Analysis

All data were entered into SPSS version 22.0. General Estimating Equation (GEE) analysis [23] was used to develop an agreement model between the groups of participants' responses to the contributing factors and the pre-determined answers for each case. The dependent variable in the GEE model was disagreement regarding each factor. An odds ratio greater than one indicated greater disagreement than the reference. In comparing the simulated cases, Case 5 was set as the reference. If the agreement model using GEE was not able to be fitted (e.g. due to unanimous agreement), the results were summarised using descriptive statistics. Participants' comments regarding the contributing factors were entered into QSR NVivo version 10.0 to assist coding of emergent themes.

2.4 Ethics approval

Study approval was granted by the Human Research Ethics Committees of the study hospital (2923) and university (PH-14-112923).

3. Results

Of the 111 RCA questionnaires administered to physicians, nurses and pharmacists, six (19%), 11 (26%) and eight (22%) were returned, respectively (overall response rate 23%). All of the returned questionnaires were included in the analysis. This sample size, while low, enabled the planned analysis. Most participants (52%) were aged 31 to 40 years, and the majority (84%) identified as female. Each group showed a similar pattern of clinical experience (Table 2). Three of the physicians were registrars and three were consultants/specialists. Four of the nurses were clinical nurses/clinical midwives/clinical development nurses, and one was a clinical nurse/midwife consultant. Four of the pharmacists held clinical pharmacist roles.

3.1 Analysis of the Cases

Case 1 hypothetically described a prescribing error involving digoxin, a high-risk drug, in a six-month-old baby. The physician wrote the digoxin dose inappropriately (not including a leading zero before the decimal point), resulting in a 100-fold higher dose and patient death. All but one of the participants rated the error as 'life threatening'. All physicians and pharmacists perceived all three health professionals (physician, nurse, pharmacist) as accountable. Nine of the 11 nurses agreed, while the remaining two nurses pointed to their own profession as primarily responsible.

Case 2 illustrated a dispensing error where a locum pharmacist with poor vision and inadequate supervision filled medication orders for a patient with a history of seizures. The dispensary was arranged alphabetically by generic name, and the locum dispensed prednisolone instead of primidone. All nurses and pharmacists rated the error as 'major' or 'life threatening'. The majority of the physicians (83%) offered a similar assessment. Most (76%) participants identified two health professionals (i.e. nurse and pharmacist) as responsible.

Case 3 described an error during drug administration. The patient, with a history of asthma and seizures, was admitted due to asthma exacerbation. As levetiracetam was out of stock, five doses of levetiracetam were omitted, triggering a seizure. All physicians and pharmacists and just over half (55%) of the nurses rated the error as 'major'. There was little consensus between the groups regarding who was responsible for the error.

Case 4 illustrated inadequate communication and documentation resulting in an anaphylactic reaction in a patient with history of penicillin allergy. Over half (physicians 67%, nurses 55%, pharmacists 88%) assessed the error as 'life threatening', with varied perspectives about responsibility.

Case 5 related to a transcribing error, where an antifungal medicine was not re-charted for a newly-diagnosed oncology patient. A non-oncology nurse had been deployed to this ward, and was unable to identify the error. Over half of the nurses (55%) and the pharmacists (63%) rated the error as 'major'

in significance, whilst physicians most commonly (50%) considered it 'moderate'. All respondents felt the physician had some responsibility for the error.

All errors were considered to have multiple contributing factors (Table 3). Dismissal of hospital policies/protocols/clinical guidelines and human resources were perceived as the key issues in all cases. In addition, half of the participants indicated that patient-specific issues had contributed to the error in Case 1 (complexity of medical condition and young age) and Case 4 (patient's drug allergy).

Participants' comments relating to contributing factors identified the following themes: miscommunication between staff, miscommunication between staff and the patient and/or patient family, poor lighting, workspace, medication storage, documentation of administration, internal transfer of medication, and staff health (only applicable to Case 2).

Suggestions regarding ME prevention mapped to the following themes: improved availability and accessibility of clinical guidelines and strict adherence to hospital policies/protocols for high-risk drugs; adequate staffing and staff supervision; adequate staff education and training/competencies; effective communication between staff; patient empowerment (e.g. through education and counseling); use of technology (e.g. electronic prescribing); and improving the physical environment of the healthcare facilities (e.g. pharmacy layout).

3.2 Agreement between Pre-Determined Contributing Factors and Participants' Responses

Of the six contributing factors, two demonstrated convergence in the GEE model, due to very high or complete agreement between responses from health professional groups and the pre-determined factor. These factors were dismissal of policies/procedures or guidelines, and physical environment of the health service.

Table 4 outlines the agreement model for the remaining four factors using GEE analysis. The analysis showed significantly greater agreement about the contribution of patient-specific issues (i.e. low odds ratios) for Cases 2 (dispensing error) and 4 (communication and documentation error) compared to Case 5 (transcribing error). Case 4 was an outlier regarding human resources issues, with the high odds ratio suggesting disagreement that human resources issues contributed to the communication and

documentation error. The participants were more likely to agree with the contribution of communication in Case 3 (error during drug administration) and Case 4 (inadequate communication and documentation), compared to Case 5 (transcribing error). With respect to control/provision of medication as the contributing factor, the agreement with the pre-determined factors was similar across all professions. The level of agreement was significantly higher for Case 4 than for Case 5.

4. Discussion

This study used paper-based simulated case studies; this method can reflect reality without potentially identifying individuals implicated in authentic errors reported through hospital safety and quality systems [18, 19]. Overall, a similar perspective was revealed among the participants across the three professions on the clinical significance of the MEs, with the majority of participants rating the MEs as "major" or "life threatening", as intended in the design of the cases. However, the present findings were not consistent with prior studies assessing medication-related events (i.e. MEs) either in paediatric or adult patients. In such studies, physicians often rated the severity of the consequences of MEs lower than pharmacists [24-26]. The observed high level of agreement in the assessment of clinical significance of the MEs presented in this study might be due to less ambiguity in statements of the outcomes of the MEs in the case studies, as opposed to documented interventions without clear endpoints in the aforementioned studies. Furthermore, the majority of participants in this study thought the MEs were the consequence of action/inaction of at least two health professionals. It has been evident in this study that there was no clear pattern with each group to blame the other two groups. In this sense, the health professionals substantiate the accountability of roles and acknowledgment of shared responsibilities and teamwork in patient care. To some extent, the findings of this study confirmed those of previous studies highlighting the nature of the healthcare process as being 'tightly coupled' and 'interdependent', whereby deviations during the process were likely due to the results of interactions among the care providers rather than a single person [7, 14].

In the present study, the varied responses to the likely contributing factors to each ME suggests robustness in the simulated cases and depth of consideration by respondents. Furthermore, it highlights the complexity in identifying root causes for errors, a concept recognised in the literature

[14, 27, 28]. Two contributing factors that were consistently identified by the researchers and participants in all five cases were dismissal of policies/procedures or guidelines, and human resources. As with this study, RCA of 17 critical incidents in a children's hospital in the Netherlands found task and team factors were the most frequent contributing factors [14]. The task factors were associated with awareness among the staff regarding the existence and implementation of clinical guidelines and/or hospital protocols. Team factors referred to issues that can be resolved through training [14].

The findings of a report on incident management (including medication-related incidents) in the New South Wales public health system during 2005-2006 was in accordance with those of this study [29]. That study found issues related to policy and procedures, and communication (particularly deficiencies in patient handover) to be the major contributing factors [29]. Consistent with this study, RCA reports on adverse drug events submitted to the Veteran Affairs National Center for Patient Safety in the USA in 2004 uncovered problems with policies or procedures, staff training and education, communication, and equipment as common factors contributing to adverse drug events [30]. Meanwhile, analysis of ME reports submitted to MedMARx (a National Medication Error Reporting Program in the USA) revealed workplace distractions, staffing issues and workload increases as the most frequently cited contributing factors related to MEs during hospitalization [31]. The similar perceptions among the health professionals collectively in our study indicated the key professions are capable of identifying contributing factors to medication safety-related events.

As the contributing factors of MEs are numerous, evidence underlines the need for multiple strategies for ME prevention [32]. Accordingly, analysis of the common themes of strategies proposed by participants in this study identified the need for numerous strategies to prevent each ME. In line with this study, the aforementioned Dutch study reported an average of five recommendations per analysis; most recommendations related to task factors (36%), and required providing and/or adjusting hospital protocols or guidelines (43%) [14]. The other recommendations were associated with team-based staff training and technical adjustment to improve the work environment (e.g. quiet area for medication preparation unit) [14]. In addition, findings of the current study correspond with strategies for ME

prevention in peadiatrics recommended by the American Academy of Pediatrics Committee on Drugs and the Committee on Hospital Care [33] and the Pediatric Pharmacy Advocacy Group [34].

As suggested by this study and other RCA studies, education of healthcare staff is an important component of ME reduction [32, 35]. Pharmacists, with their knowledge and expertise of medicines, are ideal educators for other health professionals, and their educator role has been shown to be an effective ME prevention measure in a range of patient populations [33, 36]. Patient empowerment is also recognised as a valuable strategy for ME prevention. Healthcare staff should educate patients (and in the present case, families of paediatric patients) [37, 38] to improve their health literacy regarding their medical conditions, medications and healthy lifestyles [39]. One common issue among healthcare staff is their lack of awareness of hospital policies and procedures. In the current study, it has been suggested that pharmacists are able to contribute not only to development of policies on medication use (e.g. high-risk drugs, discharge medications), but also to communicate these policies to other staff. Our study also confirmed the findings of previous RCA research that identified the necessity of adequate communication between staff and patients and their families [40-42].

There are several limitations to this study. The response rate was low, possibly due to the perceived time requirement to complete the task, and the study involved a single institution. A larger number of participants and involvement of other paediatric institutions may reveal different trends in the data on the clinical significance of the MEs, the contributing factors and participants' suggestions for ME prevention. Additionally, presentation of pre-determined options could bias the results. The pre-determined options were determined via consensus between the researchers, and other clinical experts may give different assessments.

5. Conclusion

This is the first-known study demonstrating the use of RCA with simulated case studies in the field of paediatric medication safety. RCA successfully evaluated healthcare professionals' (physicians', nurses' and pharmacists') ability to assess the clinical significance of MEs, identify potential

contributing factors in MEs, and suggest strategies to prevent MEs. Knowledge and skills in this area are critical in minimising medication misadventure in clinical practice and ensuring optimal patient outcomes.

Acknowledgements

The authors thank the participating physicians, nurses and pharmacists at the study hospital, and the statistician at the study university for statistical assistance.

Conflicts of interest

None declared.

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Table 1. Researchers' pre-determined factors contributing to the mediction errors

Contributing factors	Case 1	Case 2	Case 3	Case 4	Case 5
Patient specific issues	Y	N	Y	Y	Y

Dismissal of policies/procedures or guidelines	Y	Y	Y	Y	Y
Human resources	Y	Y	Y	Y	Y
Miscommunication	Y	Y	Y	Y	Y
Physical environment of the health service	N	Y	N	N	N
Control/provision of medication	Y	Y	Y	N	N
'Other'	N	N	N	N	N

Y = contributing factor, N = non-contributing factor

401 **Table 2. Description of participants**

Characteristics	Number of participants (%)		
	Physicians (n=6)	**Nurses (n=11)**	**Pharmacists (n=8)**
Age (years)			
21-30	1 (16.7)	3 (27.3)	0 (0.0)
31-40	4 (66.7)	4 (36.4)	5 (62.5)
41-50	0 (0.0)	2 (18.2)	1 (12.5)
>50	1 (16.7)	2 (18.2)	2 (25.0)
Gender			
Male	2 (33.3)	1 (9.1)	1 (12.5)
Female	4 (66.7)	10 (90.9)	7 (87.5)
Clinical experience (years)			
<5	0 (0.0)	2 (18.2)	0 (0.0)
5-10	2 (33.3)	2 (18.2)	2 (25.0)
11-20	3 (50.0)	4 (36.4)	3 (37.5)
>20	1 (16.7)	3 (27.3)	3 (37.5)
Paediatric experience (years)			
<5	0 (0.0)	2 (18.2)	2 (25.0)
5-10	2 (33.3)	4 (36.4)	4 (50.0)
11-20	3 (50.0)	4 (36.4)	2 (25.0)
>20	1 (16.7)	1 (9.1)	0 (0.0)

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404 **Table 3. Factors perceived to contribute to the medication error**

Factors	Number of participants, N=25 (%)				
	Case 1	**Case 2**	**Case 3**	**Case 4**	**Case 5**
Patient specific issues	13 (52)	1 (4)	8 (32)	22 (88)	11 (44)
Dismissal of policies/ procedures or guidelines	24 (96)	25 (100)	23 (92)	20 (80)	20 (80)
1. Error/omission in medication reconciliation	8 (32)	14 (56)	15 (60)	4 (16)	15 (60)
2. Clinical guidelines	15 (60)	15 (60)	8 (32)	0 (0)	3 (12)
3. Coordination of care	9 (36)	11 (44)	19 (76)	12 (48)	3 (12)
4. Medical record documentation	15(60)	1 (4)	2 (8)	12 (48)	7 (28)
5. Level and frequency of monitoring of patient	7 (28)	0 (0)	4 (16)	2 (8)	1 (4)
Human resources issues	22 (88)	24 (96)	23 (92)	16 (64)	24 (96)
1. Staff workload and inadequate staffing	10 (40)	19 (76)	15 (60)	2 (8)	24 (96)
2. Recruitment	0 (0)	0 (0)	0 (0)	1 (4)	4 (16)
3. Staff training and competencies	20 (80)	14 (56)	15 (60)	12 (48)	9 (36)
4. Staff supervision	14 (56)	14 (56)	7 (28)	1 (4)	6 (24)
Miscommunication	13 (52)	8 (32)	22 (88)	24 (96)	9 (36)
1. Miscommunication between staff	13 (52)	5 (20)	22 (88)	15 (60)	8 (32)
2. Miscommunication between staff and patient and/or family	2 (8)	5 (20)	7 (28)	20 (80)	6 (24)
Physical environment of the health service	1(4)	23 (92)	0 (0)	0 (0)	0 (0)
Control/provision of medication	11 (44)	20 (80)	21 (84)	3 (12)	9 (36)
1. Medication storage	1 (4)	14 (56)	4 (16)	0 (0)	0 (0)
2. Labeling	1 (4)	9 (36)	1 (4)	1 (4)	0 (0)
3. Documentation of administration	5 (20)	1 (4)	3 (12)	1 (4)	9 (36)
4. Internal transfer of medication	3(12)	6 (24)	17 (68)	0 (0)	0 (0)
'Other'	9 (36)	14 (56)	6 (24)	4 (16)	10 (40)

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Table 4. Agreement betweenresearchers and participants regarding contributing factors

Variables	Odds ratio of contributing factors (p-value)*			
	Patient-specific issues	Human resources	Communication	Control/ provision of medication
Case study[#]				
Case 1 (Prescribing error)	0.702 (0.406)	3.290 (0.160)	0.501 (0.318)	2.299 (0.191)
Case 2 (Dispensing error)	0.027 (0.003)	1.000 (1.000)	1.205 (0.763)	0.439 (0.206)
Case 3 (Administration error)	1.748 (0.369)	2.093 (0.568)	0.067 (<0.001)	0.334 (0.132)
Case 4(Communication and documentation error)	0.090 (0.001)	13.744 (0.006)	0.020 (<0.001)	0.238 (0.034)
Case 5 (Transcribing error)**	1	1	1	1
Participants' role[##]				
Physician	1.114 (0.865)	1.677 (0.541)	0.299 (0.030)	0.522 (0.382)
Nurse	3.719 (0.039)	1.044 (0.954)	0.402 (0.125)	1.068 (0.900)
Pharmacist**	1	1	1	1

*Using General Estimating Equation analysis

**Set as a reference

#High agreement across the four contributing factors was seen in Case 4.

##Nurses shared less agreement with pre-determined answers regarding the contribution of patient-specific issues. Physicians were more likely to agree with researchers signifying communication as the contributing factor. No agreement with pre-determined answers for human resources and control/provision of medication as contributing factors of MEs.